THE ECONOMICS OF THE MEDICAL DIAGNOSTIC IMAGING EQUIPMENT INDUSTRY

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ABSTRACT

This is a study of the economic behavior of firms manufacturing medical diagnostic imaging equipment, machines that take diagnostic pictures. The basic conditions, market structure, and firm conduct are used to analyze industry performance and to evaluate the effects of various government policies. Two new data sets were utilized in the research: a survey of firms in the industry and a constructed data file of industry composition and firm characteristics over a ten year period.

After an introduction outlining the study, Chapter 1 presents the basic conditions of the industry, including product descriptions, supply and demand conditions, and the regulatory environment. Quality characteristics are found to be especially important in this market. Market structure is analyzed in Chapter 2. This is an unconcentrated industry which has been characterized by steady growth of real sales and a substantial amount of net entry over the past ten years. In Chapter 3, an examination of firm conduct, the pivotal role of innovation in this industry is revealed. And, it is found that firms compete not only on the basis of price, but also on the basis of quality, service facilities, and innovation.

Chapter 4 uses the results of the previous chapters to assess industry performance. Overall, medical imaging equipment appears to be sold in a competitive market, due to the ease of entry combined with the high degree of product differentiation and the rapid rate of innovation. In Chapter 5 the impacts of various government regulatory programs are examined. Neither radiation safety regulation nor medical device regulation was found to have adversely affected market structure or innovation in this industry. And demand for medical imaging equipment does not appear to have been decreased by hospital regulation.

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Finally, I dedicate this thesis to my mother. She has been an inspiration to me and has always listened.

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INTRODUCTION

The subject of this study is medical diagnostic imaging equipment, machines that take diagnostic pictures, and the firms which manufacture these machines. In particular, it is an industry study, using the basic conditions of the industry, market structure, and firm conduct to analyze industry performance and to evaluate the effects of various government policies.

An industry study has intrinsic merit as a way of understanding the economy. This industry is particularly interesting because it exhibits two characteristics of special interest currently. In the first place, it is what is sometimes called a "high technology" industry, the product is technologically complex and there is a rapid rate of technical change. Secondly, it is a part of the health care sector, a source of national concern due to rapidly rising health care costs. With respect to the medical care sector, there has been little work done on the supply of non-labor inputs, a category encompassing medical imaging equipment. Finally, the existing literature on product safety regulation consists largely of studies of the pharmaceutical industry. Given that safety regulation has become common during the past 20 years, examination of another industry will provide a useful point of comparison for the effects of this type of regulation.

The study utilizes two new data sets in addition to a variety of secondary sources. In the first place, first-hand information about a variety of issues was obtained from a survey of firms in the industry. Secondly, a data file of industry composition and firm characteristics over the period 1971 to 1981 was constructed by correlating and cross-checking information from over twenty-five different sources, including a weekly trade newsletter, the financial press, industry reports by others, and government publications.

In Chapter 1 the basic conditions of the industry are presented. This includes product descriptions, supply and demand conditions, and the regulatory environment. Chapter 2 analyzes market structure, beginning with a history of industry and product sales and an overview of the firms which sell in this market. Then the patterns of concentration are examined, followed by a discussion of barriers to entry. Finally, changes in industry composition over time are described. Chapter 3 explores the conduct of firms in this industry. First the pricing behavior of firms is described, followed by an examination of marketing strategies. The nature of innovation receives special attention, including a history of important technical developments, an analysis of innovation inputs and outputs, and a consideration of the use of innovation as a competitive strategy. Finally, the various bases for nonprice competition in this industry are examined.

In Chapter 4 the results of the previous chapters are used to assess industry performance. Finally, Chapter 5 is an investigation of the impacts of various government regulatory programs on this industry. Specifically, both the effects of direct regulation of imaging equipment firms via radiation safety and medical device programs, and the indirect effects of hospital regulation are analyzed.

CHAPTER 1: BASIC CONDITIONS

The basic conditions are the fundamental circumstances of an industry which firms must take into account when making decisions. After a discussion of the relevant market, the nature of the products is described. Then supply conditions, such as the production technology and inputs, and demand conditions, such as the nature of the buyers, price elasticities, and utilization rates, are examined. Finally, government policies affecting the industry are discussed.

MARKET DEFINITION

The relevant market must be defined in order to provide a boundary for the analysis. In the lexicon of economic theory, a market is simply a context within which transactions or exchanges occur and an industry consists of all firms producing the same good or service. These definitions are straightforward when products are homogeneous, or perfectly substitutable, a condition that rarely holds. When products are not homogeneous, the task is to determine what products are sufficiently substitutable to belong to the same market.

The antitrust approach to market definition involves first defining a provisional product market which includes those products considered to be good substitutes at current prices. Then a small but significant market price increase is hypothesized. If available substitutes are sufficiently attractive that the price rise would not be profitable, then the market is defined too narrowly. This process is continued until the market is defined by the ability of a hypothetical single seller to raise price profitably (U. S. Department of Justice, 1982). Landes and Posner (1981) and Schmalensee (1982) present in more formal terms the argument that own-price elasticity of demand is the key element in the problem of market definition.

Important criteria in evaluating product substitutability are buyers' and sellers' perceptions as to product substitut-

ability, similarities in usage, design, or technical characteristics, and similarities in price movements (U. S. Department of Justice, 1982). Other factors such as similar technologies, identical inputs to production, or close geographical location may play a role. And, the time frame is also important; for example, individual firm demand is more price-elastic in the long run than in the short run (Schmalensee, 1982).

Medical diagnostic imaging equipment is used to take pictures which help physicians determine a patient's medical condition. There are four primary types of equipment included in this market: X-ray equipment, CT scanners, ultrasound devices, and nuclear scanning equipment. These machines are used primarily by radiologists, doctors who specialize in the use of radiant energy for both diagnostic and therapeutic purposes. And in the radiology literature, "diagnostic imaging" and "medical imaging" are accepted labels for the class of clinical procedures which utilizes these types of machines.[1]

There is some potential for substitution between medical imaging equipment and other types of diagnostic equipment. For instance, thermographic equipment is effective for detection of breast cancers and endoscopes can be used to actively view portions of the anatomy accessible via one of the body orifices. However, general diagnostic equipment, including such machines as electrocardiographs and blood chemistry

analyzers, offers little opportunity for substitution because different clinical information is obtained by different types of equipment. In general, diagnostic imaging is one of the very few ways the physician can gain information about structures within the body. For example, if the doctor wants to pinpoint the location of a tumor within the body, exploratory surgery is usually the only viable alternative to medical imaging. And a small rise in the price of imaging equipment is unlikely to affect the choice between diagnostic imaging and exploratory surgery.

With regard to the four types of imaging equipment, each type of equipment has preferred uses and, from an antitrust perspective, the product line is likely to be the relevant market (see the discussion of antitrust action against mergers in Chapter 2). There is, nevertheless, also substantial functional overlap and potential for substitution among the product lines (this is discussed in detail in the next section). Consequently, in addition to considering the medical diagnostic imaging equipment industry as a whole, each product line will be discussed separately in the ensuing analysis.

PRODUCTS

This section is devoted to a detailed description of each of the types of medical diagnostic imaging equipment. For each product there is a discussion of the scientific principles behind the technology, a description of a typical machine, and an account of the relevant medical applications. The potential for substitution among the various imaging techniques is also discussed. Lastly, two emerging technologies which may well lead to the introduction of new products in this market are described.

X-Ray Equipment

X-rays are a form of electromagnetic radiation, with a wavelength such that they can pass through many materials that would block the passage of light waves (e.g., soft tissue), but are stopped by metals (such as the calcium in bones). If X-rays are beamed through the body toward a piece of photographic film covered with a silver-salt (metal) solution, then the rays which can pass through the body will expose the film, resulting in an image of that portion of the body (Bleich, 1960).

Soft tissues, such as internal organs, are often not distinguishable on a standard X-ray. However, clear X-ray images of soft tissues can be obtained by injecting or ingesting substances containing metals, called contrast materials, into the organ of interest (Miller, 1982). Fluoroscopy is a type of X-ray technique in which a continuous image is obtained. In this procedure the X-rays are beamed through the body toward an X-ray-sensitive fluorescent screen (Hendee et al., 1977).

An X-ray machine consists basically of an X-ray source and a detector. The source is an X-ray tube, which produces an X-ray beam by accelerating electrons to high speeds and then directing them onto a metal target (Hendee et al., 1977). The detector is either film (for static imaging) or a fluorescent screen (for fluoroscopy). Other important components include timers, grids (to remove scattered radiation),

and generators.

X-rays were discovered in 1895 by Wilhelm Roentgen, for which he received the first Nobel prize in physics. The medical potential of this discovery was recognized almost immediately, and within a year X-rays were being used in clinical applications (Bleich, 1960). In the early 1900's various improved X-ray tubes were introduced, and by the 1920's the basic type of tube still used today (rotating anode) had been developed (Thompson, 1978). Since that time, there have been advances in film quality and the development of image intensifiers for fluoroscopy.

In the 1970's, the application of computer technology to the medical imaging field led to the development of digital radiography, a technique in which the information contained in an X-ray image is stored in a computer (digitalized). The data can then be processed and enhanced in various ways. For example, digital subtraction techniques involve making a digitalized image before and after injection of contrast material and then electronically subtracting one from the other to eliminate superfluous structures (Miller, 1982).

There are well-established clinical procedures using X-ray equipment for a large number of medical conditions. These range from a simple bone X-ray for a fracture to contrast media studies of the gastrointestinal tract for the detection of a tumor. In standard radiology texts, the

bulk of discussion is devoted to conventional X-ray techniques.[2] And, although newer techniques are more publicized, the basic X-ray still constitutes the majority of radiology procedures (Miller, 1982), and is the "bread and butter" of any radiology department.

CT Scanners

Computed tomography (CT) scanning is a relatively recent innovation in the field of radiology. Invented by G. N. Hounsfield of EMI, Ltd. in 1967, the first clinical trials took place in London in 1971. The technology was so successful at imaging lesions of the brain that it was demonstrated at professional meetings in 1972 and was commercially available by mid-1973 (Banta and Sanes, 1978).

CT scanning is a technique in which X-ray equipment and an on-line computer are used to produce cross-sectional images of the body. X-rays are beamed through the patient and the radiation which passes through the body is recorded by detectors placed opposite the radiation source. This process is repeated at a number of different positions. The measurements at each position are recorded in the computer and then the complete set of readings is used in a series of complex mathematical calculations to determine the density of each small area of the body scanned. This information is then used to form an image of a thin slice of the body (Miller, 1982).

CT scanners consist of four basic components: (1) a source, or X-ray tube, which produces the beam of X-rays; (2) a detector to pick up the radiation; (3) a computer to process the information; and (4) an imaging device, often a television screen, to display the image (Banta and Sanes, 1978).

The scanning procedure can be accomplished in various ways and there are three methods of CT scanning currently in use: (1) the X-ray tube and detectors are linked and both rotate around the patient; (2) the X-ray tube and detectors move across the body, then rotate until 180° has been covered; and (3) the X-ray tube rotates, but the detectors are stationary (Hounsfield, 1979). Fixed anode, oil-cooled X-ray tubes are used for 20-second or slower scanners, while for faster scanners, rotating anode, air-cooled X-ray tubes are the norm. And, there are two types of detectors currently in use: crystal scintillation and gas ionization, with crystal scintillation detectors having a higher detection efficiency, but being more expensive (Walmsley, 1979).

As mentioned previously, the initial application of CT scanning was in evaluation of lesions of the brain. And, in a short time CT scanning emerged as the major diagnostic tool of neuroradiology. CT technology has also been extended to scanning of the body, and is frequently used for studies of the liver, pancreas, kidneys, and chest masses (Miller, 1982).

The advantages of CT scanning are that it improves image resolution (gives a clearer image) and is less invasive than alternative techniques such as exploratory surgery (Miller, 1982). Note, however, that contrast media are coming to be used more often in CT scanning and the use of contrast media is a relatively invasive procedure (Banta and Sanes, 1978). The primary disadvantage of CT scanning

is that it is generally more costly than alternative image procedures (Miller, 1982).

Ultrasound Devices

Ultrasound is not a type of electromagnetic energy, rather it is mechanical vibration at frequencies above the range of human hearing. In an ultrasound diagnostic procedure, these high frequency sound waves are passed through the body and the echoes of those signals are used to construct an image of that portion of the body (Miller, 1982).

Bats and porpoises use ultrasound for echolocation, but ultrasound was not used by humans until Pierre Curie discovered the piezoelectric properties of certain crystals. Piezoelectric crystals are crucial to ultrasound technology because they both generate and detect ultrasonic waves. By the early 1900's the first echolocation device had been developed by the French engineer Paul Langeuvin. This work eventually culminated in sonar techniques for the detection of underwater objects (Fleischer and James, 1980).

After World War II ultrasound techniques were used in medical therapy for the treatment of cancer. By the late 1950's, diagnostic applications of ultrasound were being proposed. However, it was the need for a nonradioactive imaging procedure for the fetus that was the major force behind the development of ultrasound imaging techniques in the early 1960's (Fleischer and James, 1980).

The most important component of an ultrasound device is the transducer which contains a piezoelectric crystal. This crystal has the property of producing ultrasound when

electrically excited and of producing electrical signals in response to ultrasonic waves. The transducer thus acts both as the generator and the detector of ultrasonic signals (Wells, 1979a). The electrical signals are then amplified, processed, and displayed (Fleischer and James, 1980).

The nature of the processing and display equipment depends on the type of ultrasound procedure being performed. A-scope displays are used to present straightforward time vs. amplitude information, whereas a B-scope can detect intensity modulations. The B-scan is especially useful because it is the basis of both time-position recording (for the study of changes in structure) and of two-dimensional scanning (which produces a cross-sectional image). Another type of ultrasound procedure is real-time imaging, with which it is possible to study moving structures. Lastly, there are Doppler scanners, which operate by measuring the shift in the frequency of sound waves reflected from a moving object and which are used primarily for blood flow studies (Wells, 1979b).

A major innovation in ultrasound was the development of gray scale imaging, a technique which allows a range of echo amplitudes to be expressed as various shades of gray, rather than as the previous dots of set intensity. This technique was introduced by George Kossoff in the late 1960's (Fleischer and James, 1980) and gray-scale ultrasound equipment was commercially available by 1974 (Meire, 1979).

As mentioned previously, ultrasound was first used for imaging of the fetus and in utero procedures continue to be the major use of diagnostic ultrasound procedures. Other important applications are evaluation of the liver, gallbladder, and cardiac walls and valves (Kreel and Meire, 1979). Ultrasound is particularly effective for the identification of cystic structures and thus is often used to analyze the nature of masses already located by other imaging modalities (Miller, 1982).

The primary advantages of diagnostic ultrasound are that it is nonradioactive, noninvasive, does not require the use of potentially toxic contrast media, and is generally less expensive than other imaging procedures (Fleischer and James, 1980). The main disadvantages are that ultrasound displays can be confusing and that it requires considerable experience to accurately interpret ultrasound images (Miller, 1982).

Nuclear Scanning Equipment

Nuclear scanning procedures are unique in the radiological repertoire in that the energy source is a radioactive substance which is inside the patient. These radioactive substances are termed radiopharmaceuticals, and nuclear medicine is the branch of radiology concerned with the diagnostic and therapeutic use of radiopharmaceuticals. Nuclear medicine includes both in vivo (in body) and in vitro (in glass) procedures, but only the equipment associated with in vivo testing will be considered here.

Henri Bequerel and Pierre and Marie Curie are credited with the discovery of radioactivity in the late 1890's, for which they jointly received the 1903 Nobel prize for physics (Dewing, 1962). By the early 1930's, the development of the cyclotron made it possible to produce artificial radioisotopes, but it was not until the introduction of the nuclear reactor in the 1940's that it became practical to produce radioisotopes in quantity. In 1938 a group headed by Robley D. Evans investigated the uptake of iodine-128 in the thyroid of the rabbit, and application to the imaging of the human thyroid gland, the first concern of nuclear medicine, was not far behind (Lange, 1973). Medical uses of radioisotopes expanded over the years to the extent that nuclear medicine formally became a medical specialty in 1971 with the establishment of a certification board (Epstein and Grundy, 1974).

Radioactive substances emit, among other things, gamma rays, a type of electromagnetic radiation with very short wavelengths similar to X-rays. In nuclear scanning, a radiopharmaceutical is ingested or injected into the patient. The pattern of radioactivity (emission of gamma rays) that results is detected and then transformed to a visual display (Miller, 1982).

Most nuclear scanning equipment uses sodium iodide scintillation crystals. These crystals and various detectors are housed in a camera or a scanner. There are two basic types of scintillation (gamma) cameras: the Anger type with one large crystal surrounded by many detectors, and the multi-crystal type with many smaller crystals and one detector associated with each crystal position. And, there are two principal types of scanners: the rectilinear scanner (largely outmoded now), in which the detector moves across the patient's body in a series of parallel lines; and the multi-crystal whole body imager which makes one comprehensive scan (Frost and Sullivan, 1979). A collimator is often used to prevent the detection of extraneous radiation, and the use of a computer to process the information coming from the detecting system has become commonplace (Spencer, 1979).

The key to nuclear scanning lies in the discovery (or production) of radiopharmaceuticals which will tag only particular organs or which have different rates of absorption

for healthy and diseased tissues (Russell, 1978). Other desirable properties of radioisotopes include a short half-life, availability at a low cost, and emission of the type of radioactivity detectable by standard instrumentation. These requirements severely limit the set of radioisotopes suitable for medical imaging and, in practice, technetium-99m is generally used in clinical applications (Spencer, 1979). It is estimated that in 1978 over 80 per cent of all *in vivo* procedures utilized technetium-99m. Other important radioisotopes include iodine-131, iodine-123, xenon-133, thallium-201, selenium-75, and gallium-67 (Frost and Sullivan, 1979).

As noted previously, evaluation of the thyroid gland was the first medical application of nuclear scanning, and radioisotope scanning is still the standard procedure for studying that organ (Miller, 1982). Other primary uses are for the detection of pulmonary emboli and bone metastases (Kreel and Meire, 1979). Also important are cardiac and liver function tests. It is estimated that, in 1982, cardiac and lung perfusion studies, bone scanning, and liver function tests accounted for about 70 per cent of all nuclear imaging procedures.[3]

Since the choice of radiopharmaceutical depends on the organ and function being studied, nuclear scanning technology consists of a set of diagnostic tests for particular medical conditions. In fact, this provision of functional, rather than structural, information is what sets nuclear scanning

apart from the other imaging techniques (Robinson, 1979).

The advantages of nuclear scanning techniques are that they are low-risk, and especially useful for detection of functional disturbances (Robinson, 1979). The primary disadvantage is that the resolution of a radioisotope image is relatively low compared to standard radiographic images (Miller, 1982).

Substitution Among Medical Imaging Techniques

The focus of the market definition section was the common function of all types of medical imaging equipment, i.e., the production of diagnostic imaging tests. The potential for substitution among the types of imaging equipment depends entirely on the potential for substitution among imaging techniques. This section is a consideration of the medical potential for substitution among diagnostic imaging techniques.

It is important to note that the purpose of a given procedure is to image a particular part of the body. In other words, the decision to perform an imaging test is based on the patient's particular medical problem, and the choice of imaging modality will depend primarily on what specific question is being asked about the patient's condition (Kreel and Meire, 1979). Also note that, although standard radiography, CT scanning, and ultrasound can be used to image any part of the body (however effectively), radioisotope scanning is limited to a particular set of procedures defined by the type of radiopharmaceutical used and by the organ into which the tagged substance is injected or ingested.

Until about 15 years ago, X-ray tests were the standard imaging procedure. With the advent of other techniques, an image can now be obtained in several different ways. On the one hand, this means that there are greater opportunities for substitution. On the other hand, specialized techniques have developed for particular medical conditions. In general,

each imaging technique has specific uses for which it is clearly superior and the method of choice. These will be presented and then the areas of overlap will be discussed.

Standard radiographic techniques are preferred for imaging of the chest and lungs, the skeleton (except when cancer is suspected), and the gastrointestinal tract (Miller, 1982). X-ray examinations are the least expensive type of imaging procedure and the image depicts clear details of structural anatomy in the above cases (Robinson, 1979).

CT scanning is the acknowledged method of choice for neurological problems. Its preeminence for this purpose is indicated by the effects on alternative techniques after CT scanning was introduced. Although sources refer to different time periods and there is disagreement about the actual magnitude of the effect (see Table 1-1), it is clear that the introduction of head CT scanning decreased the utilization of radioisotope scanning of the brain, pneumoencephalography (X-ray visualization of the brain with contrast provided by injections of carbon dioxide), and cerebral angiography (X-ray visualization of blood vessels in the brain with the aid of injection of contrast materials).

CT scanning of the body does not enjoy the clear superiority over other procedures that CT head scanning does for neurodiagnostic purposes (McNeil, 1981). When used for body scanning there is a tradeoff between the sometimes clearer

Table 1-1

Effects of the Introduction of Head CT Scanning on Alternative Medical Imaging Techniques

	Alternative Techniques		
Source	Radioisotope Scanning of Brain	Pneumoencephalography	Cerebral Angiography
Arthur D. Little (1976)	45% decrease	70% decrease	20% decrease
Banta and Sanes (1978)	35% decrease	60% decrease	15% decrease
Kreel and Meire (1979)	effectively eliminated	80% decrease	60% decrease

image produced by CT technology and the fact that CT scans are the most expensive type of imaging procedure (Kreel and Meire, 1979).

Ultrasound is the accepted imaging procedure for obstetrical purposes. This is because X-rays are dangerous to the fetus and because the suspension of the fetus in the amniotic fluid is particularly conducive to clear ultrasonic imaging (Fleischer and James, 1980). Ultrasound also dominates other techniques in imaging of the movements of the cardiac walls and valves (Kreel and Meire, 1979).

Radioisotope scanning is the modality of choice for the detection of pulmonary emboli and as a screening procedure for bone metastases. It is particularly suited for these purposes since it reveals function, rather than structural anatomy (Kreel and Meire, 1979).

For many medical conditions, there is no generally accepted standard specifying which imaging technique should be used. It should be noted that the physician does not always know ex ante the nature of the patient's complaint, and which procedure is used will depend initially on the tentative diagnosis. The choice of modality will also be influenced by a number of other factors. First, it must be determined whether functional or structural detail is more important; radioisotope scanning being preferable for collection of information about function (Robinson, 1979).

It also must be decided whether a cross-sectional image is necessary. And, acceptable levels of risk must be determined: X-radiation is known to be dangerous to the fetus and there is always the possibility of an adverse reaction when contrast media are used. Other factors to consider are image resolution (or clarity) and ease of interpretation (Kreel and Meire, 1979). The cost of the examination is also important in the choice of diagnostic imaging modality (although not as important as might be expected due to methods of third-party payment for hospital expenses). Lastly, availability of equipment and personal preference on the part of the doctor will influence the imaging technique decision.

Although the emphasis in this section is on substitution among techniques, it should be noted that doctors often order multiple tests for the same diagnosis. This is because the reading of a diagnostic image is not cut and dried, there is a substantial amount of variation in the interpretation of any given image. Ordering a different type of procedure reduces uncertainty about the diagnostic conclusion. Defensive medicine is another reason for the use of multiple modalities, i.e., given the possibility of a malpractice suit, the doctor tends to accumulate evidence to justify his or her decisions.

Since the demand for a given type of medical imaging equipment is directly related to the demand for the procedure which uses that equipment, the preceding discussion of the substitution among techniques makes it clear that medical imaging machines are not homogeneous, perfectly substitutable products. Rather, they fit the description of a differentiated product, that is, one for which the price may rise without the loss of all sales. For instance, interpretation of the image takes up the radiologist's time. Therefore, ultrasound, which is relatively difficult to interpret, has a higher (time) price to the radiologist than other imaging techniques. In spite of this higher price, ultrasound is still an integral part of the radiologist's repertoire. For each imaging modality, there is some dimension in which that modality's "price" is higher, and yet there is substantial demand for each type of equipment. In general, the notion of differentiated products is especially suitable for describing this market.

New Technologies

In addition to the established imaging techniques described previously, there are two emerging imaging technologies which deserve attention. These are nuclear magnetic resonance and positron emission tomography. And, although positron emission tomography is still very much in the experimental stage, nuclear magnetic resonance is currently being clinically evaluated and is expected to be commercially available within a few years.

Nuclear magnetic resonance (NMR) technology is based on the fact that in a strong magnetic field the nuclei of certain elements will align themselves with the field. When radiowaves of a specific frequency are applied, energy is released. This energy can then be detected and used to form an image that gives both structural and functional information (Portugal, 1982).

Although the principles of NMR have been known since the late 1940's, it is only very recently that the technology has been applied to medical imaging. The advantages of NMR are that it produces very sharp images (much contrast detail), is relatively safe since it uses non-ionizing radiation, and can provide chemical, as well as structural, information. The disadvantages are that it is extremely costly (between $1 million and $2 million for a single unit) and that there are technical problems, largely involving production of the magnetic field (Brody, 1982).

The primary clinical applications of NMR are expected to be in the early diagnosis of ischemic brain disease, the detection of multiple sclerosis, and differentiation between malignant and benign tumors (Brownell et al., 1982). Although NMR is still being clinically evaluated, firms in the industry are actively developing equipment for this market, and some orders have already been placed (Portugal, 1982).

Another developing technology is positron emission tomography (PET). This technique utilizes certain radioisotopes which emit positrons (positively charged electrons). When a positron collides with an electron, two photons are produced which are emitted at 180° from one another. By positioning multiple detectors around the source, the location and depth of the original positron can be plotted (Brownell et al., 1982).

The chief advantage of PET is that it can reveal cellular activity as well as structure. This is expected to be particularly useful for evaluating brain damage and mental disorders, such as schizophrenia and Alzheimer's disease (Portugal, 1982). However, there are problems which limit PET to experimental uses at this time. The major difficulty is that the radioisotope to be used in the procedure is quite short-lived and must be produced very near the site of the procedure. In general this means that there must be a cyclotron close to the hospital, a requirement that makes this technique prohibitively costly at this time (Miller, 1982).

SUPPLY CONDITIONS

An important aspect of the basic conditions in an industry is the nature of supply, the topic of this section. The production technology is discussed first, with emphasis on the central role of electronics in this industry. Then there is a description of the various inputs to the production process. Lastly, the distribution of supply is examined, including patterns of plant size and value of shipments, as well as changes over time in the cost of materials and production wages as a proportion of value of shipments.

Production Process

Any piece of medical diagnostic imaging equipment is composed of a number of different components. For example, a diagnostic X-ray system may include an X-ray tube, high-voltage generator, control panel, table, film changer, cassette holder, and collimator. The production process varies by type of component. There are two general types of production techniques which are important in the manufacture of medical imaging equipment: mechanical and electronic.

The mechanical side of the production process involves ordinary sheet metal (fabrication) work, as well as more detailed punch drilling and other machine tooling. By these means, the basic construction is performed, i.e., the housing of the equipment is fabricated. The techniques involving electronics, on the other hand, produce the workings, or inner mechanism, of the equipment. There are two types of electronics processes which are important: general electronics assembly and computer systems.

General electronics assembly is used to manufacture components such as X-ray tubes and gamma radiation detectors. This may involve hand work or an automated process. For example, circuit boards may be hand installed and soldered on a predrilled board, or there may be equipment which automatically performs the installation and soldering.

Computers have become more and more important in the manufacture of diagnostic imaging equipment. In the first place, micro computers are often used as process controllers. For example, a CT scanner uses micro-processors to control the rotation of the X-ray tube and detectors. Secondly, many types of medical imaging equipment now use a computer for data processing and analysis. For instance, there is a wide variety of data processing systems available for use with nuclear scanning equipment, and computerized data processing is an integral part of CT scanning and digital radiography.

Inputs

The capital inputs used to produce medical diagnostic imaging equipment include raw materials, inputs manufactured by others, and capital equipment. The most important raw materials are aluminum and steel, with copper and silicon also playing a role. Producer goods purchased from other firms include plastics, insulating media, and, most importantly, electronic components. And, capital equipment covers sheet metal equipment and drill presses, as well as all the basic plant and equipment associated with a manufacturing establishment.

Much of the labor in the production process is semi-skilled, in which on-the-job training is provided by the company. For example, the construction of X-ray tubes involves a great deal of hand work. At many of the larger plants, the production workers are represented by the International Brotherhood of Electrical Workers. Skilled labor is used for quality control, supervisory tasks, and staff positions. Trained technicians are often used to perform the quality assurance procedures, while production engineers oversee the production process. Scientists, design engineers, and managers are all staff personnel.

Distribution of Supply

Information on the distribution of establishments (plants) producing medical diagnostic imaging equipment is contained in the Census of Manufactures, which is published every five years and which uses the Standard Industrial Classification (SIC) code. The 4-digit SIC group of interest here is 3693 which in 1967 and 1972 was titled "X-Ray Apparatus and Tubes." Although some other medical equipment was included (e.g., EEG equipment), in general the classification is quite close to imaging equipment. However, in 1977 the title of SIC 3693 was changed to "X-Ray, Electromedical, and Electrotherapeutic Apparatus" and data on a number of new categories of medical equipment (such as pacemakers, automated blood analyzers, etc.) were included. Nevertheless, comparison of various statistics for 1967 to 1977 is informative because the focus here is on where imaging equipment is manufactured, and the SIC code emphasized the supply side. In fact, similarity of production processes is a criterion for SIC industry definition. Moreover, almost all the products made in SIC 3693 plants are primary products, i.e., few products properly assignable to other industries are manufactured in these establishments.[4]

Tables 1-2 and 1-3 reveal that in this industry small plants account for a large proportion of the total number of establishments, but a very small proportion of total value of shipments. Looking at the distribution of the size of establishment (measured by number of employees) both by number of establishments and by value of shipments over time provides

Table 1-2

Industry 3693
Employment Size Distribution of Establishments

Number of Employees per Establishment	Number of Establishments					
	1967		1972		1977	
	(Number)	(%)	(Number)	(%)	Number)	(%)
1-4	30	36.6	26	25.0	66	27.2
5-9	5	6.1	16	15.3	32	13.2
10-19	6	7.3	8	7.7	19	7.8
20-49	14	17.1	21	20.2	28	11.5
50-99	10	12.2	8	7.7	27	11.1
100-249	10	12.2	15	14.4	38	15.6
250-499	3	3.7	4	3.9	17	7.0
500-999	2	2.4	4	3.9	8	3.3
1000-2499	2	2.4	2	1.9	8	3.3
TOTAL	82		104		243	

From: Census of Manufacturers, Industry Series, U. S. Department of Commerce, Table 4, 1967, 1972, 1977.

Table 1-3

Industry 3693
Distribution of Value of Shipments
by Employment Size of Establishment

Number of Employees per Establishment	Value of Shipments (1967$)					
	1967		1972		1977	
	(million$)	(%)	(million$)	(%)	(million$)	(%)
1-4	1.0	.4	.9	.2	2.4	.3
5-9	.8	.3	2.2	.6	6.8	.7
10-19	2.0	.9	3.1	.8	8.7	.9
20-49	8.8	3.8	20.5	5.5	33.1	3.4
50-99	17.1	7.3	14.3	3.8	47.8	5.0
100-249	34.7	14.9	74.3	19.7	180.8	18.7
250-499	26.4	11.3	47.0	12.5	175.0	18.1
500-2499*	142.4	61.1	214.1	56.9	511.4	52.9
TOTAL	233.2		376.4		966.0	

*Categories combined to avoid disclosing figures for individual companies.

Derived from: Census of Manufacturers, Industry Series, U. S. Department of Commerce, Table 4, 1967, 1972, 1977; nominal values adjusted by Wholesale Price Index for Industrial Commodities (1967=100), Wholesale Prices and Price Indexes, U. S. Department of Labor, Bureau of Labor Statistics, 1972, 1977.

information about possible changes in the production technology. If neither the percentage of plants in each plant size class nor the percentage of value of shipments in each plant size class has changed, then it is unlikely that the production technology has changed significantly. For example, if a new production process was introduced which had a major effect on the minimum efficient scale of production, then this change would affect both the size distribution of plants and the distribution of value of shipments by plant size.

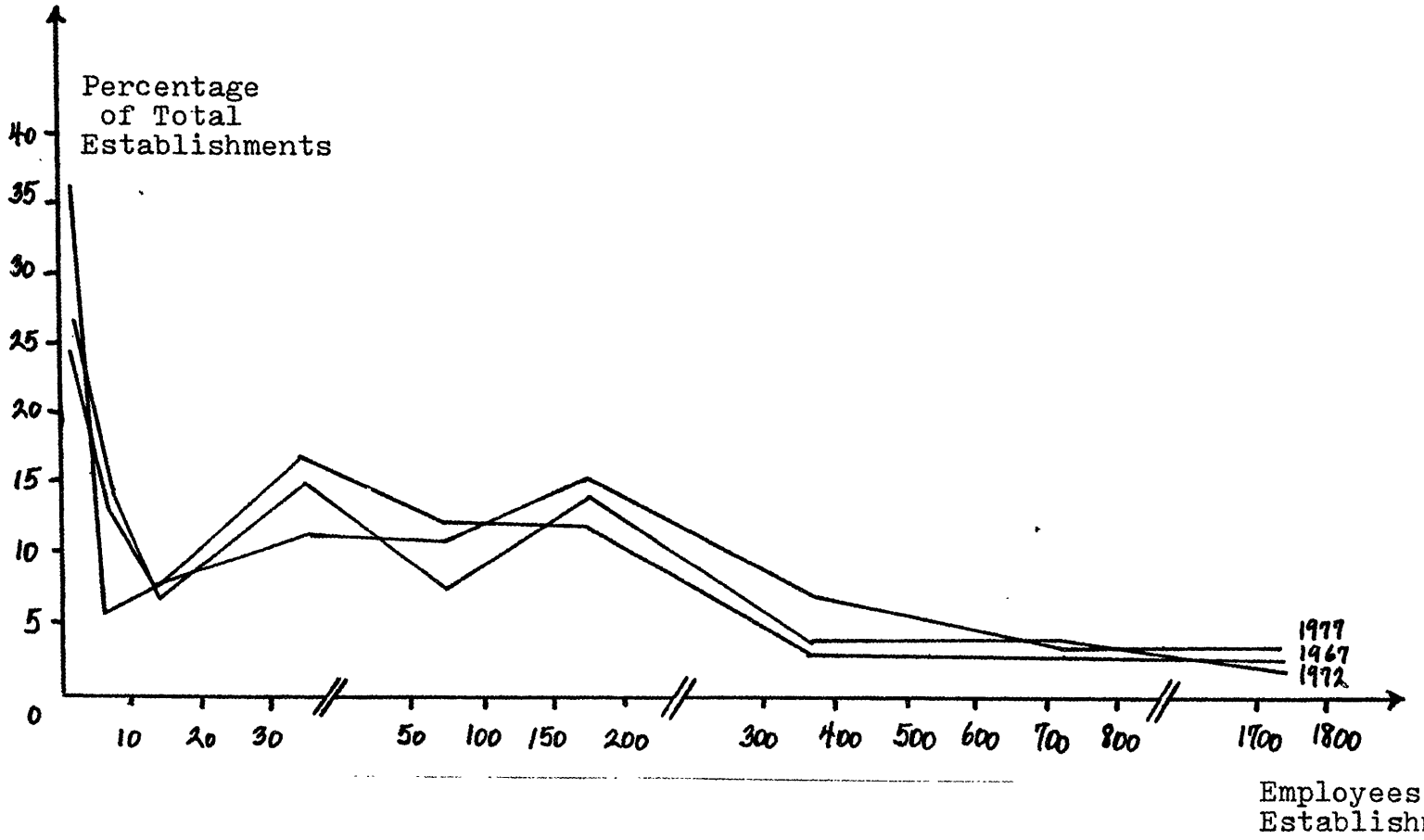
Figures 1-1 and 1-2 plot the percentage of plants in each employment size category and the percentage of value of shipments in each employment size category, respectively. The distributions of plant size and value of shipments are shown to have been quite stable over the period 1967 to 1977,[5] and it can be concluded that it is unlikely that the production technology changed significantly over that period.

Information about other aspects of the nature of supply is presented in Table 1-4. The first thing to notice is the large increase in the total number of plants between 1972 and 1977. This was largely due to the change in industry definition. Even with the addition of these new equipment categories, it can be seen that multi-plant firms are not very prevalent in this industry, with the average number of production establishments per firm ranging from 1.05 in 1967 to 1.15 in 1977.

The total number of employees and the number of production workers has increased as the number of plants has grown,

Figure 1-1

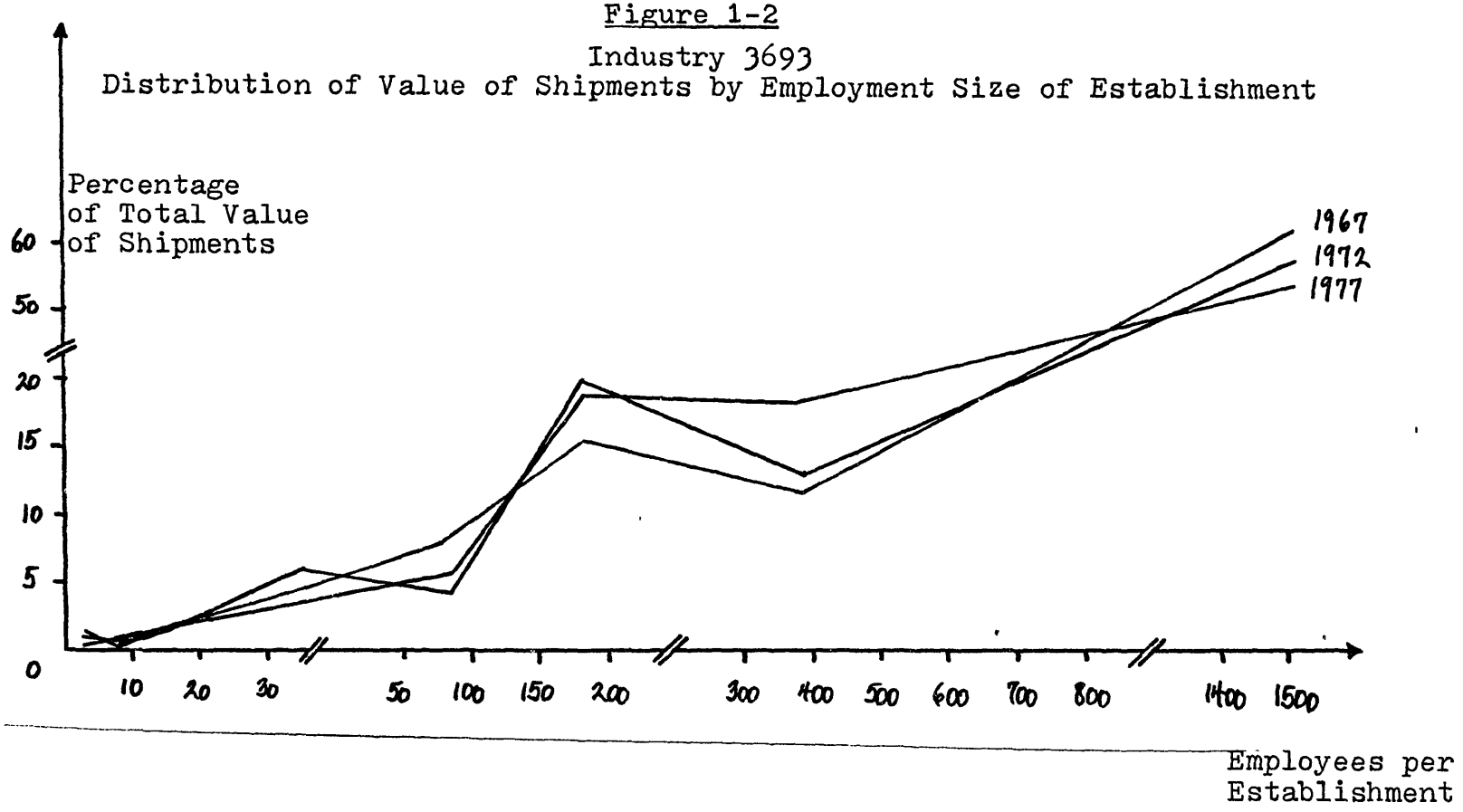
Industry 3693
Employment Size Distribution of Establishments



Derived from: Census of Manufacturers, Industry Series, U. S. Department of Commerce, Table 4, 1967, 1972, 1977.

Figure 1-2

Industry 3693
Distribution of Value of Shipments by Employment Size of Establishment



Derived from: Census of Manufacturers, Industry Series, U. S. Department of Commerce, Table 4, 1967, 1972, 1977; nominal values adjusted by Wholesale Price Index for Industrial Commodities (1967=100), Wholesale Prices and Price Indexes, U. S. Department of Labor, Bureau of Labor Statistics, 1972, 1977.

Table 1-4

Industry 3693
Selected Statistics

	1967	1972	1977
Number of Companies	78	95	211
Number of Establishments	82	104	243
Establishments per Company	1.05	1.09	1.15
Total Number of Employees	7900	12,100	30,900
Number of Production Workers	4300	6900	17,100
Production Workers as % of Total Employees	54.4	57.0	55.3
Value of Shipments, 1967$ (million$)	233.2	376.4	966.0
Cost of Materials, 1967$ (million$)	104.0	124.9	372.5
Cost of Materials as % of Value of Shipments	44.6	33.2	38.6
Production Wages, 1967$ (million$)	26.3	47.1	100.2
Production Wages as % of Value of Shipments	11.3	12.5	10.4

Derived from: Census of Manufacturers, Industry Series, U. S. Department of Commerce, Table 1a, 1977; nominal values adjusted by Wholesale Price Index for Industrial Commodities (1967=100), Wholesale Prices and Price Indexes, U. S. Department of Labor, Bureau of Labor Statistics, 1972, 1977.

but the number of production workers as a proportion of total employees has been steady over the period 1967 to 1977. Likewise the value of shipments has been growing, but the constant dollar cost of materials and production wages as a proportion of value of shipments has been relatively stable over the period.

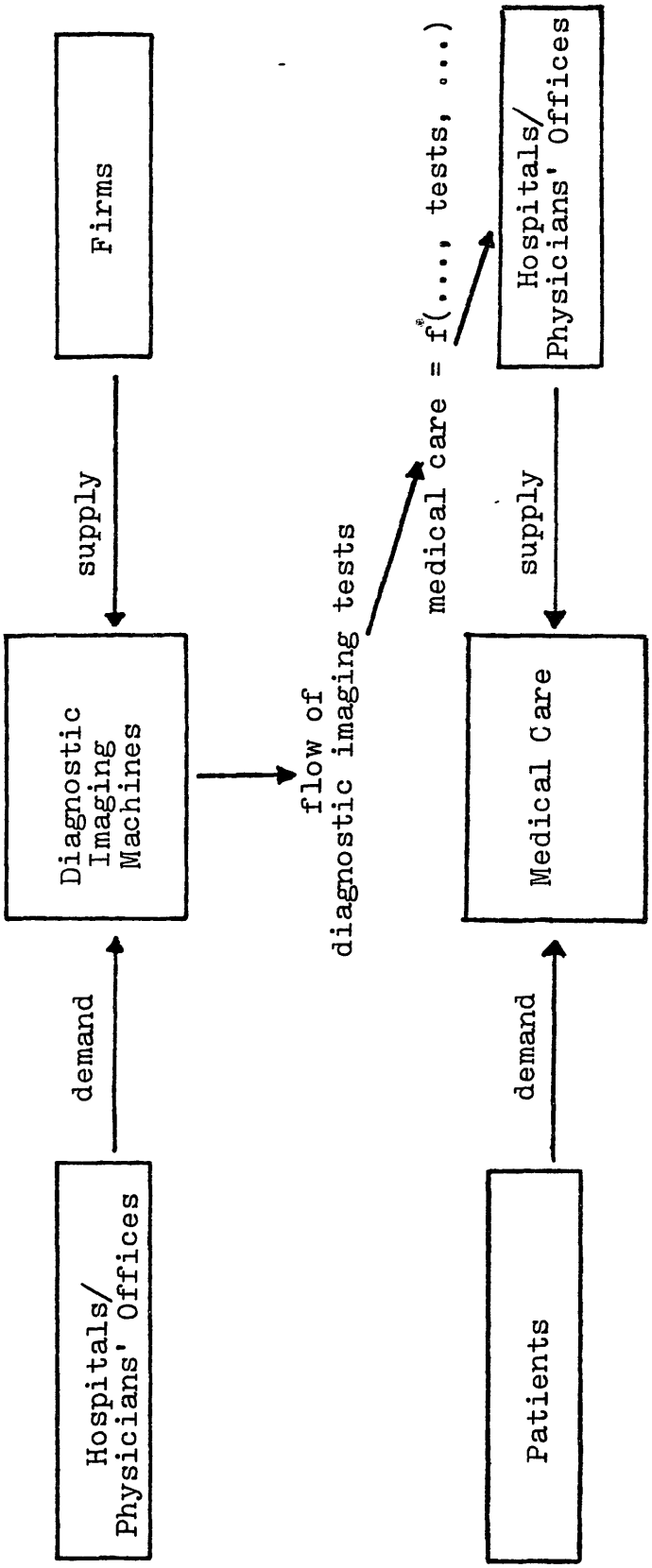
DEMAND CONDITIONS

The market for medical diagnostic imaging equipment consists of firms which supply the machines and hospitals and physicians' offices[6] which demand them. As Figure 1-3 illustrates. the machines are demanded for the flow of services, or diagnostic imaging tests, which they provide. These tests are then an input into the production function for medical care. The final product of medical care is demanded by consumers and supplied by hospitals or physicians' offices.

In this section the nature of demand for medical imaging equipment is examined. This begins with a discussion of the role of health insurance in the market for medical care. Then the distribution of demand, or who the buyers are, is investigated. Next, the determinants of demand are analyzed, with hospitals and physicians' offices treated separately. Finally, the nature of demand is explored by looking at the price elasticity of demand and utilization rates.

Figure 1-3

The Market for Medical Diagnostic Imaging Equipment



Health Insurance

One of the most important features of the medical care market is that payment for services rendered is generally made by a third party, i.e., by a private insurance company or a public program such as Medicare. The percentage of the population in the U. S. covered by some type of health insurance has increased steadily from about 50% in 1950 to over 80% in 1980.[7]

The relevant price of medical care is the net price, or what the patient actually pays. Health insurance reduces the effective price of medical care to the consumer. For the individual, health insurance means a lower price--the consumer moves down his or her demand curve. However, the aggregate effect is an outward shift of the demand for medical care (Feldstein, 1979). This implies that demand for inputs to medical care, such as imaging equipment, is also increased. Moreover, given such extensive insurance coverage, the method of reimbursement chosen by third-party payers will affect resource allocation (and thus demand for inputs) by the suppliers of medical care (Joskow, 1981).

Distribution of Demand

As noted previously, both hospitals and physicians' offices demand medical imaging equipment. The economic behavior of these buyers may differ (see next section) and it is useful to know the relative importance of these buyers. One source of information about the distribution of demand is the survey of firms in the industry (see Appendix A). One of the questions in the survey asked about the distribution of sales. The responses, reported in Table 1-5, show that, for the 25 companies responding to the question, about half of imaging equipment sales are to hospitals, about a quarter to physicians' offices, and the remainder to other companies and other. The relatively high percentage of sales to other companies (15%) is due to responses from firms which produce only imaging equipment components (see Chapter 2). The responses for the multiproduct firms, which are more representative of firms selling imaging systems, show that about 80% of imaging equipment sales are to hospitals and about 15% are to physicians' offices. This is consistent with the estimate by International Resource Development (1978) that hospitals account for about 85% of total U. S. purchases of medical imaging systems.

With respect to X-ray equipment, Miller (1977) reports that less than 40% of all medical diagnostic X-ray systems are located in hospitals. And, a FDA report[8] estimated that over 60% of all X-ray procedures in 1970 were performed in

Table 1-5

Responses to the Medical Diagnostic Imaging Equipment Industry Questionnaire, Distribution of Demand Question

Question: "What percentage of your sales is -- to hospitals, to physicians/physicians' offices, to other companies, or other?"

	Mean				
	"to hospitals"	"to physicians/ physicians' offices"	"to other companies"	"other"	Number of Companies Responding
X-Ray Equipment	54%	21%	17%	8%	14
CT Scanners	67%	17%	14%	2%	5
Ultrasound Devices	61%	29%	7%	3%	13
Nuclear Scanning Equipment	51%	26%	2%	21%	5
TOTAL	48%	27%	15%	10%	25*
Multiproduct Firms Only	79%	17%	2%	2%	6

*Rows do not sum to this figure due to multiproduct sellers.

hospitals. Since larger, more expensive X-ray equipment will tend to be found in hospitals, it is expected that annual sales of X-ray equipment to hospitals will be at least half of total sales. This agrees with the survey finding that slightly over half of X-ray equipment sales are to hospitals.

The situation is rather different for sales of CT scanners. Banta and Sanes (1978) report that as of August 1976, 83% of the scanners they were able to identify were located in hospitals and 17% were operated in private physicians' offices and clinics. This agrees with a survey by the National Electrical Manufacturers Association which found that, of the CT scanner units installed in the U. S. as of December 1977, approximately 85% were in hospitals and 15% were in physicians' offices and clinics.[9] And by May 1980, the Office of Technology Assessment reported that 78% of the operational CT scanners in the U. S. were located in community hospitals.[10] The survey results correspond to these findings after a firm which produces CT components is excluded from the tabulation; the four remaining firms report that about 80% of CT scanner sales are to hospitals and about 15% are to physicians' offices.

The demand for ultrasound devices is similar to that for X-ray equipment. Both technologies are long established, and the machines are relatively inexpensive and easy to use. Particularly since the dosage levels used in diagnostic ultrasound are not considered to be dangerous (Fleischer

and James, 1980), many private physicians specializing in obstetrics have ultrasound devices in their offices. Portugal (1982) estimated that about 60% of ultrasound units are sold to hospitals, the remainder going primarily to physicians' offices, a conclusion in accordance with the survey results.

For the five nuclear scanning equipment manufacturers responding to the survey, about 50% of sales are to hospitals and about 25% are to physicians' offices. The large percentage of sales to other (21%) is due to one company which sells all its equipment for clinical research. When this firm is excluded, the remaining four firms report that 65% of sales are to hospitals and about 30% to physicians' offices.

The distribution of demand thus varies by type of equipment, with hospitals accounting for most CT scanner sales. For X-ray equipment, ultrasound devices, and nuclear scanning equipment, on the other hand, physicians' offices are also an important component of demand.

Determinants of Demand

There are two components of the decision to purchase medical diagnostic imaging equipment: the decision to purchase and the choice among alternative pieces of equipment. The periodic nature of the decision to purchase is a result of the fact that diagnostic imaging machines are durable goods. This is a technical decision, the buyer can be thought of as solving an optimal stock purchase problem given flow characteristics of the machines and final demand for flow services.

In standard derived demand analysis, demand for an input being supplied to a cost-minimizing producer will depend only on input prices and the level of final output. In the case of medical care, however, "output" is multidimensional, with both quantity and quality being important aspects of the level of output. Quality in this context is determined both by the level of inputs used and by the range of services provided (Joskow, 1980). For example, the quantity "100 bed-days of hospital care" could be associated with many different levels of quality as measured by such things as number of nurses per bed, in-house clinical chemistry capabilities, number of intensive care beds, etc. The producers of medical care, in choosing the level of output, thus choose both a level of quantity and a level of quality. This choice, along with input prices, will determine the demand for inputs.

Hospitals

A number of early papers modeled hospitals as striving to maximize some economic variable subject to various constraints. As Jacobs (1974) observes, these models can be identified by the fact that they treat the hospital as an "organism" or monolithic decision-making entity. The maximand in these models ranges from net revenue (Davis, 1971) to net income of staff physicians (Pauly and Redisch, 1973). A major drawback of the "organism" models is that they assume that production decisions in the hospital are made either by the hospital administrator or by the medical staff. In fact, as Harris (1977, 1979) demonstrates, the most relevant fact for understanding hospital behavior is the largely autonomous dual lines of authority that characterize the organizational structure of the hospital.

The medical staff makes the clinical decisions about medical care and thereby allocates hospital resources, while the hospital administration is responsible for making the resources available to doctors, getting supplies from outside sources to the appropriate hospital personnel. The administration in principle faces a budget constraint and must pay attention to input costs in making purchase and budget decisions. For example, in considering the purchase of a piece of medical imaging equipment, the administration must look at the difference between hospital revenues (projected number of diagnostic imaging tests times expected reimbursement per test)

and costs (price of the machine, operating costs, physician and technician labor costs). However, when third-party payment is cost-based, the expected reimbursement per test is tied to the price of the machine (and other costs) and the nominal budget constraint is nonbinding over time. As for the doctors, with the exception of a loose departmental budget constraint (which generally does not cover capital expenditures), there is no incentive for taking input costs into account when making clinical decisions.

Consumers of hospital care pay very little of the costs of hospital care out of their own pocket. Joskow (1981) estimates that 80% to 90% of the population in the United States has insurance coverage for about 95% of hospital charges. This means that the price of care is not very important in the consumer's choice among hospitals. It also means that hospitals must shift the basis of their competition for patients to something other than price. And hospitals have found that competition on the basis of quality and scope of services provided is an effective means of attracting patients (Joskow, 1980).

Quality competition in the medical care market influences the demand for inputs into the production of medical care. Because medical imaging equipment is technologically complex, there are numerous dimensions to the quality of such a machine. Foremost are aspects of the image itself, such as clarity, lack of artifact, and resolution. Properties of the machine, such as speed, ease of operation, reliability, and service

and maintenance characteristics are also important (see Chapter 2 for further detail).[11] And, quality will also be a very important determinant of the demand for medical imaging equipment because both lines of authority in the hospital have an incentive to emphasize quality in the choice among alternative pieces of equipment.

As argued above, the pervasiveness of third-party payment and cost-based reimbursement methods makes the price of diagnostic equipment a secondary consideration for the hospital administration. And, administrators can point to up-to-date diagnostic facilities as tangible evidence of the quality of care provided by their hospital.

For the doctors, a better quality image is thought to lead to a better diagnosis, and thus to a higher quality of medical care. The availability of high quality, state-of-the-art equipment also enhances the radiologist's reputation as a specialist, thereby increasing his or her potential income, and is a protection against malpractice actions. And the staff physicians can reassure their patients that the latest diagnostic advances are at their service.

A study by Cromwell et al. (1976) supports this line of reasoning. They found that factors such as improvements in patient care and patient safety tended to be much more important than price in a hospital's decision to adopt a new piece of equipment. This is consistent with a Frost and Sullivan (1974) report which finds that the choice of diag-

nostic equipment depends on (in order of importance): performance, safety, service, ease of use, and price.

Thus, the hospital's choice among alternative pieces of medical imaging equipment will be determined primarily by perceived quality variations. However, hospitals account for only a portion of the demand for this type of equipment, with physicians' offices accounting for the remainder.

Physicians' Offices

Physicians in private practice, like hospitals, must choose levels of both quantity and quality when making "output" decisions. In a review of the literature on physician behavior, the National Academy of Sciences (1979) reported that physicians were influenced by income, prestige, leisure, ethics, and the quality of medical care. More formally, Zweifel (1981) presents a model of physician behavior in which utility depends on labor income, leisure time, and an ethical variable. For Zweifel's purposes, the ethical variable is defined in terms of the doctor's time and the patient's symptom severity level. It is easy to see, however, that production costs as a signal of quality could enter the utility function positively through the ethical variable, as well as negatively through the income variable. By emphasizing quality in the choice of inputs, the physician can avoid giving the appearance of providing "cut-rate" care and can fulfill the ethical commitment to put the welfare of the patient first.

Patients are often ignorant about the prices charged by various doctors (Newhouse, 1970). This raises the question of how doctors compete for patients, if not on the basis of price. As with hospitals, quality competition is likely to be an effective means of attracting patients. And, the possession of highly visible, technologically sophisticated equipment is a signal of quality care by the doctor.

It is important to note that physician's offices appear to operate under a more rigid budget constraint than do hospitals. Sloan and Steinwald (1975) found that insurance coverage for surgical procedures and in-hospital visits is much more complete than that for outpatient visits. This means that patients will pay more of the cost of office visits out of their pocket. They also found that cost-based reimbursement procedures were not the norm for physician repayment, rather they present evidence that insurers' fee schedules are generally set well below physicians' mean fees. This means that physicians' offices will tend to be more sensitive to price than hospitals when choosing among alternative pieces of medical equipment (but less sensitive than a producer without third-party payment).

As a result of both ethical considerations and competition for patients, quality will be an important determinant of the demand for medical diagnostic imaging equipment by physicians' offices. However, because reimbursement procedures tend not to be cost-based, the demand by physicians' offices will be more price-sensitive than the demand by hospitals.

Price Elasticity of Demand

Hicks (1963) derives Marshall's rules for the determinants of derived demand elasticity in the two factor case. He finds that demand for the input is more elastic:

(1) the more readily substitutes are obtained,

(2) the larger that input's share in total cost (provided that the elasticity of final demand exceeds the elasticity of substitution),

(3) the more elastic the demand for the final product, and

(4) the more elastic the supply of other inputs.

This is a convenient way of assessing the price elasticity of the derived demand for medical diagnostic imaging equipment. Each of the determinants will be considered in turn.

As was discussed in the market definition section, there is little opportunity for substitution between medical imaging equipment and other types of diagnostic equipment or services. This is because medical imaging equipment provides the physician with a unique type of clinical information. Diagnostic imaging tests allow the doctor to visualize internal organs. The only potential substitutes are exploratory surgery, endoscopic examinations, and thermographic (heat sensitive) diagnostic tests. There are serious dangers and costs associated with exploratory surgery and endoscopy and thermography are viable only for particular medical conditions. This suggests that, for most diagnostic uses, there would have to be very extreme price changes in order to induce any significant

substitution between medical imaging equipment and other inputs into the production of medical care.

In terms of the share of diagnostic imaging tests in the total costs of medical care, Theta Technology Corp. (1978) estimated that the radiology department accounts for approximately five per cent of total hospital costs. This is consistent with a Frost and Sullivan(1980b) report that, on average, diagnostic imaging operating costs accounted for about 4.5 per cent, and imaging labor costs about 5.3 per cent, of the respective hospital totals for those costs.

Feldstein (1979) reviewed the extensive literature on the demand for medical care and found that medical care is demand inelastic. The price elasticity for hospital patient days ranged from -.2 to -.7, for hospital admissions from -.03 to -.5, and for physician visits from -.1 to -.2.

There is little empirical work on the supply elasticity of the inputs into medical care. Given this and the fact that there are no strong a priori grounds for assessing relative supply elasticities, it will be assumed that the supply elasticity of other inputs is not a predominant determinant of the price elasticity of medical imaging equipment.

Putting the various effects together, we find that:

(1) there is little substitution among diagnostic imaging tests and other inputs into the production of medical care,

(2) the costs of medical imaging do not account for a

significant share of the total costs of medical care, and

(3) the final output, medical care, is demand inelastic.

This suggests that the demand for medical diagnostic imaging equipment will tend to be relatively price inelastic.

Utilization Rates

Changes in the rate of utilization of diagnostic imaging procedures technically do not give information about changes in demand, rather they tell how the equilibrium quantity position has changed. But, when demand is relatively inelastic and prices have not decreased, conditions which hold in this market, increases in utilization will be associated with outward shifts of the demand curve.

In general, the utilization of non-labor inputs (including diagnostic imaging equipment) has increased over the past 15 years.[12] In particular, a National Academy of Sciences (1979) study found that the use of equipment-intensive ancillary services (including diagnostic imaging procedures) has increased over the past ten years.

Turning to the utilization rates of specific procedures, Epstein and Grundy (1974) present evidence that 108 million people received an X-ray examination in the U. S. in 1964 and that by 1970 this had increased to 129 million people. The Food and Drug Administration estimates that by 1979 this had increased to 160 million people.[13] Epstein and Grundy (1974) also show that the number of X-ray procedures in the U. S. increased from 173 million in 1964 to 210 million in 1970. This had increased to 240 million X-ray procedures per year by 1977 (Theta Technology Corp., 1978).

Banta and Sanes (1978) estimated that in August 1976 there were 320 CT scanners in use in the U. S., and that by the beginning of 1978 1200 machines were in operation. They also estimated that, early in 1976, the average machine performed 3000 scans annually. By May 1980 there were 1470 scanners in operation in the U. S.[14] Provided that the average number of scans per machine per year did not decrease substantially (an unlikely prospect), this implies that the number of CT scans performed per year increased substantially over the period 1976 to 1980.

Frost and Sullivan (1974b, 1979) estimated that there were 4.2 million in vivo radiodiagnostic procedures performed in the U. S. in 1971, 7.5 million in 1973, and 8 million in 1977. And, Michela (1976) found that between 1971 and 1975 the number of nuclear medicine procedures per 100 hospital admissions increased from 11.7 to 22.2.

These various pieces of evidence demonstrate that the utilization rate of diagnostic imaging procedures has increased over the past 15 years. And, they are consistent with an increase in the demand for medical imaging equipment over the period.

REGULATORY ENVIRONMENT

There is an extensive set of government regulations which have an impact on the market for medical diagnostic imaging equipment. In the first place, there are two federal regulatory programs which directly affect the manufacturers of medical imaging equipment. These are:

(1) radiation safety regulation by the Food and Drug Administration (FDA), a program covering all radiation-emitting electronic products in order to protect the public from the hazards of radiation exposure; and

(2) medical device regulation by the FDA, a program designed to provide for the safety and efficacy of all medical devices.

There are also a number of regulatory programs which affect the demanders of diagnostic imaging equipment. Hospitals, in particular, are subject to a wide array of regulations at the federal, state, and local levels. These regulations can be classified as pertaining to hospital investment, expenditure, utilization, or safety. Hospital investment is regulated primarily by certificate-of-need (CON) programs and hospital expenditures by reimbursement controls. Utilization regulation includes such programs as Professional Standards Review, designed to evaluate the appropriateness of health care provision. Safety is regulated by a variety of programs, such as state safety inspections and licensure of medical users of radioactive materials by the Nuclear Regulatory

Commission. Regulatory constraints on physicians' offices are limited primarily to reimbursement controls in the Medicare and Medicaid programs.

In this section the legislative history, purpose, and provisions of radiation safety and medical device regulation will be described. Then CON and reimbursement regulation of hospitals will be discussed. The purpose of this section is to specify the web of regulatory constraints affecting the medical diagnostic imaging equipment market; a consideration of the impacts of these programs is postponed to Chapter 5.

Radiation Control Act

The Radiation Control for Health and Safety Act of 1968 (P.L. 90-602) provides for federal regulation of all radiation-emitting electronic products. In the U. S., X-ray examinations account for over 90 per cent of the population's total exposure to man-made ionizing radiation (Epstein and Grundy, 1974) Public concern about the potential for excessive radiation dosage from medical and dental X-ray procedures and the emission of X-rays from televisions and microwave ovens resulted in passage of this legislation.[15]

The purpose of radiation safety regulation is to protect both patients and imaging equipment operators from the hazards of long-run low-level exposure to radioactive materials. For example, medical X-ray examinations use a radiation dosage for which there are no immediately observable effects. However, although expert opinion on the biological effects of radiation is by no means unanimous, it is generally agreed that the effects are cumulative over time (Epstein and Grundy, 1974). The social concern, therefore, is with the long-term effects of radiation exposure such as an increased incidence of cancers and the potential for genetic defects.

The radiation safety regulatory program is administered by the National Center for Devices and Radiological Health of the FDA, and operates primarily by means of performance standards which set minimum safety standards for any radiation-emitting electronic product. Although the authorizing legis-

lation was passed in 1968; the performance standards were not announced until 1972, and did not become effective until 1974.

In terms of medical imaging equipment, X-ray equipment, CT scanners, and ultrasound devices all fall within the authority of this regulation. However, the potential radiation hazard to health of diagnostic ultrasound devices was not considered to be serious enough to warrant the imposition of performance standards for this class of equipment. Note that nuclear scanning equipment is not covered because the radiation associated with a nuclear scan comes not from the equipment, but from the ingested or injected radioactive material. Thus, radiation safety regulation affects only the manufacturers of diagnostic X-ray equipment (a term which includes both conventional X-ray equipment and CT scanners).

The salient aspects of radiation safety regulation are:[16]

(1) Safety performance standards.
Directions for maximum allowable radiation leakage, maximum allowable exposure time, limitation of the beam until adjusted to the image receptor size (called "positive beam limitation"), minimum allowable source to skin distance, safety interlocks, etc.

(2) Labeling and safety information requirements.
Directions for content and placement of warning and identification labels, provision of detailed technical information, safety instructions, and necessary maintenance schedules, etc.

(3) Specified quality control procedures.
Required characteristics of equipment used to measure compliance (e.g., aperture size), directions for the number, timing, and range of measures of compliance, etc.

(4) Recordkeeping and reporting requirements.
Requirements for records of quality control procedures, results of compliance tests, and distribution of products; and submission of initial and annual reports on safety testing procedures.

Radiation safety regulation affects the manufacturers of X-ray equipment and CT scanners. The most notable feature of the program is the use of standards as a means of protecting the public from the hazards of long-run low-level radiation exposure.

Medical Device Amendments

The Medical Device Amendments of 1976 to the Food, Drug, and Cosmetic Act (P.L. 94-295) authorized federal regulation of all medical devices in order to assure safety and efficacy. Interestingly, this rather sweeping legislation (it is estimated that as many as 5000 products may be affected[17]) was enacted at a time when deregulatory sentiment was strong in Congress (Baram, 1978). The legislation was initiated in response to public fears about rapid technological change in medical devices and the potential harm to users without federal standards. Rapid diffusion of the use of intrauterine devices, specifically the Dalkon shield (later shown to have potentially serious side-effects), was of particular concern.[18]

Medical device regulation, like radiation safety regulation, is administered by the National Center for Devices and Radiological Health, an agency which is the result of a recent merger of the Bureau of Medical Devices and the Bureau of Radiological Health within the FDA. The enabling legislation calls for devices to be classified into one of the following groups according to the extent of regulatory control: Class I, General Controls; Class II, Performance Standards; and Class III, Premarket Approval. In addition, there are general reporting and recordkeeping requirements.

The rationale behind medical device legislation is that, as medical devices become more technologically sophisticated and more complex, premarket testing and quality control stan-

dards are necessary to ensure safety and efficacy. There is a role for the government because many devices are so complicated that even highly trained users, such as doctors, are unable to evaluate their performance.[19]

Class I devices are subject only to general regulatory controls such as prohibitions against adulterated or misbranded devices. Devices in Class II must comply with safety standards governing their performance. And, Class III devices must pass approval requirements, involving in some cases clinical investigations, before they can be marketed. Expert advisory panels have been established to advise on the classification of devices. To date, the final classification has been published only for devices in the following general categories: hematology and pathology; cardiovascular; general hospital and personal use; neurological; and obstetrical and gynecological.[20]

FDA device categories are narrowly defined. For example, what is here called X-ray equipment includes a large number of device categories ranging from Electrostatic X-Ray Imaging System to Cine Fluorographic X-Ray Camera to Chest X-Ray Unit to Diagnostic X-Ray High Voltage Generator. In general, medical diagnostic imaging equipment is Class II, with safety performance standards for X-ray equipment, CT scanners, and ultrasound devices already established as a result of radiation safety regulation.

All medical devices are subject to the general provisions of the regulations. These are such things as labeling re-

quirements, establishment registration and device listing for manufacturers, premarket notification procedures, applications for investigational device exemptions, and compliance with good manufacturing practice standards (quality control and testing, recordkeeping). It is important to note that a manufacturer must submit a premarket notification form (510-K) before the introduction of a "new" product. If the manufacturer can demonstrate that the product is substantially equivalent to a device already being sold, then premarket approval is not required. If, however, it is a truly "new" product, then premarket approval is required. In this case the manufacturer must present evidence that the device is both safe and efficacious.[21]

Regulation of medical devices is similar in some ways to drug regulation by the FDA. However, the medical device amendments were written with an eye to avoiding some of the problems associated with the regulation of pharmaceuticals. Thus, for example, the use of three classes, to differentiate between levels of potential risk. And, the advisory expert panels were established to encourage flexibility and responsiveness by the FDA (National Academy of Sciences, 1979).

It is interesting to note that the medical devices industry actually supported the establishment of safety standards for medical devices.[22] The rationale was that this would serve as a guarantee against the possibility of irresponsible actions by a few firms which could greatly harm the reputation

of the industry (Baram, 1978). On the other hand, firms in the industry are adamantly opposed to the premarket approval provisions of the regulation, arguing that they will lead to a significant retardation in innovation.[23]

Medical device regulation affects the manufacturers of all types of diagnostic imaging equipment. Manufacturers must ensure the safety and efficacy of their medical devices by compliance with safety performance standards for established products and by receipt of premarket approval for new products.

Hospital Regulation

The rapid rise of health care expenditures is a well-known source of public concern. The increases in total expenditures are a result of both price and quantity increases. For example, over the period 1970 to 1980, personal health care expenditures increased at a 12.9% average annual rate when measured in nominal terms, and at a 4.3% average annual rate when measured in constant dollars.[24]

The attempt to control these medical care expenditure increases has focused almost exclusively on the hospital. One of the reasons for this emphasis on the hospital is that over the period 1970 to 1980 the consumer price index for a hospital room not only increased much faster than the consumer price index for all items, but also increased substantially faster than the consumer price index for all medical care.[25]

As was mentioned previously, there are several different types of hospital regulations: investment, expenditure, utilization, and safety. The certificate-of-need (CON) program (investment) and reimbursement controls (expenditure) will be discussed in detail, because they are directly related to the issue of controlling hospital costs and thus have an impact on the firms which supply inputs to the hospitals.

Certificate-of-Need Programs

Under a certificate-of-need (CON) program, a hospital[26] must demonstrate to a state or local health systems agency that certain need criteria have been met before making a capital expenditure of over $100,000 or $150,000.[27] The purpose of CON review is to control hospital cost inflation by preventing excess capacity and restraining "unnecessary" expansion (Salkever and Bice, 1979). There are some common characteristics, but CON programs differ substantially from state to state, and thus the objectives and implementation of the program will also vary by state (Russell, 1979).

Although some states already had programs, CON became widespread after the passage of the National Health Planning and Resource Development Act of 1974 (P.L. 93-641), which provided for the withholding of certain federal funds if a state did not establish a CON program meeting given standards. This legislation reinforced and extended the intent of Section 1122 of the Social Security Amendments of 1972, which authorized the denial of reimbursement for capital expenditures under Medicare and Medicaid without approval of the appropriate health systems agency (Joskow, 1981).

As of January 1980, 47 states had passed CON laws. These programs all meet the federal guidelines. Beyond that, however, there are substantial differences among states. In the first place, agency objectives vary, with some states focusing on regional health planning needs and others emphasizing strict

control of facility duplication or expansion. The stated criteria for approval also differ from state to state, as well as agency budgets and the extent of information that must be provided by the applicants (Joskow, 1981).

CON has the potential to significantly affect the demand for medical diagnostic imaging equipment. The price of many medical imaging machines exceeds the CON threshold and, in these cases, purchase of the machine becomes contingent upon receiving CON approval. Although firms will often work with the hospital to prepare a CON application, the final impact on the manufacturers depends on how the CON criteria are interpreted by the regulatory agency. The effects of CON on the industry will be analyzed in Chapter 5. In the meantime, CON, as an important part of the regulatory environment, must be kept in mind when analyzing the structure, conduct, and performance of the medical imaging equipment industry.

Reimbursement Regulation

Since over 80 per cent of the population in the U. S. has insurance coverage for about 95 per cent of hospital charges (Joskow, 1981), the method of third-party reimbursement is a very important link in the chain of hospital costs. In the past, cost-based retrospective reimbursement, in which the hospital was repaid on the basis of a markup over actual costs incurred, was common. When costs are fully reimbursed, hospitals have no incentive to conserve resources or hold down costs.

Beginning in the early 1970's, there was a movement toward prospective reimbursement, in which repayment rates are set in advance. Prospective reimbursement is sometimes the result of rate-setting regulation at the state level and sometimes the result of private rate regulation programs, usually Blue Cross (Dowling, 1977). Although there are various methods for setting prospective reimbursement rates, the general purpose is to force hospitals to face a binding budget constraint.

The price controls stemming from the Economic Stabilization Program in the early 1970's were the first widespread effort to constrain hospital budgets. The Carter administration attempted to extend this initiative by proposing a hospital cost containment program. However, this legislation was not passed by Congress, and, as a result, responsibility for controlling hospital inflation reverted to the state level.

The lack of federal leadership has resulted in a great deal of variation among states in hospital reimbursement policies. As of the end of 1980, only eight states had mandatory rate regulation programs; four states had mandatory rate review programs, and there were private rate regulation programs in 12 states. Even among the mandatory programs, there were significant differences in the method of rate determination, coverage, and organizational structure (Joskow, 1981).

Prospective reimbursement of hospitals can affect the demand for medical imaging equipment. In the first place, effective prospective rate-setting will reduce the utilization rate of growth for diagnostic imaging tests and thus, prices held constant, will reduce the quantity of medical imaging equipment demanded. A binding budget constraint may also affect the choice among alternative machines, i.e., since price will play a larger role in the purchase decision relative to quality, which machine is chosen may change. The effect of various public policies, including reimbursement regulation, on the medical diagnostic imaging equipment industry will be examined in Chapter 5.

FOOTNOTES: CHAPTER 1

[1]For example, there is a medical journal called Diagnostic Imaging and a radiology reference entitled Medical Imaging (Kreel, 1979), both covering exactly these types of procedures.

[2]See, for example, Introduction to Clinical Radiology (Miller, 1982) or A Textbook of Radiology and Imaging, Third Ed. (Sutton, 1980).

[3]Changing Medical Markets, 50 (February 1983), pg. 5.

[4]The primary product specialization ratio, the ratio of primary product shipments to the sum of primary and secondary product shipments, for SIC 3693 was 98% in 1977, 95% in 1972, and 93% in 1967 (U. S. Department of Commerce, Census of Manufactures, Industry Series, 1967, 1972, 1977).

[5]An analysis of variance was used to test the null hypothesis that the average number of employees per establishment was the same in 1967, 1972, and 1977. The F statistic was insufficient to reject the null hypothesis. However, this test is not valid because the underlying populations are not normally distributed with the same standard deviation. A Kruskal-Wallis nonparametric analysis of variance was not feasible due to the nature of the data (reported in averages for employment size ranges).

[6]Although medical clinics also demand medical imaging equipment, they will not be considered separately in this analysis. Clinics may be organized on either a non-profit or a for-profit basis. If they are non-profit, then they are similar to hospitals; if they are for-profit, then they are similar to physicians' offices. Therefore, the nature of demand can be examined by considering only hospitals and physicians' offices.

[7]Derived from Source Book of Health Insurance Data, 1981-82, Washington, D.C.: Health Insurance Association of America, pg. 12; and Statistical Abstract of the United States, 1981, U. S. Department of Commerce, Bureau of the Census.

[8]U. S. Department of Health, Education, and Welfare, "Population Exposure to X-Rays, U.S. 1970," November 1973.

[9]Cited in the "Gray Sheet" (Medical Devices, Diagnostics, and Instrumentation Reports), May 1, 1978.

[10]Ibid., February 23, 1981.

[11]This refers to the quality of a given piece of equipment. Quality of a radiology department will depend not only on characteristics of individual machines, but also on the range of services provided.

[12]Health, U.S., 1982, pg. 147.

[13]Federal Regulation of Radiation Health and Safety, Committee on Governmental Affairs, U. S. Senate, 1978, pg. 158.

[14]The "Gray Sheet," February 23, 1981.

[15]U. S. Code Congressional and Administrative News, 90th Congress, 2nd Session, 1968, pg. 5947.

[16]Summarized from relevant sections of Code of Federal Regulations, Title 21.

[17]U. S. Department of Commerce (1979), pg. 61.

[18]U. S. Code Congressional and Administrative News, 94th Congress, 2nd Session, 1976, pg. 1071.

[19]Ibid., pg. 1075.

[20]Summarized from relevant sections of Code of Federal Regulations, Title 21.

[21]Ibid.

[22]Baram (1978), pg. 195; National Academy of Engineering (1971), pp. 39-40; U. S. Congressional Record--Senate, February 1, 1974, pg. 1794.

[23]U. S. Department of Commerce (1979), pg. 65.

[24]Derived from Health, U.S., various years.

[25]See Statistical Abstract of the United States, various years; and Health, U.S., various years.

[26]In addition to hospitals, the programs apply to nursing facilities, health maintenance organizations, kidney treatment centers, and ambulatory surgical facilities (National Academy of Sciences, 1979).

[27]The threshold varies by state.

CHAPTER 2: MARKET STRUCTURE

This chapter is an examination of structure in the medical diagnostic imaging equipment industry. The first section provides a broad overview of the industry, both market size and the nature of the firms selling imaging equipment are investigated. Then concentration patterns are explored, by product line and for the industry as a whole. Barriers to entry are the next aspect of structure analyzed. In particular, absolute cost advantages, economies of scale, and product differentiation are considered as sources of entry barriers. Finally, patterns of entry, exit, and merger are surveyed.

OVERVIEW OF THE INDUSTRY

The firms which supply medical diagnostic imaging equipment are assumed to be profit-maximizing entities: they are legally for-profit, usually incorporated, and often traded on the major stock exchanges. Medical imaging equipment is "supplied" both by original equipment manufacturers and also by firms which buy components from the manufacturers and then assemble the components at the purchase site. The industry to be analyzed here consists of the firms which manufacture imaging equipment.

This section is a foundation for the analysis of market structure in this industry. A broad overview of the industry is provided, beginning with a description of the extent of the market, both in the aggregate and by product line, along with changes in market size over time. Then the nature of the sellers is examined by looking at the number of sellers, the prevalence of multiproduct suppliers, the size distribution of sellers, and a description of the primary firms in the industry.

Market Size

Before considering the extent of the market for medical imaging equipment, it is informative to put this market in perspective by describing its position within the economy. Over the years 1969 to 1980, the size of the health care sector increased relative to other sectors of the economy, as indicated by the increase in the proportion of gross national product accounted for by national health expenditures from 7.1% to 9.5%. Within the health care sector, medical equipment and supplies as a proportion of national health expenditures increased slightly from 3.1% to 3.5%. And, medical imaging equipment's share of the medical equipment and supplies market remained steady at about 10% over the period.[1] Thus, the relative share of the diagnostic imaging equipment industry in the economy's output increased over the years 1969 to 1980.

Aggregate sales of medical imaging equipment in the United States were calculated by International Resource Development (1978) for selected years over the period 1969 to 1978 (see Table 2-1). According to these estimates, medical imaging equipment sales grew at an average annual nominal rate of 14.8% and at an average annual real rate of 7.1% over the years 1969 to 1978.[2] These computations for aggregate sales are consistent with those of other sources: total sales in 1977 and 1978 of $780 million and $850 million, respectively, are cited in the "Gray Sheet,"[3] and Frost and Sullivan (1980b) estimated 1980 shipments of diagnostic imaging equipment at

Table 2-1

Sales of Medical Diagnostic Imaging Equipment, U.S., Selected Years 1969-78

	1969 (million$)	1972 (million$)	1974 (million$)	1976 (million$)	1978 (million$)
X-Ray Equipment	200	240	270	300	330
CT Scanners		10*	75	200	215
Ultrasound Devices	2	10	21	50	125
Nuclear Scanning Equipment	35	35	60	55	100
Other	3	5	8	23	60
TOTAL	240	300	434	628	830

*No CT scanner sales in 1972, see discussion in text.

Derived from: International Resource Development (1978), pg. 44.

$900 million.

For the breakdown of sales by product line, however, the estimates of International Resource Development (1978) do not always agree with those of other sources. In regard to X-ray equipment, the 1972 sales figure of $240 million shown in Table 2-1 is relatively close to the Frost and Sullivan (1974a) calculation of $192 million for the same year. But, for the later years, International Resource Development estimates are consistently below those from other sources. Theta Technology Corp. (1978) assessed 1976 and 1977 sales of X-ray equipment at $467 million and $506 million, respectively; a 1978 sales figure for conventional X-ray equipment of $500 million was cited in the "Gray Sheet,"[4] and Frost and Sullivan (1980b) put 1980 shipments of X-ray equipment at $549 million.

For CT scanners, on the other hand, the estimates shown in Table 2-1 are generally high in comparison with assessments by other sources. In the first place, since the CT scanner was first commercially placed in the United States in mid-1973 (Banta and Sanes, 1978), the appraisal of CT sales in 1972 at $10 million is obviously incorrect. For the years after 1974, Frost and Sullivan (1975a) assessed 1975 CT scanner sales at $20 million, and Theta Technology Corp. (1978) calculated that 1976 and 1977 sales were $79 million and $108 million, respectively. For 1978, the estimate of $215 million shown in Table 2-1 is relatively close to the Hale and Hale (1978) figure of $195 million, but both are substantially higher than the

$100 million estimate cited in the "Gray Sheet."[5] Finally, Frost and Sullivan (1980b) put 1980 shipments of CT scanners at $114 million.

The size of the diagnostic ultrasound market as computed by other sources in general conforms with the figures shown in Table 2-1. Frost and Sullivan (1975b) calculate that sales of diagnostic ultrasound devices were $4.7 million, $8.4 million, $13.3 million, and $24.7 million in 1971, 1972, 1973, and 1974, respectively. However, the 1978 sales estimate of $125 million in Table 2-1 is higher than the $100 million figure quoted in the "Gray Sheet,"[6] and the Hale and Hale (1978) estimate of $95 million. And, for 1980, Frost and Sullivan (1980b) put shipments at $122 million.

For nuclear imaging equipment, the Frost and Sullivan (1974b) assessment that 1973 sales were $41 million agrees with the figures in Table 2-1, but Frost and Sullivan (1979) calculations that 1975, 1976, and 1977 sales were $71.1 million, $79.6 million, and $92 million, respectively, are significantly higher than the estimates in Table 2-1. 1978 sales of $100 million are cited in the "Gray Sheet,"[7] and Frost and Sullivan (1980b) put 1980 shipments at $115 million.

Information from a variety of sources indicates that the size of the medical diagnostic imaging equipment market has steadily increased from approximately $240 million in 1969 to about $900 million in 1980. And, there have been significant changes in the relative positions of the various product lines

over this period. In 1969, X-ray equipment dominated industry sales, accounting for approximately 83% of total sales, with nuclear imaging and diagnostic ultrasound equipment accounting for about 15% and 1%, respectively. By 1980 there had been a major shift in relative product shares, with X-ray equipment accounting for about 61% of total industry sales, diagnostic ultrasound for about 14%, and CT scanners and nuclear imaging equipment for about 13% each. Nuclear imaging equipment maintained its share of the market over the period 1969 to 1980, with the market share gains for CT scanners and ultrasound devices coming at the expense of conventional X-ray equipment.

Sellers

Using a variety of sources,[8] a data file of firms in the medical imaging equipment market for the period 1971 to 1981 was constructed. This file is the basis for the descriptive statistics presented in this section. Included in the file is information on each firm's medical imaging product line in any given year. Table 2-2 shows the total number of firms manufacturing medical imaging equipment for the years 1971 to 1981, along with a breakdown of the total by single product and multiproduct sellers, i.e., whether a firms sells one or more than one of the four types of diagnostic imaging equipment, respectively.

Over this period, the total number of firms in the industry increased steadily from 42 in 1971 to a high of 87 in 1979, after which there was a slight decrease to 79 firms in 1981. Also over this period the proportion of multiproduct firms increased from 12% in 1971 to a high of 26% in 1977, after which the proportion remained steady at 23% for the years 1978 to 1981.

Note that this movement toward multiproduct sellers parallels the decline of X-ray equipment's share of total sales: as other products accounted for a greater share of sales, more firms began to supply these other products. The forces behind the rapid expansion in the number of sellers will be analyzed in the section on entry patterns.

Table 2-2

Number of Manufacturers
of Medical Diagnostic Imaging Equipment,
By Number of Medical Imaging Product Lines, 1971-81

Year	Single Product*		Multiproduct**		Total
	(Number)	(%)	(Number)	(%)	(Number)
1971	37	88	5	12	42
1972	41	89	5	11	46
1973	43	86	7	14	50
1974	46	85	8	15	54
1975	49	79	13	21	62
1976	54	76	17	24	71
1977	57	74	20	26	77
1978	66	77	20	23	86
1979	67	77	20	23	87
1980	63	77	19	23	82
1981	61	77	18	23	79

*Firm manufactures only one type of imaging equipment.

**Firm manufactures more than one type of imaging equipment.

Derived from: See footnote (8).

It is also instructive to consider the breakdown of sellers by product line. This is shown in Table 2-3, along with the proportion of total number of firms producing each type of medical imaging equipment. The decline in the sales share of X-ray equipment is here reflected in the fact that the proportion of firms in the industry supplying that product declined from 71% in 1971 to 65% in 1981, even though the number of X-ray producers increased over this period. The proportion of firms selling nuclear scanning equipment also decreased over the period, with the number of suppliers remaining approximately the same. Firms producing CT scanners and ultrasound devices, on the other hand, increased in terms of both number of firms and proportion of total firms in the industry.

Recall from the discussion of supply conditions that any piece of medical diagnostic imaging equipment is composed of a number of different components. The example was given of a diagnostic X-ray system which may include an X-ray tube, high-voltage generator, control panel, table, film changer, cassette holder, and collimator. This distinction between components and systems is important for the medical imaging equipment industry because some firms manufacture only components. This is especially true for X-ray equipment, as can be seen in Table 2-4 which gives the breakdown by product line of whether firms produce components or systems.

Of the firms manufacturing X-ray equipment, in 1971 20% produced components and by 1981 this had increased to about

Table 2-3

Number of Manufacturers of Medical Diagnostic Imaging Equipment, By Medical Imaging Product Line, 1971-81

Year	X-Ray Equipment		CT Scanners		Ultrasound Devices		Nuclear Scanning Equipment		Total
	(Number)	(%)*	(Number)	(%)*	(Number)	(%)*	(Number)	(%)*	(Number)
1971	30	71			7	17	11	26	42
1972	33	72			8	17	11	24	46
1973	36	72			11	22	12	24	50
1974	35	65	2	4	16	30	12	22	54
1975	39	63	11	18	18	29	13	21	62
1976	45	63	16	23	24	34	14	20	71
1977	48	62	18	23	28	36	14	18	77
1978	52	60	20	23	31	36	15	17	86
1979	52	60	19	22	34	39	15	17	87
1980	51	62	16	20	34	41	13	16	82
1981	51	65	15	19	31	39	13	16	79

*Per cent of total number of firms, rows do not sum to 100% due to multiproduct sellers.

Derived from: See footnote (8).

Table 2-4

Number of Manufacturers of Medical Diagnostic Imaging Equipment, By Medical Imaging Product Line and Systems/Components, 1971-81

Year	X-Ray Equipment				CT Scanners				Ultrasound Devices				Nuclear Scanning Equipment
	Systems		Components		Systems		Components		Systems		Components		Systems
	(#)	(%)	(#)	(%)	(#)	(%)	(#)	(%)	(#)	(%)	(#)	(%)	(#)
1971	24	80	6	20					6	86	1	14	11
1972	27	82	6	18					7	88	1	12	11
1973	29	81	7	19					10	91	1	9	12
1974	28	80	7	20	2	100			14	88	2	12	12
1975	29	74	10	26	10	91	1	9	16	89	2	11	13
1976	30	67	15	33	14	88	2	12	22	92	2	8	14
1977	33	69	15	31	16	89	2	11	26	93	2	7	14
1978	34	65	18	35	18	90	2	10	29	94	2	6	15
1979	34	65	18	35	17	89	2	11	32	94	2	6	15
1980	35	69	16	31	14	88	2	12	33	97	1	3	13
1981	35	69	16	31	13	87	2	13	30	97	1	3	13

Derived from: See footnote (8).

30%; the number of firms producing components also increased over this period. For CT scanners, both the number (2) and proportion (about 10%) of components firms remained about the same over the period 1975 to 1981. The number of ultrasound firms making components was approximately constant over the years 1971 to 1981 (1 or 2 firms), but as a proportion of the total, components production decreased from 14% in 1971 to 3% in 1981. And for nuclear scanning equipment, all the firms manufacture systems.

The concentration of components production in the X-ray equipment segment of the industry is a function of the size of the market and technology. The trend toward specialization is limited by the extent of the market, but as we have seen, there is a large sales volume for medical X-ray equipment (approximately $550 million in 1980, Frost and Sullivan, 1980b). It should also be noted that the dental and industrial X-ray equipment markets, which include many of the same components, are also sizeable. For example, in 1980 the value of product shipments for irradiation equipment, a category covering medical, dental, and industrial X-ray equipment, as well as X-ray tubes, accessories, and components, was $798 million.[9] Another factor is that X-ray technology for basic components has been quite stable over the past ten years, with the development of more advanced peripheral equipment (such as data processing systems) accounting for the bulk of innovation (see Chapter 3). Thus there has been an opportunity for specialization within

the X-ray segment of the market, while in the other market segments the potential for specialization has been limited by the high rate of technological change and a substantially lower sales volume.

Another notable characteristic of the firms in this industry is their tendency to be diversified, i.e., also active in industries other than medical imaging equipment. In general, the medical imaging equipment firm is a subsidiary or division of the larger firm. Table 2-5 shows that over the period 1971 to 1981, about 60% of the firms in the industry were diversified and that the proportion was relatively stable over the period.

Table 2-5 also shows the importance of foreign-based firms in this industry. For the years 1971 to 1981, approximately 30% of the firms had company headquarters located outside the United States.

The size distribution of firms is another important aspect of the industry. Due to the prevalence of firms which are diversified, there are two measures of firm size which are of interest. Table 2-6 shows the size distribution of firms measured both by sales of medical imaging equipment and by total firm sales, where total sales refer to the parent company in the case of subsidiaries and divisions. The proportion of small firms measured in terms of medical imaging equipment sales increased from about 70% in 1971 to about 80% in 1981, while the proportion of small firms measured in

Table 2-5

Number of Manufacturers
of Medical Diagnostic Imaging Equipment,
By Diversification and Company
Base of Operations, 1971-81

Year	Diversified*				Company Base of Operations			
	Yes		No		U.S.		Foreign	
	(#)	(%)	(#)	(%)	(#)	(%)	(#)	(%)
1971	24	57	18	43	30	71	12	29
1972	28	61	18	39	31	67	15	33
1973	30	60	20	40	34	68	16	32
1974	33	61	21	39	36	67	18	33
1975	35	56	27	44	43	69	19	31
1976	41	58	30	42	49	69	22	31
1977	47	61	30	39	54	70	23	30
1978	53	62	33	38	59	69	27	31
1979	53	61	34	39	59	68	28	32
1980	50	61	32	39	54	66	28	34
1981	46	58	33	42	52	66	27	34

*Firm is diversified if it also sells in other industries.

Derived from: See footnote (8).

Table 2-6

Number of Manufacturers
of Medical Diagnostic Imaging Equipment,
By Medical Imaging Equipment
and Total Firm Sales, 1971-81

Year	Sales of Medical Imaging Equipment				Total Firm Sales			
	Small (<$5million)		Large (>$5million)		Small (<$100million)		Large (>$100million)	
	(#)	(%)	(#)	(%)	(#)	(%)	(#)	(%)
1971	30	71	12	29	21	50	21	50
1972	34	74	12	26	21	46	25	54
1973	38	76	12	24	23	46	27	54
1974	41	76	13	24	26	48	28	52
1975	49	79	13	21	33	53	29	47
1976	58	82	13	18	37	52	34	48
1977	62	81	15	19	36	47	41	53
1978	69	80	17	20	40	47	46	53
1979	70	80	17	20	41	47	46	53
1980	66	80	16	20	38	46	44	54
1981	64	81	15	19	37	47	42	53

Derived from: See footnote (8).

terms of total firm sales remained steady at about 50% over the period. The forces behind these patterns will be discussed further in the section on changes in industry composition.

In general, the diagnostic imaging equipment industry can be characterized as having a three-tier structure: there are the components-producing firms, fringe firms, and primary firms. A primary firm has annual medical imaging equipment sales that exceed 5% of total industry sales, while a fringe firm's sales are less than 5% of total industry sales. There have been between six and nine primary firms in any given year over the period 1968 to 1981 and collectively the primary firms account for between 75% and 80% of total industry sales.[10] In general, primary firms are active in more than one market segment, while fringe firms tend to produce only one type of imaging equipment.

As of 1981, the set of primary firms consisted of seven companies, all but two of which are associated with a very large, multinational, broadly diversified corporation. Table 2-7 lists these firms, along with a brief description. The connection to the electronics industry is striking: GE, GEC Ltd., Philips, and Siemens are all giant conglomerates with a major interest in electronics and they compete world-wide in many markets. It is also interesting to note that four of the seven primary firms are foreign-based operations.

Table 2-7

Medical Diagnostic Imaging Equipment
Primary Firms, 1981

COMPAGNIE GENERALE DE RADIOLOGIE (CGR Medical Corporation)

1979 sales about $400 million (latest available data)
French producer of radiological equipment. CGR supplies all but one type of medical imaging equipment in the U.S.

GENERAL ELECTRIC CO. (Medical Systems Division)

1981 net sales $27 billion
One of the largest industrial firms in the world, manufacturing a wide range of electrical and electronic products. Supplies all four types of medical imaging equipment.

GENERAL ELECTRIC CO. LTD. (Picker Corporation)

1981 sales approximately $7 billion
British producer of electrical and electronic products, bought Picker from RCA in April 1981. Picker supplies all four types of medical imaging equipment.

JOHNSON & JOHNSON (Technicare Corporation)

1981 total sales $5 billion
Major producer of consumer products and health care equipment and supplies. Technicare, purchased by J&J in 1978, supplies all four types of medical imaging equipment.

N.V. PHILIPS GLOEILAMPENFABRIEKEN (Philips Medical Systems)

1981 sales approximately $17 billion
Dutch-based firm with world-wide operations in the electrical and electronics fields. Supplies all four types of medical imaging equipment.

SIEMENS AKTIENGESELLSCHAFT (Siemens Corporation)

1981 net sales approximately $15 billion
West German electronics and electrical engineering firm. Supplies all four types of medical imaging equipment.

XONICS, INC.

1981 sales $77 million
U. S. firm with over 90% of sales in medical imaging. Supplies two types of medical imaging equipment.

Derived from: See footnote (8).

In summary, over the period 1969 to 1980, constant-dollar sales of medical imaging equipment increased, as did the relative share of the industry in the economy's output. The share of industry sales accounted for by X-ray equipment decreased over the period, while that of nuclear scanning equipment remained about the same, and the shares of CT scanners and ultrasound devices increased.

Over the years 1971 to 1981 the number of firms manufacturing diagnostic imaging equipment increased, as did the proportion of firms producing more than one type of imaging equipment. In terms of product lines, the proportion of firms in the industry producing X-ray and nuclear scanning equipment decreased, while the proportion producing CT scanners and ultrasound devices increased. The industry includes a substantial number of firms which produce only components for X-ray equipment, and the proportion of components-producing firms increased over the period.

The majority of firms in the medical imaging equipment industry are diversified, and foreign-based corporations play an active role in the industry. The proportion of small firms as measured in terms of imaging equipment sales increased over the period; and about half the firms were small as measured by total firm sales, this proportion was steady over the period.

Finally, the diagnostic imaging equipment industry has a three-tier structure: there are components-producing firms, fringe firms, and primary firms. Several primary firms are connected to the electronics industry.

CONCENTRATION PATTERNS

Concentration indices measure the size distribution of firms in the industry, and thereby provide information about market structure. The most widely used measure of concentration is the four-firm concentration ratio, the percentage of total industry sales attributable to the four firms with the largest market shares. From a theoretical perspective, a comprehensive concentration measure, which takes all the firms in the industry into account, is preferable. A number of these summary indices have been proposed, the Herfindahl index being the most widely used. The difference among the various summary measures lies in the underlying assumptions about the weighting of market shares. For example, in the Herfindahl index, the distribution of sales among the larger firms is a more important determinant of industry concentration than is the distribution of sales among the smaller firms. It is also interesting to note that Dansby and Willig (1979) demonstrated that a transformation of the Herfindahl index measures potential improvement in industry performance in a Cournot quantity model with identical firms.

The Herfindahl (H) index is defined as the sum of the squares of the market shares for all firms in the industry:

$$H = \sum_{i=1}^{n} (s_i)^2$$

where s_i = market share of firm i
n = number of firms in the industry
$H \in (0, 10{,}000]$

Note that calculation of H requires that the market share of every firm in the industry be known. When the shares of smaller firms are not known, the H index is sensitive to alternative assumptions about the distribution of shares among these firms (Schmalensee, 1977).

Since market share data were not available for all firms in the medical diagnostic imaging equipment industry, the "true" H index cannot be calculated. Therefore, two measures of concentration are presented in this section: the standard four-firm concentration ratio and the H index assuming equal market share distribution among the smaller firms (the number of firms having known market shares will be given in footnotes).

The strong emphasis on concentration as a component of industry structure derives from the links among concentration, pricing behavior, and performance. A highly concentrated industry is often taken as evidence that firms in the industry have market power, or the ability to raise price above marginal cost. However, it must be remembered that size distribution says nothing about welfare per se, the cost structure and entry conditions of the industry must be examined before any conclusions about market power can be reached.

Chapter 4 is devoted to an assessment of industry performance, and evidence on concentration will be utilized in that analysis. The purpose of this section is to describe

concentration patterns in this industry. Measures of concentration will be presented and discussed for each product line. Then the overall pattern of concentration will be described. Finally, the level of concentration in the medical imaging equipment industry will be assessed in light of the critical concentration levels used for antitrust policy.

X-Ray Equipment

Market shares for the six largest producers of X-ray equipment in 1974 and 1978 are shown in Table 2-8. The four-firm and six-firm concentration ratios changed little over these years, with CR_4 decreasing from 69% to 64% and CR_6 decreasing from 89% to 86%. H was also essentially unchanged, declining from 1460 in 1974 to 1340 in 1978.[11]

The set of market leaders likewise was stable over this period, with Xonics taking the place of Litton after purchasing Litton's X-ray business in early 1978. Even the ranking of firms by market share was stable, the only change being Philips' move from fourth to third position, exchanging places with Litton/Xonics.

Note that all the firms described in the previous section as primary firms, with the exception of Technicare, are also leaders in the X-ray equipment market segment. Also note that in 1974 the remaining 11% of X-ray equipment sales was shared among 29 firms, and in 1978 the remaining 14% was shared among 46 firms. In other words, although there was substantial entry over this period, the market shares of the leading X-ray firms were largely unaffected.

Table 2-8

Market Shares for Major Manufacturers of X-ray Equipment, 1974 and 1978

Firm	1974 Market Share (%)	1978 Market Share (%)
GE	22.5	21.4
Picker	20.0	15.7
Litton	13.8	Sold X-ray business to Xonics in 1978
Philips	12.5	14.3
Siemens	10.0	11.4
CGR	10.0	10.0
Xonics	<2.0	12.9
	CR_4 = 68.8%	CR_4 = 64.3%
	CR_6 = 88.8%	CR_6 = 85.7%
	H = 1460	H = 1340

Derived from: Hale and Hale (1975), pg. 469; Hale and Hale (1978), pg. 669; sources listed in footnote (8).

CT Scanners

As is frequently the case for a new product, market shares for manufacturers of CT scanners have been quite volatile, especially in the period immediately after the new technology was introduced. This was compounded by extremely rapid diffusion of CT scanners during 1975 and 1976, followed by a sudden decline in the diffusion rate in 1979 and 1980.[12]

CT scanning was invented by an employee of EMI, Ltd. (U.K.) and virtually all the machines sold in 1973 and 1974 were manufactured by EMI. Other diagnostic imaging firms were quick to pick up on this opportunity and by mid-1977, EMI was competing with six other suppliers.[13] As the market continued to grow, so did the number of suppliers, and by 1978 there were 18 firms selling CT scanner systems (see Table 2-4). This peak number of firms coincides with the peak of CT scanner sales. As sales declined in 1979 and 1980, due primarily to market saturation, the number of CT manufacturers also declined.

Assessing market shares is difficult in such a rapidly changing market. Table 2-9 presents market shares for the major producers of CT scanners in 1978. In this particular year, the CT scanner market had a CR_4 of 80%, a CR_8 of 94%, and H amounted to 1830.[14] However, there was a great deal of change in the market subsequent to 1978; EMI left the CT market in 1980, Pfizer departed in 1981, and Artronix exited in 1979. Thus, within three years, firms accounting for almost 40% of the CT sales in 1978 had left the market. And, al-

Table 2-9

Market Shares for Major Manufacturers of CT Scanners, 1978

Firm	1978 Market Share (%)
Ohio-Nuclear	30.8
EMI	20.5
Pfizer	15.4
GE	12.8
Siemens	5.1
Picker	4.1
Artronix	2.6
Philips	2.6

$CR_4 = 79.5\%$

$CR_8 = 93.9\%$

$H = 1830$

Derived from: Hale and Hale (1978), pg. 669; sources listed in footnote (8).

though both EMI and Pfizer sold their CT scanner businesses to smaller CT firms, the surviving large CT firms were the primary beneficiaries of these exits. It is also interesting to note that the five firms remaining after these exits are primary firms. Although not a measure of sales concentration, it is suggestive that a report by the Office of Technology Assessment estimated that three manufacturers (EMI, Ohio-Nuclear, and General Electric) accounted for almost 90% of the scanners in operation in the U. S. as of May 1980.[15]

Ultrasound Devices

Market shares for the largest producers of ultrasound devices in 1974 and 1978 are shown in Table 2-10. Concentration appears to have decreased over these years, with the CR_4 declining from 69% to 61% and H declining from 1410 to 1260.[16]

There was also a significant amount of change in the set of market leaders over this period. Five of the largest ultrasound firms in 1978 were not important market participants only four years before, and two of the largest ultrasound firms in 1974 were purchased in 1976 by primary firms in the industry. And, at the same time that there was a large net inflow of firms into the ultrasound market, primary firms were accounting for a greater proportion of the largest ultrasound firms (1 of 5 in 1974, 5 of 8 in 1978).

Table 2-10

Market Shares for Major Manufacturers of Ultrasound Devices, 1974 and 1978

Firm	1974 Market Share (%)		1978 Market Share (%)
Picker	22.3		26.3
Unirad	20.2	Purchased by Technicare in 1976	8.4
SmithKline	16.2		3.2
Roche	10.1		2.1
Rohe	10.1	Purchased by Philips in 1976	10.5
Searle	--		15.8
Advanced Diagnostic Research	--		8.4
Varian	--		5.3
Advanced Technology Laboratories	--		3.2
Siemens	--		3.2
	CR_4 = 68.8%		CR_4 = 61.0%
	CR_5 = 78.9%		CR_5 = 69.4%
	H = 1410		CR_8 = 81.1%
			H = 1260

Derived from: Frost and Sullivan (1975b), pg. 6; Hale and Hale (1978), pg. 670; sources listed in footnote (8).

Nuclear Scanning Equipment

Market shares for the eight largest producers of nuclear scanning equipment in 1973 and 1977 are shown in Table 2-11. Measures of concentration decreased over this period, with the CR_4 falling from 85% to 79%, the CR_8 declining from 97% to 93%, and H decreasing from 2560 to 2010.[17] The top three firms were solidly entrenched in this market over the years 1973 to 1977, while the composition and ranking of the remaining market leaders were more variable.

Primary firms accounted for three of the eight largest nuclear imaging firms in 1973 and four of the eight largest in 1977. And, all three of the leading triad of firms were primary firms in 1977. It is interesting to note that in 1979 Searle announced its intention to sell its nuclear medical equipment business to Siemens, another primary firm. The Justice Department filed suit to block the purchase, claiming that the proposed acquisition would lessen competition in the nuclear medical equipment market.[18] However, a request for an injunction enjoining the sale was denied, and the sale was completed in May of 1980[19] (see the discussion on mergers for further detail).

Table 2-11

Market Shares for Major Manufacturers of Nuclear Scanning Equipment, 1973 and 1977

Firm	1973 Market Share (%)	1977 Market Share (%)
Searle	42.2	32.9
Picker	19.3	23.6
Ohio-Nuclear (Technicare)	18.3	16.7
Raytheon	4.9	<2.0
Baird	4.0	2.3
Nuclear Data	4.0	Sold nuclear medical equipment business to GE in 1975
Medical Data Systems	2.4	5.4
GE	2.0	5.0
Union Carbide	--	3.7
ADAC	<2.0	3.3
	CR_4 = 84.7%	CR_4 = 78.6%
	CR_8 = 97.1%	CR_8 = 92.9%
	H = 2560	H = 2010

Derived from: Frost and Sullivan (1974b), pp. 86-88; Frost and Sullivan (1979), pp. 13, 165; sources listed in footnote (8).

Comparing concentration patterns for the various product lines, we find that ultrasound is unambiguously the least concentrated market segment. This is true in spite of the fact that there were fewer manufacturers of ultrasound devices in any given year than there were manufacturers of X-ray equipment. The X-ray market is more concentrated than ultrasound, but less so than CT. And, the nuclear imaging market is the most concentrated.

In terms of changes in concentration, the X-ray market experienced little change in concentration over the period 1974 to 1978, a pattern consistent with a long-established market. Concentration in the CT market decreased over the period 1974 to 1978 as other firms entered to compete with EMI, and probably increased after 1978 in the consolidation after the exit of three of the largest CT firms. And, concentration decreased over the period 1974 to 1978 in the ultrasound and nuclear imaging markets.

Industry Concentration

Market shares for the largest producers of medical diagnostic imaging equipment in 1974 and 1978 are presented in Table 2-12. Concentration patterns were quite stable over this period, with CR_4 decreasing from 52% to 50%, CR_8 falling from 78% to 77%, and H decreasing from 950 to 890.[20] The primary firms maintained their collective market share in spite of a net increase in the number of firms in the industry from 54 in 1974 to 86 in 1978 (see Table 2-3).

There was a substantial amount of change in the set of the eight largest firms. In the first place, two members of this set in 1974 were replaced by 1978. In one case, there was a substitution of Xonics for Litton, largely as a result of Xonic's purchase of Litton's X-ray business. In the other case, EMI dropped out of the group, and was replaced by Technicare. Secondly, although the top two firms maintained a solid lead over this period, there was substantial change below this rank. Technicare catapulted from the ninth to fourth position in only four years, Philips moved from fourth to third, and Xonics rose from about fifteenth to sixth. It is also notable that individual market shares were quite variable--this was clearly not a static industry over this period.

With respect to the Census of Manufactures SIC data, the 4-digit SIC industry closest in definition to the medical imaging equipment industry is 3693. As noted in Chapter 1,

Table 2-12

Market Shares for Major Manufacturers of Medical Diagnostic Imaging Equipment, 1974 and 1978

Firm	1974 Market Share (%)	1978 Market Share (%)
Picker	18.9	15.8
GE	15.5	15.4
Litton	9.3	Sold X-ray business to Xonics in 1978
Philips	8.4	10.1
Siemens	6.8	8.0
CGR	6.8	5.9
EMI	6.2	3.6
Searle	5.8	5.7
Unirad	2.5	Purchased by Technicare in 1976
Technicare	2.5	8.4
Xonics	0.8	7.6
	CR_4 = 52.1%	CR_4 = 49.7%
	CR_8 = 77.8%	CR_8 = 76.9%
	H = 950	H = 890

Derived from: Tables 2-8 through 2-11; International Resource Development (1978), pg. 44; the "Gray Sheet" (Medical Devices, Diagnostics, and Instrumentation Reports), November 13, 1978; sources listed in footnote (8).

the title of 3693 was changed in 1977 from "X-Ray Apparatus and Tubes" to "X-Ray, Electromedical, and Electrotherapeutic Apparatus" and data on a number of new categories of medical electronic equipment were added. Also in 1977, data on 5-digit SIC group 36931 entitled "Irradiation Equipment," which corresponds to the previous 3693 classification, were included. Therefore, the proper approach is to compare pre-1977 data for SIC 3693 with post-1977 data for SIC 36931.

In 1972 the CR_4 for SIC 3693 was 54% and the CR_8 was 75%. These figures are very similar to those shown in Table 2-12. In 1977 the CR_4 for SIC 36931 was 63% and the CR_8 was 79%, not as consistent with the data for medical imaging equipment. Recall that the SIC classification is closer to the definition of the X-ray equipment market segment than to that for the industry as a whole. By 1977 X-ray equipment had ceased to completely dominate the medical imaging equipment industry, leading to the discrepancy between the two statistics in that year.

It is interesting to note that in 1968 the largest firms in the X-ray equipment market (accounting for at least 80% of industry sales[21]) were: General Electric, Picker, Philips, Siemens, CGR, and Litton (Theta Technology Corp., 1978). In 1974 these same six firms held the top six positions in the diagnostic imaging equipment industry ranking. By 1978, Technicare had become the fourth largest imaging equipment firm, Xonics had moved to sixth position, and CGR had been

bumped to seventh place. The point is that during a period in which X-ray equipment came to account for a significantly lower proportion of industry sales, and CT scanning and ultrasound increased their industry shares, the leading X-ray firms managed to maintain their position as primary firms in the industry. And it is notable that over this same period these firms expanded their product lines. In 1974 the bulk of sales for the six largest medical imaging equipment firms was accounted for by sales of X-ray equipment. By 1978 all had significant portions of total sales attributable to non-X-ray business. Also, by 1978 it was possible for Technicare to become a primary firm without playing an active role in the X-ray market.

With respect to changes in industry concentration after 1978, two firms (EMI and Searle), accounting for almost 10% of industry sales in 1978, left the industry in 1980. Secondly, Searle sold its diagnostic imaging businesses to Siemens, another large firm. Therefore, although precise market share information is not available for this period, it is likely that industry concentration has increased somewhat since 1978.

In summary, concentration in the medical imaging equipment industry was stable over the period 1974 to 1978, but there was a significant amount of change in the membership and ranking of the set of leading firms. In the past there was a one-to-one correspondence between the largest X-ray firms and the largest industry firms. This link has been weakened by the relative decline of X-ray equipment as a share of industry sales. But most of the largest X-ray firms have managed to maintain their positions as primary firms by diversifying into other diagnostic imaging product lines.

Critical Concentration Levels

In order to assess the level of concentration in the diagnostic imaging equipment industry, what constitutes "highly concentrated" must be defined. This is a controversial topic within the economics profession and there are basically two schools of thought on this subject. One, based on Bain's original work on the relationship between profits and concentration, argues that it is possible to define a critical level of concentration. A number of studies have estimated a single critical concentration level, usually found to be around 50% for the CR_4 and 70% for the CR_8 (see Kwoka, 1978). Along these same lines, Bradburd and Over (1982) developed a model based on organizational costs with two critical levels of concentration. The integrative level is where a cooperative equilibrium will become attainable as concentration increases, the disintegrative level is where an existing cooperative equilibrium will break down as concentration decreases. The maximum likelihood estimates were 68% for the integrative CR_4 level and 46% for the disintegrative CR_4 level. The other school of thought on critical concentration points out that what really matters is the relationship between price and marginal cost and that to define a critical level across the economy without considering particular industry characteristics is meaningless.

For antitrust purposes, the U. S. Department of Justice (1982) divides the range of market concentration (as measured

by the Herfindahl (H) index) into three regions: H less than 1000, unconcentrated; H between 1000 and 1800, moderately concentrated; and H greater than 1800, highly concentrated. By this classification, the medical imaging equipment industry is unconcentrated. Note, however, that the X-ray and ultrasound product markets are moderately concentrated, the CT market is moderately to highly concentrated, and the nuclear imaging market is highly concentrated.

The pattern of concentration in the medical imaging equipment industry can be described as follows: in the first place, there are differences in concentration among the various product lines, with ultrasound being the least concentrated, followed by X-ray and CT, with nuclear imaging being the most concentrated. Secondly, the changes in concentration over the period 1974 to 1978 also varied by product line: concentration in the X-ray market basically did not change, while it decreased in the CT, ultrasound, and nuclear imaging markets.

For the industry as a whole, the CR_4 was about 50%, the CR_8 about 75%, and the H index about 1000 in both 1974 and 1978. Shares of individual firms were relatively volatile for such a short period as four years, but, in general, the primary firms maintained their position over these years. Finally, the medical diagnostic imaging equipment industry is unconcentrated by the standards of the U. S. Department of Justice, while the product markets are moderately to highly concentrated.

BARRIERS TO ENTRY

The existence of barriers to entry in an industry is indicated by the ability of established sellers to consistently raise price above marginal cost without attracting entry. The degree of entry barrier is measured by the difference between the selling price and marginal cost. The condition of entry is a crucial aspect of market structure because it is directly related to industry performance: the "higher" the entry barrier, the less competitive the industry.

Three potential sources of entry barriers will be examined in this section: absolute cost advantages, economies of scale, and product differentiation. It is assumed that in general the condition of entry is stable over time and cannot be affected by prospective entrants. The exception to this is the case of a pathbreaking new product introduction, which can alter the condition of entry, particularly if an entrant is the source of the innovation.

Strategic conduct can also, under certain conditions, lead to entry barriers. For example, Spence (1977) argues that entry is deterred in an industry when existing firms have enough capacity to make a new firm unprofitable in the event of entry. Investment in excess capacity is effective because it is irreversible and a highly visible demonstration of commitments by established firms. The strategy can be used when products are differentiated if established firms invest in advertising or other means of securing customer

loyalty, rather than in plant and equipment. Dixit (1979), on the other hand, emphasizes the role of fixed costs in entry-deterring behavior. Using a duopoly model with an established firm and a prospective entrant, he demonstrates that fixed costs can enlarge the range within which an established firm chooses to deter entry by limit pricing. And Schmalensee (1981) shows that durable capital, commitment to excess capacity in advance, and scale economies are all necessary for an established firm to profitably deter entry by limit pricing.

Ideally, comprehensive price and cost data would be used to directly measure the extent of barriers to entry in the industry. Lacking such complete information, each potential source of barriers to entry will be discussed, and an argument developed as to the expected condition of entry in the medical imaging equipment industry. Then in the next section evidence on entry patterns will be examined. Assessment of the effect of entry barriers on industry performance will be discussed in Chapter 4.

Absolute Cost Advantages

Established sellers enjoy an absolute cost advantage over potential rivals if the long-run average cost curve of the prospective entrant lies everywhere above that of the established firms. The costs referred to here are production costs, any significant differences in promotion costs are the result of product differentiation and will be discussed in that section.

There are three major sources of absolute cost differences between entrants and established firms:

(1) Unique production technology, usually protected by patents or secrecy;

(2) Imperfect factor markets, most commonly ownership of some strategic input; and

(3) Limited factor supply relative to demand, such that input prices will rise if entry occurs.

Patents have been widely used in the diagnostic imaging equipment industry. For example, the scintillation camera was patented by developer Harold Anger, and the exclusive license granted to Nuclear-Chicago (later bought by Searle Radiographics) has undoubtedly been the key to that firm's success in the nuclear imaging market. Another example is EMI, which not only patented its CT scanner technology, but also vigorously defended the patents by filing a series of patent infringement suits against other major CT manufacturers (Ohio-Nuclear, Pfizer, and General Electric).

There is, however, a divergence of opinion within the industry as to the effectiveness of patent protection. In the survey of firms in the industry, 13 of the 25 firms responding to the question replied that patents were not important for medical imaging equipment, while 12 companies answered that patents were important (see Appendix A). In commenting on why patents might not be important for imaging equipment, the phrases "easily circumvented" and "unenforceable" appear in several of the firms' replies. The scientific principles underlying most medical imaging technology are long-established, and although specific engineering techniques can be patented, there is frequently "more than one way to skin a cat."

The importance of trade secrets is also emphasized in the firms' comments. When there is extremely rapid technical change, the lag induced by trade secrecy will often be sufficient to ensure that a new product will have been introduced by the time a rival has caught up with the previous development. In this industry a good example of rapid product improvements is the reduction in the time from the start of a CT scan through the completion of picture reconstruction. EMI's first generation scanner (introduced in 1973) required 16 minutes for picture reconstruction, while fourth generation scanners (available in 1978) had reduced this to an initial reconstruction time of less than 15 seconds and single slice scanning times of less than two seconds (Theta Technology Corp., 1978). Note, however, that although EMI protected its product designs by both trade

secrecy and patents and even though EMI's scanners were on the cutting edge of CT technology, these rapid changes by no means insulated the firm from vigorous competition in the CT market during the late 1970's.

Overall, control of production techniques can be expected to give some established medical imaging equipment firms a cost advantage in the short run. But experience in the industry to date indicates that, with a few exceptions, it is not long before some resourceful engineer with a rival firm finds a way to sidestep patent protection or penetrate the veil of trade secrecy.

Factor supplies are not a basis for cost differentials in the diagnostic imaging equipment industry. In the first place, all potentially "strategic" inputs (primarily aluminum, steel, and electronic components) are readily available from a variety of outside sources. Secondly, there are effectively no limitations on the supply of these inputs, given the small quantities needed relative to the total factor market. Think, for instance, of the use of micro-processors in medical imaging equipment in comparison to those used in video games (only one of the many alternative employments of this input).

In the medical imaging equipment industry, the use of patents and trade secrets to protect production techniques does lead to the potential for absolute cost differentials between established sellers and prospective entrants. But, this advantage is rarely long-lived because the basic scientific principles underlying medical imaging technology are long-established and thus unpatentable. And trade secrecy is frequently circumvented by ingenious engineering. Therefore, absolute cost differences are not the source of a significant barrier to entry in the diagnostic imaging equipment industry.

Economies of Scale

A second potential source of barriers to entry is economies of large scale, which exist when the firm's long-run average cost decreases as output increases, at least over some range of output. The firm's minimum efficient scale (MES) is defined to be the smallest output at which the lowest average cost is achieved. If the MES represents a significant portion of the total industry output, then costs would rise if entry occurred and the established sellers can charge a price above marginal cost without attracting entry: a barrier to entry exists.

There are a number of possible sources of scale economies. These include: fixed setup costs which do not vary with expected output; gains from specialization of factors as output increases; the fact that costs tend to be proportional to the materials needed for construction (area), while output tends to be proportional to capacity (volume); factor indivisibilities below some level of utilization; and the use of automation at large output levels. Economies of scale can be experienced in any stage of the manufacturing process: production, distribution, promotion, or sales and service. There is also the potential for scale economies in research and development, but this will be discussed as an aspect of innovation in this industry (see Chapter 3).

The concept of scale economies must be re-examined when more than one product is manufactured in the same plant (see Panzar and Willig, 1977). In this case, economies of scope, which exist if the average cost of joint production is less than the sum of the average costs of separate production, must also be considered.

Although cost and output data are unavailable for medical imaging equipment firms, there are several pieces of evidence which can be used to gauge the extent of scale economies. The most important source of information on this subject is the survey of firms in the industry (see Appendix A).

One of the questions in the survey asked how production costs vary with increases in output. The responses, shown in Table 2-13, present a picture of an industry in which production economies of scale are <u>not</u> considered to be significant. Only four of the total 40 responses claimed that average cost decreases substantially as output increases. It is particularly striking that two of the four "a lot" responses were from firms manufacturing only components. It is also notable that none of the multiproduct sellers (likely to be the larger, most established firms) who responded to the questionnaire considered production scale economies to be sizeable.

The finding that firms in the industry do not experience significant economies of scale in production is partially explained by the fact that the production process for medical imaging equipment differs in several important ways from the

Table 2-13

Responses to the Medical Diagnostic Imaging Equipment Industry Questionnaire, Economies of Scale Question

Question: "Regarding production, does the cost of one unit of output decrease as volume increases -- a little, some, or a lot?"

	Number Responding			Total Number of Responses
	"a little"	"some"	"a lot"	
X-Ray Equipment	4 (27%)	11 (73%)	0	15
CT Scanners	1 (17%)	4 (67%)	1 (17%)	6
Ultrasound Devices	2 (15%)	9 (69%)	2 (15%)	13
Nuclear Scanning Equipment	0	5 (83%)	1 (17%)	6
TOTAL	7 (18%)	29 (72%)	4 (10%)	40
Multiproduct Firms Only	5 (24%)	16 (76%)	0	21

process for products typically subject to substantial economies of scale (think, for example, of ball bearings or automobiles). In the first place, the unit volume for any given medical imaging equipment firm is relatively low. For example, Theta Technology Corp. (1978) estimated that in 1977 60 head CT units and 180 whole body CT units were sold in the United States. Even if a firm had a third of the market, the total annual production of CT head scanners would be only 20 units (60 for whole body scanners). Secondly, continuous process techniques are generally not used in the manufacture of diagnostic imaging equipment. And lastly, a portion of the total output, particularly some of the more specialized equipment, is manufactured to order.

There is disagreement among economists as to the potential for economies of scale in promotion activities, specifically in advertising. There are those who claim that promotion scale economies do exist because advertising expenditures must reach a "take-off" level before they are effective and because the impact of advertising is cumulative over time (Clarkson and Miller, 1982). On the other hand, Ornstein (1977) reviews the empirical work on this subject and concludes that there is no evidence supporting the existence of scale economies in advertising. A large portion of medical imaging equipment advertising is spent on conventions, a type of promotion expenditure for which advantages of large scale are likely to be insignificant. And therefore, promotion activities

in the medical imaging equipment industry are not expected to be subject to significant scale economies (see Chapter 3 for a detailed examination of advertising in this industry).

Finally, sales and service operations may be a source of scale economies. Expensive, technologically sophisticated products tend to be sold on a direct basis. This is primarily due to the salesman's role as an "interpreter"--making the technical specifications of the product comprehensible to the buyer. Access to a service and repair organization also tends to be very important for these types of products because breakdowns are costly to the owner and call for specialized, highly skilled repairmen (National Academy of Engineering, 1971).

For such complex, costly goods, there will be scale economies in sales, largely because the more competent salesmen will be attracted to higher volume routes (larger firms). In addition, there are likely to be substantial cost savings for a high volume firm due to the large fixed costs associated with a service establishment. For example, a fully-equipped service outfit requires specialized tools, a large inventory of repair parts, and a staff of highly skilled service engineers and technicians (Scherer, 1980).

Medical imaging equipment clearly fits into this class of expensive, technically complicated products. And, most firms sell imaging equipment on a direct basis. This is revealed in the analysis of the industry survey responses and is confirmed by industry observers (see Chapter 3 for a discussion

of selling methods). In addition, service is repeatedly stressed as being extremely important in this market. For example, on the basis of a survey of hospital imaging departments, Frost and Sullivan (1980b) report that service characteristics are key factors in the purchase decision. Medical imaging equipment sales and repair require highly skilled personnel and an extensive parts and tools inventory. As a consequence, there are advantages to operating an imaging equipment sales and service organization at large scale; and there are thus likely to be economies of scale in sales and service for medical imaging equipment manufacturers.

Neither production nor promotion activities in the medical imaging equipment industry exhibit significant economies of scale and therefore they do not lead to a barrier to entry. There are, on the other hand, cost-saving aspects to large-scale sales and service operations and these put prospective entrants at a disadvantage relative to established sellers. Service characteristics are also an important basis for product differentiation in this industry. The interaction of scale economies and product differentiation in service, as well as the effect of this on entry conditions, will be discussed in the next section.

Product Differentiation

The last potential source of barriers to entry to be considered is product differentiation. If, at a given price, buyers prefer the products of established sellers, then prospective entrants face the alternatives of selling at a lower price (at least until their product is accepted) or having higher selling costs than firms already in the industry.

Product differentiation exists when products sold in the same market are not perfect substitutes. A firm's product is differentiated if a rise in price does not result in the loss of all sales. Product differentiation is both an aspect of market structure and a component of conduct. Certain product characteristics which are associated with a high degree of product differentiation will be discussed with reference to medical diagnostic imaging equipment and conclusions drawn about the condition of entry in this industry. Product differentiation as a method of nonprice competition will then be investigated in Chapter 3.

There are four bases for product differentiation: location of the firm, physical attributes of the product, provision of repair and maintenance services, and subjective image (Scherer, 1980). Location differentiation is not relevant for diagnostic imaging equipment and will not be considered here.

Differentiation on the basis of physical attributes involves variations in product design and quality. Particularly for a complex product, quality will be multi-dimensional and firms can be thought of as positioning themselves in product characteristics space (Lancaster, 1966). Also for technically complicated equipment, access to repair and maintenance services can be very important to a buyer. The service factor will be more important as the cost of a breakdown, in terms of lost revenues, is larger. The performance of some goods is difficult to assess prior to purchase. For these goods, firm reputation, a type of image differentiation, serves as a signal of quality and reliability. Finally, there is often a product differentiation premium associated with being the first to introduce an innovative new product (Bond and Lean, 1977). These first-mover advantages are a form of image differentiation if they persist even after other firms offer objectively equivalent products.

Some products are inherently more "differentiable" than others. Salient characteristics are: product complexity such that assessments or comparisons by buyers are difficult, relatively high price per unit, durability such that the need for service is likely, and infrequency of purchase. Products with these characteristics tend to be associated with a high degree of product differentiation (Bain, 1956; Needham, 1978; Scherer, 1980).

Medical imaging equipment clearly fits this description: it is expensive, technologically sophisticated, and infrequently purchased. Breakdowns are a matter of serious concern, not only due to lost revenues, but also because of the potentially grave consequences for patients. And, both highly skilled technicians and specialized equipment are necessary for repair and maintenance activities. The primary bases for product differentiation in the diagnostic imaging equipment industry are product quality attributes and the provision of repair and maintenance services.

There are a number of quality characteristics which are relevant for diagnostic imaging equipment. The most important have to do with image quality, since that is crucial for the doctors who use the equipment. Clarity, spatial resolution, contrast discrimination, and lack of artifact are the characteristics of interest in this regard. It should be noted that, for a given machine, picture quality varies according to the portion of the body being imaged (Kreel, 1979). Thus, image quality can only be defined in relation to how the equipment will be used.

Another important set of product attributes have to do with the rate of throughput of the imaging system, i.e., the time it takes to produce a final picture. This includes not only the speed of the scan, or "picture-taking" itself, but also the time to process and display the image. In general, a

faster throughput rate is desirable because it means a higher potential utilization rate (and higher potential revenues) and because faster image processing means more rapid diagnosis, which can be decisive in life-threatening situations.

Other significant quality characteristics are image display and storage options. For example, the final output can be hard copies, film, or a video display. The widespread use of computers in diagnostic imaging has increased the variety of options available to the purchaser. Software programs for data processing can be tailored to the user's particular needs and, in some cases, the computer's display and storage capabilities have obviated the need for film or paper copies of the image. Other important features are ease of operation and the degree of mobility of the equipment.

The existence of such a large number of quality characteristics which matter to purchasers is in itself evidence of product differentiation. And it is clear that firms have responded to this multi-dimensionality of diagnostic imaging equipment quality by positioning themselves differently with respect to the various product features. For example, there are a couple of firms which specialize in the manufacture of mobile X-ray systems. Other companies emphasize image quality or software options.

Access to maintenance and repair services is also an aspect of quality and one which is very important to the owners of medical imaging equipment. In some cases, large hospitals have an in-house service engineer in charge of maintaining diagnostic imaging equipment (Frost and Sullivan, 1980b). However, the training of such staff repairmen becomes quickly outmoded in such a rapidly changing field, it is sometimes difficult to obtain parts from the manufacturers, and most hospitals cannot offer salaries comparable to those of the manufacturers' service organizations (Thompson, 1978). In addition, small hospitals do not have enough work to keep a full-time repairman occupied.

Another means by which hospitals arrange for repair and maintenance is by signing annual service contracts with the manufacturer. Frost and Sullivan (1980b), in a survey of 400 hospitals, found that slightly over a quarter of the hospitals had a total or partial service contract covering diagnostic X-ray equipment. Hospitals not having an in-house serviceman or service contract depend on as-needed calls to the manufacturer's (or dealer's) service organization. And the existence of a widespread and reputable service operation is a major factor in the purchase decision (Kreel, 1979 and Frost and Sullivan, 1980b). Note, however, that small firms often cannot support a widespread sales and service organization.

The products of the various medical imaging equipment manufacturers are differentiated on the basis of quality attributes such as image clarity and system throughput rate and on the basis of repair and maintenance services provided by the manufacturer. Although there is a high degree of product differentiation on the basis of product quality characteristics, this is not the source of substantial barriers to entry. That product differentiation tends not to deter entry in this case is due to the fact that successful product designs are easily imitated and also because there is such a rapid rate of innovation in this industry--consumer preferences change as new products are introduced.

There is, on the other hand, a barrier to entry in this industry that is the result of the importance of service as a basis for product differentiation combined with the economies of scale associated with a widespread sales and service organization. Recall, for example, that several of the primary firms are companies with connections to the electronics industry, in which technical sales and repair services are also quite important. In general, firms which cannot offer extensive service facilities will face a market in which they must accept either a price discount or a smaller market share at a given price. It must be stressed, however, that an innovative firm can sidestep this barrier by offering a product with such desirable product attributes that the importance of service takes a backseat. And this has happened in the medical imaging equipment industry, as we will see.

In an industry like this, it is particularly difficult to disentangle the influence of product differentiation, which can block entry, and that of innovation, which often promotes entry. In such a situation, the central issue is the condition of effective entry. To assess this, not only which firms enter, but also which firms survive must be considered. The next section examines entry, exit, and merger patterns and the importance of service characteristics will once again emerge.

CHANGES IN INDUSTRY COMPOSITION

Changes in the set of firms in an industry over time are an important aspect of industry structure. In the first place, freedom of entry (in order to take advantage of profit opportunities) and freedom of exit (in order to escape losses) are primary mechanisms of the competitive model. This means that entry and exit patterns are useful in assessing industry performance. Moreover, an examination of merger patterns provides additional detail by investigating entry and exit movements which leave the total industry output unchanged.

In addition, as mentioned in the previous section, barriers such as scale economies or product differentiation can deter entry, while innovation can make entry easier. In an industry such as this one, facing a rapidly changing environment, a consideration of effective entry, or which firms survive in the long run, can be used to disentangle the opposing forces of barriers to entry and innovation.

Entry and Exit

Although there has been relatively little empirical work on this topic, it is generally agreed that the most important determinant of the rate of net entry is the rate of growth of industry demand (Scherer, 1980). A rapidly growing industry often experiences short-run profits and attracts entry by firms eager to share these profits. As to other determinants, Duetsch (1975) finds that more intense product promotion is associated with a lower rate of net entry, via a product differentiation barrier to entry. This agrees with Orr's (1974) analysis. The relationship between the level of concentration and the rate of net entry, on the other hand, is a topic of disagreement. Orr (1974) finds that a higher level of concentration is associated with a lower rate of net entry, while Duetsch (1975) finds that concentrated industries are more likely to be entered than unconcentrated industries.

Gorecki (1975) distinguishes between two types of entry determinants: barriers to entry, such as scale economies and product differentiation, and entry-inducing factors, such as the rate of industry growth. He argues that, although new and diversifying entrants should be affected similarly by entry-inducing factors, barriers to entry can be expected to be less effective for diversifying firms than for new entrants. He then presents evidence to support this contention. This evidence is consistent with the proposition of Hines (1957) and Kottke (1966) that the most likely entrants into an industry

are firms already solidly established in another, generally closely related, market.

The rapid growth of medical imaging equipment sales suggests that a relatively high rate of net entry into the industry is to be expected. The entry barrier resulting from the combination of scale economies and product differentiation in service, on the other hand, is expected to deter entry. On balance, the rapid pace of technical change in this industry, given that research and development in medical imaging does not exhibit substantial scale economies (see Chapter 3), can be expected to interact with rapid growth and outweigh the entry barriers due to the importance of service characteristics.

Caves and Porter (1977) present an analysis of mobility barriers among intra-industry subgroups that is relevant in this regard. Recall the three-tier structure of this industry: components producers, fringe firms, and primary firms. Components producers are not affected by the repair and maintenance needs of diagnostic imaging equipment users. And a number of the fringe firms manufacture only imaging equipment accessories, such as tables or cassette holders, for which service requirements are minimal. In addition, the products of the fringe firms are much more likely to be sold through an independent dealer who may also provide repair and maintenance services (see Chapter 3). Consequently, service characteristics are much more important to equipment users who purchase from the primary firms than to those who buy from

the fringe firms or components producers. Therefore, service characteristics can be expected to be more important in deterring entry into the set of primary firms than in blocking entry into one of the other industry subgroups.

At the beginning of this chapter, the number of suppliers of medical diagnostic imaging equipment was presented for various categories, e.g., by product line. In this section the components of the year-to-year changes will be presented, i.e., how many firms entered the market and how many exited. One problem is how to classify changes due to mergers. For purposes of this analysis, an "absorption" merger, in which a firm already in the market takes over another diagnostic imaging equipment firm, will be counted as an exit for the acquired firm (two firms effectively become one). On the other hand, a "title transfer" merger, in which a firm not currently in the market takes over a diagnostic imaging equipment firm, will not be counted as an exit for the acquired firm. Mergers are discussed in further detail in the next section.

Industry Entry and Exit

Entry and exit patterns for the medical diagnostic imaging equipment industry over the period 1971 to 1981 are shown in Table 2-14. During the period 1971 to 1978 there was a steady inflow of firms into the industry, with very little exit. The picture is reversed for the years 1979 to 1981, with a substantial amount of exit, but little entry. Note, in particular, the contrast between the period 1974 to 1978, when seven to ten firms entered the industry each year, and the period 1979 to 1981, when four to six firms left each year. This pattern is consistent with the rapid growth of demand and sales during the 1970's, the shakeout in the late 1970's resulting from overoptimistic sales growth projections and market saturation.[22]

It is also instructive to consider the breakdown of entering and exiting firms by product line. This is shown in Table 2-15, where it is the primary product line of firms entering the medical imaging equipment industry for the first time or exiting completely from the industry which is tabulated. X-ray is the primary avenue of entry into the industry, followed by ultrasound and then CT, with nuclear imaging being the least common portal of entry. This is consistent with the relative sizes of these product markets. For exit, X-ray is the most common outlet, followed by ultrasound and then nuclear imaging, with CT being the least common avenue of exit. Note, however,

Table 2-14

Entering and Exiting Firms,
Medical Diagnostic Imaging Equipment Industry, 1971-81

Period	Number of Firms at Beginning of Period (#)	Entry (#)	Exit (#)
1971-72	42	+4	
1972-73	46	+4	
1973-74	50	+5	-1
1974-75	54	+9	-1
1975-76	62	+10	-1
1976-77	71	+7	-1
1977-78	77	+9	
1978-79	86	+2	-1
1979-80	87	+1	-6
1980-81	82	+1	-4
1971-81		+52	-15

Table 2-15

Entering and Exiting Firms,
Medical Diagnostic Imaging Equipment Industry,
By Primary Product Line, 1971-81

Period	X-Ray Equipment (#)	CT Scanners (#)	Ultrasound Devices (#)	Nuclear Scanning Equipment (#)	Net Gain/Loss (#)
1971-72	+3		+1		+4
1972-73	+3			+1	+4
1973-74	-1	+2	+3		+4
1974-75	+5 -1	+2	+2		+8
1975-76	+5		+3	+2 -1	+9
1976-77	+1	+3	+3 -1		+6
1977-78	+4	+1	+3	+1	+9
1978-79	+1 -1		+1		+1
1979-80	-2	-1	+1 -1	-2	-5
1980-81	+1 -1	-1	-2		-3
1971-81	+23 -6	+8 -2	+17 -4	+4 -3	+37

that this is not the whole story, because some entry into a given market segment occurs within the industry; entry and exit within each market segment will be examined subsequently.

The size of entering and exiting firms is another important aspect of industry structure. As noted previously, due to the prevalence of diversified firms, two measures of firm size are used here: sales of medical imaging equipment and total firm sales. As would be expected, virtually all entering firms are small in terms of medical imaging equipment sales (less than $5 million annually). The exception is EMI, the firm which introduced CT and is therefore an unusual case. The size of entering firms as measured by total firm sales is shown in Table 2-16: just over 60% of firms entering during the period 1971 to 1981 are small on this scale. Four of the firms exiting the industry over this period (27% of all exiting firms) are large in terms of medical imaging equipment (sales greater than $5 million annually). It is notable that all four of these exits were via merger, i.e., the firms were bought by other diagnostic imaging equipment firms. And, Table 2-16 shows the size of exiting firms as measured by total firm sales: 60% of firms exiting over the period 1971-81 are small on this scale. Thus, as measured by total firm sales, the percentage of small entering firms is approximately the same as the percentage of small exiting firms. As measured by medical imaging equipment sales, however, the percentage of small entering firms exceeds the percentage of small exiting firms.

Table 2-16

Entering and Exiting Firms,
Medical Diagnostic Imaging Equipment Industry,
By Total Firm Sales, 1971-81

Period	Total Firm Sales: Small (< $100 million) (#)	Total Firm Sales: Large (> $100 million) (#)	Net Gain/Loss (#)
1971-72		+4	+4
1972-73	+2	+2	+4
1973-74	+4 -1	+1	+4
1974-75	+8 -1	+1	+8
1975-76	+6 -1	+4	+9
1976-77	+5 -1	+2	+6
1977-78	+5	+4	+9
1978-79	+1	+1 -1	+1
1979-80	+1 -3	-3	-5
1980-81	+1 -2	-2	-3
1971-81	+33 -9	+19 -6	+37

The medical diagnostic imaging equipment industry experienced a boom period during the 1970's, with rapid sales growth, a great deal of entry, and little exit. At the end of the 1970's an adjustment period occurred, in which entry was virtually at a standstill and a number of firms left the industry. The X-ray market segment is the most common avenue for both entry into and exit from the diagnostic imaging equipment industry. And, whether measured by medical imaging equipment sales or total firm sales, the majority of firms entering and exiting this industry are small. In the next four sections, entry and exit patterns will be examined for each product line.

X-Ray Equipment

Entry and exit patterns for the manufacturers of diagnostic X-ray equipment over the period 1971 to 1981 are shown in Table 2-17. There was a steady inflow of firms into this market segment over these years, with relatively little exit.

It is especially interesting that virtually all the entry into this market segment came from firms entering the diagnostic imaging equipment market for the first time. Only two of the entrants (7%) during this period were firms already producing another type of medical imaging equipment. Recall from Chapter 1 that the basic X-ray accounts for the majority of radiological procedures. Thus, firms entering the imaging equipment industry often focus first on that product market, and then consider expanding into other market segments.

It was noted previously that there is a subset of the X-ray equipment market which produces only components. In Table 2-18 the firms entering the X-ray market are classified as systems or components producers. Close to half of the entrants into this market over the period 1971 to 1981 were components manufacturers; the proportion of X-ray firms producing only components increased over this period (see Table 2-4). Note that X-ray equipment is the only product line for which entry by components suppliers is significant.

Table 2-17

Entering and Exiting Firms,
Diagnostic X-Ray Equipment Market, 1971-81

Period	Number of Firms at Beginning of Period (#)	Initial Industry Entry (#)	Product Extension Entry (#)	Exit (#)
1971-72	30	+3		
1972-73	33	+3		
1973-74	36			-1
1974-75	35	+5		-1
1975-76	39	+5	+1	
1976-77	45	+3		
1977-78	48	+4		
1978-79	52	+1		-1
1979-80	52	+1		-2
1980-81	51	+1	+1	-2
1971-81		+26	+2	-7

Table 2-18

Entering and Exiting Firms,
Diagnostic X-ray Equipment Market,
By Systems/Components, 1971-81

Period	Systems (#)	Components (#)	Net Gain/Loss (#)
1971-72	+3		+3
1972-73	+2	+1	+3
1973-74	-1		-1
1974-75	+2 -1	+3	+4
1975-76	+1	+5	+6
1976-77	+3		+3
1977-78	+1	+3	+4
1978-79	+1 -1		
1979-80	+1	-2	-1
1980-81	+1 -1	+1 -1	
1971-81	+15 -4	+13 -3	+21

CT Scanners

Since the CT scanner was not marketed until 1973, Table 2-19 shows the pattern of entry and exit over the lifetime of this market segment. And, as noted previously, the rate of net entry into this market parallels the growth of sales: extremely rapid increase until 1978, followed by a decline in 1979 and 1980. It is particularly notable that well over half of the entering firms were already active in another diagnostic imaging equipment market. Recall that CT is technically a type of X-ray procedure. Therefore, X-ray firms were well positioned to move quickly into the production of CT (most of the product extension entry into CT was from the X-ray market).

Table 2-19

Entering and Exiting Firms,
CT Scanner Market, 1973-81

Period	Number of Firms at Beginning of Period (#)	Initial Industry Entry (#)	Product Extension Entry (#)	Exit (#)
1973-74	0	+2		
1974-75	2	+2	+7	
1975-76	11		+5	
1976-77	16	+3		-1
1977-78	18	+1	+1	
1978-79	20			-1
1979-80	19			-3
1980-81	16			-1
1971-81		+8	+13	-6

Ultrasound Devices

The pattern of entry and exit in the diagnostic ultrasound market over the years 1971 to 1981 is shown in Table 2-20. Once again there was a steady inflow of firms into the market until the late 1970's, when substantial exit occurred. In the case of ultrasound, entry came approximately equally from new entrants and from firms already established in the medical imaging equipment market. Ultrasound techniques are based upon different scientific principles than the radiation-based procedures, so there is little technological basis for product extension entry. But, ultrasound is similar to X-ray equipment in terms of price range, primary users, and sales and service requirements. And, as with CT, most of the product extension entry into ultrasound came from the X-ray market.

Table 2-20

Entering and Exiting Firms,
Diagnostic Ultrasound Market, 1971-81

Period	Number of Firms at Beginning of Period (#)	Initial Industry Entry (#)	Product Extension Entry (#)	Exit (#)
1971-72	7	+1		
1972-73	8		+3	
1973-74	11	+3	+2	
1974-75	16	+2		
1975-76	18	+3	+3	
1976-77	24	+3	+1	
1977-78	28	+3		
1978-79	31	+1	+3	-1
1979-80	34	+1	+1	-2
1980-81	34			-3
1971-81		+17	+13	-6

Nuclear Scanning Equipment

The number of firms entering and exiting the nuclear imaging market is presented in Table 2-21. Although not as active as the other market segments, this market also shows the pattern of steady entry during the 1970's followed by an increase in exits in the late 1970's. In the nuclear imaging market most of the entering firms were also entering the diagnostic imaging equipment market for the first time. This can be attributed to the fact that nuclear medicine technology is unique due to the use of radiopharmaceuticals. Also, demand characteristics differ from those of other imaging techniques because radiodiagnostic procedures are developed for specific medical conditions.

Table 2-21

Entering and Exiting Firms,
Nuclear Scanning Equipment Market, 1971-81

Period	Number of Firms at Beginning of Period (#)	Initial Industry Entry (#)	Product Extension Entry (#)	Exit (#)
1971-72	11			
1972-73	11	+1		
1973-74	12			
1974-75	12		+1	
1975-76	13	+2		-1
1976-77	14			
1977-78	14	+1		
1978-79	15			
1979-80	15			-2
1980-81				
1971-81		+4	+1	-3

When analyzed by product line, we find that each market segment follows the same basic pattern of entry and exit as that prevailing for the industry as a whole: there was much entry and little exit over the period 1971 to 1978, followed by little entry and a significant amount of exit during the years 1979 to 1981. Thus, the forces determining the net rate of entry in the industry appear to also be governing the product-specific entry rates. This suggests that the rate of industry growth was the major force determining the pattern of entry and exit over this period. The early 1970's were boom years for the medical imaging equipment industry and many firms entered this expansive environment in search of profits. Then the growth rate slackened and firms looked to their current performance as a prediction of future profits. This led to a period of consolidation, in which some of the less successful and solidly based firms decided to leave the industry.

Turning to the type of entry, there are distinct differences among the various product lines. The X-ray and nuclear imaging markets are similar in that virtually all the firms entering those market segments were simultaneously entering the diagnostic imaging equipment market for the first time. In the CT and ultrasound markets, on the other hand, there was an approximately equal amount of entry from firms entering the industry for the first time and from firms already established in another market segment (usually the X-ray market, as would be expected). Thus, we find that over the same period during

which there was substantial entry into the industry by outside firms, there was also a substantial amount of intra-industry entry. And, this trend toward a broader product line is directly related to changes in relative product sales shares over this period. It is notable that the typical path into this industry is entry into the X-ray market, with subsequent expansion into CT and/or ultrasound.

Primary Firms

In 1968 the following firms had medical imaging equipment sales amounting to more than 5% of total industry sales: Picker, General Electric, Philips, Siemens, CGR, and Litton. In 1974 these same six firms, plus Searle and EMI, composed the set of primary firms. By 1978 Technicare and Xonics had become members of the set of primary firms, while Litton and EMI had dropped out.[23]

Until the early 1970's the set of primary firms was long-standing, solidly established, and sold mainly X-ray equipment. The rapid growth rate and spate of new product introductions in the 1970's led not only to a great deal of entry into the industry, but also to entry into the set of primary firms.

Searle became a primary firm on the strength of its patented Anger scintillation camera. As for EMI, its sales soared with the introduction and rapid initial diffusion of the CT scanner, but substantial entry into the CT market and the decline in the sales growth rate reduced its industry sales share in the late 1970's. Xonics, a fringe firm in 1974, had become a primary firm by 1978 primarily via acquisitions, most importantly the purchase of Litton's X-ray business. Technicare also made a major acquisition during this period, buying Unirad, a major supplier of ultrasound. But, Technicare's increased industry sales share was primarily due to the success of its subsidiary, Ohio-Nuclear,

a major actor in the CT market.

The primary firms in the early 1970's all began as leaders in the X-ray market, but eventually moved into other product lines. For example, General Electric and Siemens were two of the original X-ray manufacturers, and Picker has been selling X-ray systems since the 1930's. By the late 1970's, all three of these firms were active in all four product markets. This movement from X-ray into other product lines parallels the decline of X-ray equipment's relative share of the market.

During a period in which there was a substantial amount of entry into the medical imaging equipment industry, there was also entry into the set of primary firms. Picker, General Electric, Philips, Siemens, and CGR maintained their positions over this period, with Searle, Technicare, and Xonics entering the set of primary firms. The common denominator of the firms entering or maintaining their position in the set of primary firms over this period was expansion from the X-ray market into other product lines.

Mergers

Mergers, defined as the combination of two or more firms under a single ownership, can be the source of significant changes in industry composition. Moreover, although in a merger the purchased firm technically exits the market, this is not the same type of exit as a firm which shuts down its plant and ceases production. Likewise, entry via merger is not fully equivalent to entry by construction of a new plant. The difference, of course, lies in the effect on industry output.

There are five types of mergers: horizontal, vertical, market extension, product extension, and conglomerate. In a horizontal merger, both firms sell in the same market, while a vertical merger involves firms in contiguous stages of the production process (e.g., a bakery buys a flour miller). In a market extension merger the firms sell closely related products in different geographical markets, and in a product extension merger firms have similar production processes or marketing channels. Finally, a conglomerate merger involves firms with no product or market associations (Scherer, 1980).

The theory of mergers is concerned primarily with the various motives for mergers. Steiner (1975) develops an intricate description of the components of the decision to merge. A merger is then assumed to occur when the benefits to each firm outweigh the costs.

The quest for increased market power is one example of a

motive for merger. Another incentive is the opportunity to increase profits, either by taking over a non-profit-maximizing firm or as the result of cost savings due to technological or managerial scale economies (Mueller, 1969). A merger may also reduce the tax liability of the combined firm, another means of increasing profits (Clarkson and Miller, 1982). Finally, merging may be a desirable alternative to plant expansion as a means of corporate growth, particularly since growth by merger does not increase total industry output (Heflebower, 1963).

Table 2-22 presents a chronology and brief description of merger activity in the medical diagnostic imaging equipment industry over the period 1973 to 1981. The first thing to notice is that there were no vertical mergers over this period, which is consistent with the finding that production activities are not the source of significant barriers to entry in this industry.

Horizontal mergers accounted for four of the nineteen mergers (21%) which occurred during this period. Intra-industry product extension mergers are technically horizontal mergers, but have been classified separately in order to highlight the product line expansion strategy of many of the firms in the industry. There were five intra-industry product extension mergers during this period (26% of the total), and these plus the "pure" horizontal mergers accounted for 47% of the mergers. Thus, almost half the mergers resulted in a larger market share for the acquiring firm.

Table 2-22

Merger Activity, Medical Diagnostic Imaging Equipment Industry, 1973-81

	Acquiring Firm		Acquired Firm		
Period	Already Produces in this Market?	Size*	Primary Product Line(s)	Size*	Type of Merger**
1973-74	yes	L/S	X	S/S	Horizontal
1974-75	yes	L/S	X	S/S	Horizontal
1975-76	yes	L/L	NM	S/S	Intra PE
1976-77	no	-/L	NM	S/S	Inter PE
	no	-/S	CT	S/S	Inter PE
	yes	S/L	X	S/S	Intra PE
	yes	L/L	U	S/L	Intra PE
	yes	L/L	U	L/S	Intra PE
1977-78	no	-/L	U	S/S	Conglomerate
	no	-/L	X	S/S	Conglomerate
	no	-/L	X	S/S	Inter PE
1978-79	yes	L/S	X	L/L	Horizontal
	no	-/L	CT,U,NM	L/L	Inter PE
	no	-/L	X	S/S	Conglomerate
1979-80	no	-/S	X	S/S	Conglomerate
	no	-/L	all	L/L	Conglomerate
	yes	L/L	U,NM	L/L	Horizontal
1980-81	no	-/L	U	L/S	Inter PE
	yes	S/S	CT	L/L	Horizontal

*First letter refers to sales of medical imaging equipment (Small, < $5 million; Large, > $5 million). Second letter refers to total firm sales (Small, < $100 million; Large, > $100 million).

**Intra-Industry Product Extension and Inter-Industry Product Extension are abbreviated.

There were five inter-industry product extension mergers over the years 1973 to 1981 (26% of all mergers). All of the acquiring firms in this group were based in a medical instruments and equipment or, in one case, general health-related industry. This indicates that entering firms looked upon demand side similarities as helpful in the successful penetration of the diagnostic imaging equipment market. Finally, five of the mergers during this period were of the conglomerate type, with the primary industry of the acquiring firms ranging from household cleaning products to steel.

It is instructive to consider some of the explanations given in the industry literature for various mergers. Acquisition is frequently mentioned as a method of entering this promising market. Typical is the comment that Johnson & Johnson purchased Technicare as an admission ticket to the high-priced diagnostic equipment market.[24] As for Technicare, J&J purportedly offered the "deep pocket" financing necessary for long-term product development in this industry. In other cases the purchase of ready-made large-scale manufacturing capability is cited, as when Xonics acquired Litton's X-ray business.[25] Finally, sales and service establishments are often the focus of the transaction, as when Omnimedical purchased EMI's North American operations.[26] Along these same lines, it is notable that purchase agreements commonly include a clause covering continued service for the acquired firm's equipment already in place.[27]

With regard to size, acquired firms tend to be small, regardless of whether size is measured by medical imaging equipment sales or total firm sales. And acquiring firms tend to be large, again by both measures. Although this agrees with the stereotype of a merger--small firm absorbed by large firm--there is, nevertheless, a significant amount of variation in the sizes of merger participants in this industry. For example, six of the nineteen mergers (32%) involved an acquiring firm with total firm sales of less than $100 million. Thus, in addition to their usual role as the acquired firm, small firms in this industry were also actively taking over other firms during this period.

A discussion of merger activity necessarily includes a consideration of antitrust policy. One of the objectives of antitrust policy is to restrict the power of firms to control price. Section 7 of the Clayton Act is designed to achieve this objective by prohibiting mergers which would "lessen competition." Legal challenges to mergers are based on the provisions of this Section 7 and, over time, a generally accepted body of antitrust law regarding mergers has developed. And, the U. S. Department of Justice (1982) has published a set of merger guidelines which outline the conditions under which the government can be expected to challenge a proposed merger.

There have been two recent cases of antitrust action against mergers in the medical imaging equipment industry. These cases, discussed below, indicate that for antitrust purposes, the relevant market is the product market rather than the industry as a whole. Moreover, the actions involve, not surprisingly, the two most highly concentrated product markets, i.e., the CT and the nuclear imaging markets.

In the first case, in the late 1970's EMI was losing money on its CT business and decided to get out of the imaging equipment market. After a period of negotiation, EMI announced in April 1980 the sale of its CT business to General Electric. Note that sale of EMI's CT business to General Electric assuming 1978 market shares would have increased the Herfindahl index for the CT market from about 1800 to about 3000 (see the discussion of concentration in the CT market). This would certainly be cause for antitrust concern under the merger guidelines (see U. S. Department of Justice, 1982) and the Justice Department stated that it was planning to file an antitrust suit to block the acquisition. General Electric consequently agreed to purchase only EMI's non-North American CT operations and Omnimedical, a small CT manufacturer, afterwards bought the North American portion of EMI's CT business.[28]

The second case involved G. D. Searle and Co., which announced in December 1979 that its remaining diagnostic imaging businesses (nuclear imaging and ultrasound) were to be sold to Siemens. In March 1980 the Justice Department

brought suit to block the merger and requested that an injunction against the sale be granted. The government's claim was that the proposed acquisition would eliminate Siemens as a potential rival and thus lessen competition in the nuclear imaging equipment market. This indicates that, although the relevant market is defined by product line for antitrust purposes, the Justice Department is well aware of the advantages of entry from a related product line, particularly for a primary firm (see U. S. Department of Justice, 1982). An injunction against the sale was denied and the sale was completed in May 1980. Later that year the Justice Department extended its suit to also block the ultrasound portion of the merger. In spite of the fact that an injunction was denied, the Justice Department pursued the matter and the case came to trial at the end of 1980. And, although the trial was completed in January 1981, the court's decision still had not been published as of January 1983.[29]

In summary, there were nineteen mergers in the medical imaging equipment industry over the period 1973 to 1981. About half were horizontal mergers, which resulted in an increased market share for the purchaser. About a quarter were product extension mergers, with the acquiring firm based in a health-related industry; further evidence of the prominent role of demand conditions in this market. The remainder were conglomerate mergers.

Most of the firms acquired in a merger over the years 1973 to 1981 were small and most of the acquiring firms were large, but this was not a hard-and-fast rule. In particular, small firms were active on the purchasing side of the merger scene. Finally, the Justice Department keeps a close eye on merger activities in this industry, as indicated by two recent antitrust actions.

The set of firms in the medical imaging equipment industry underwent a great deal of change during the period 1971 to 1981. Over the years 1971 to 1978 there was a steady inflow of firms into the industry, with little exit. The pattern then reversed for the years 1979 to 1981, there being little entry and substantial exit. Entry into and exit from each of the four market segments followed this same pattern: net entry during most of the 1970's, followed by net exit at the end of the period. The participants in these entry and exit movements tended to be small firms. And, entry into the X-ray or nuclear imaging markets was generally intial entry into the diagnostic imaging equipment market, whereas almost half of the entrants into the CT and ultrasound markets were firms already producing another type of imaging equipment.

The set of primary firms in the industry also experienced a considerable amount of change over this period. Between 1974 and 1978, two firms moved into the set of eight primary firms and two firms moved out. The key to success as a primary firm over this period was intra-industry diversification, i.e., the leading firms moved from the X-ray market into other product lines.

In addition, there was a substantial amount of merger activity: nineteen mergers occurred over the period 1973 to 1981. Horizontal mergers were the most common, followed by product extension (the acquiring firm based in a health-related

industry) and conglomerate mergers. Acquired firms tended to be small and acquiring firms large, but there were a number of exceptions to this rule. Lastly, the Justice Department brought two suits during these years against proposed mergers.

SUMMARY

The results of this chapter can be summarized as follows:

(1) Both sales and the number of sellers grew rapidly during the 1970's, followed by a slowdown in the late 1970's;

(2) There were changes in relative product shares, with CT and ultrasound gaining ground at the expense of X-ray;

(3) The market has a three-tier structure, with components manufacturers, fringe firms, and primary firms;

(4) The industry is unconcentrated by the standards of the U. S. Department of Justice, with the X-ray and ultrasound product markets being moderately concentrated, the CT market moderately to highly concentrated, and the nuclear imaging market highly concentrated;

(5) There are no substantial economies of scale in production and firms in this industry differentiate their products primarily on the basis of quality attributes and the provision of repair and maintenance services;

(6) There was substantial entry and little exit during the period 1971 to 1978, followed by little entry and a considerable amount of exit over the years 1979 to 1981; and

(7) There was a substantial amount of merger activity over the period 1973 to 1981, with horizontal mergers accounting for about half of the total.

The basic conditions which are the most important determinants of this structure are the nature of the technology and the demand conditions. A piece of imaging equipment is complicated, technologically sophisticated, and in general cannot be directly evaluated by the user. This, combined with the demand conditions which lead to an emphasis on quality and service, is primarily responsible for the importance of product differentiation in this market. The growth in demand, also a major force, was behind the rapid growth in sales and net entry into the market.

Factors other than the basic conditions, however, are necessary to understand the structure of this industry. In particular, the nature of innovation in this industry has been repeatedly used to explain various structural features. In the next chapter, innovation and other aspects of conduct will be examined in detail. And, as we will see, the character of innovation is crucial not only in understanding market structure, but also in evaluating industry performance.

FOOTNOTES: CHAPTER 2

[1]See Health, U.S., U. S. Department of Health and Human Services, various years; Census of Manufacturers, Industry Series, U. S. Department of Commerce, Table 1a, 1977; Annual Survey of Manufactures, U. S. Department of Commerce, Bureau of the Census, various years; International Resource Development (1978), pg. 44; and Frost and Sullivan (1980b), pg. 2.

[2]Nominal sales adjusted by Producer Price Index for Industrial Commodities, Statistical Abstract of the United States, U. S. Department of Commerce, Bureau of the Census, various years.

[3]The "Gray Sheet" (Medical Devices, Diagnostics, and Instrumentation Reports), November 13, 1978.

[4]Ibid.

[5]Ibid.

[6]Ibid.

[7]Ibid.

[8]A data file was constructed using the following sources: Directory of Corporate Affiliations, Skokie, Ill.: National Register Publishing Co., Inc., 1982; Dun & Bradstreet, Million Dollar Directory, Parsippany, N.J.: Dun's Marketing Services, 1982; Dun & Bradstreet, Principal International Businesses, New York: Dun & Bradstreet International, Ltd., 1982; Frost and Sullivan (1974a, 1974b, 1975a, 1975b, 1979, 1980a, 1980b); the "Gray Sheet" (Medical Devices, Diagnostics, and Instrumentation Reports), various years; Hale and Hale (1975, 1978); International Directory of Corporate Affiliations, Skokie, Ill.: National Register Publishing Co., Inc., 1982; International Resource Development (1978); Medical Device Register, Greenwich, Conn.: Directory Systems, Inc., 1982; Moody's Bank and Finance Manual, Moody's Industrial Manual, Moody's International Manual, Moody's OTC Industrial Manual, New York: Moody's Investors Service, Inc., various years; Standard & Poor's Register of Corporations, Directors, and Executives, New York: Standard & Poor's Corp., 1982; Theta Technology Corp. (1978); selected company annual reports, various years; Initial Report, Annual Report, and List of Certified Components data from National Center for Devices and Radiological Health; questionnaire responses (see Appendix A).

[9]Annual Survey of Manufactures, 1980.

[10]Derived from sources listed in footnote (8).

[11]Market shares were available for ten of the 35 firms in the market in 1974, and for seven of 52 in 1978; derived from sources listed in footnote (8).

[12]The "Gray Sheet," February 23, 1981.

[13]Ibid.

[14]Market shares were available for 11 of the 20 firms in the market in 1978; derived from sources listed in footnote (8).

[15]The "Gray Sheet," February 23, 1981.

[16]Market shares were available for five of the 16 firms in the market in 1974, and for 10 of 31 in 1978; derived from sources listed in footnote (8).

[17]Market shares were available for eight of the 12 firms in the market in 1973, and for nine of 14 in 1977; derived from sources listed in footnote (8).

[18]The "Gray Sheet," March 17, 1980.

[19]G. D. Searle and Co. 10-K report, year ended December 31, 1980.

[20]Market shares were available for 21 of the 74 firms in the industry in 1974, and for 24 of 86 in 1978; derived from sources listed in footnote (8).

[21]See Table 2-2 for sales in 1969.

[22]The "Gray Sheet," February 23, 1981.

[23]Derived from sources listed in footnote (8).

[24]The "Gray Sheet," October 9, 1978.

[25]Ibid., April 10, 1978.

[26]Ibid., December 8, 1980.

[27]See, for example, Ibid., September 21, 1981.

[28]Ibid., May 12, 1980; July 7, 1980; August 11, 1980; September 1, 1980; December 8, 1980; February 23, 1981.

[29]Ibid., March 17, 1980; March 31, 1980; August 4, 1980; August 11, 1980; February 9, 1981; G. D. Searle and Co., 10-K report, years ended December 31, 1980, 1981, and 1982.

CHAPTER 3: CONDUCT

In this chapter the conduct of firms in the medical diagnostic imaging equipment industry is examined. First, pricing behavior will be discussed, followed by an investigation of the marketing strategies used by medical imaging equipment firms. Then the process of innovation, one of the major forces in this industry, will be analyzed. Finally, nonprice competition among medical imaging equipment firms will be examined.

PRICING BEHAVIOR

The method by which firms set price depends on market structure, where the relevant market types are pure competition, monopoly, oligopoly, and monopolistic competition. In a monopolistically competitive market, there are a number of firms acting noncooperatively, but each firm perceives a downward-sloping demand curve for its product, i.e., there is product differentiation. There is a high degree of product differentiation in the medical diagnostic imaging equipment industry and the number of sellers ranged from about 40 in 1971 to about 80 in 1981 (see Chapter 2). This market is best described as monopolistically competitive.

With so many firms, it is unlikely that firms would be able to coordinate pricing decisions. In addition, price coordination is especially difficult when products are differentiated, because firms must then agree on quality levels in addition to price and output. Scherer (1980) comments that multidimensionality of technical features (an important characteristic of medical imaging products) is the type of product heterogeneity most likely to lead to conflicts over price agreements. It is also the case that tacit coordination is extremely difficult in an industry, such as this one, experiencing rapid technical change.

In a market like this, it is to be expected that, since firms cannot successfully coordinate their decisions, they will compete on the basis of price. And, due to the high degree of product differentiation there should be a wide range of prices to match the many product characteristics positions held by various firms in this industry.

Prices

The retail price of a standard medical X-ray system (including X-ray generator, control, tube stand, table, and beam-limiting device) was about $30,000 to $40,000 in 1974. There were price changes during the 1970's, but price increases over the period 1967 to 1976 for X-ray equipment (quality corrected) were not significantly different from price increases for other industrial commodities. By 1976 the average retail price for a typical diagnostic X-ray system (including quality improvements) was about $60,000 (Shope and Rudolph, 1978). These findings agree with the price range of $17,500 to $75,000 for conventional radiography systems cited by International Resource Development (1978).

Beyond this standardized product, price comparisons are problematical. For example, how can a specialized mammography machine priced at $165,000 be compared to an X-ray attachment for cardiac imaging with a selling price of approximately $20,000[1]? What is apparent from a survey of X-ray equipment prices is that equipment utilizing the latest technological advances is in an entirely different price class than conventional systems. For instance, in 1981 a sophisticated cardiac angiography system cost $625,000 to $875,000[2] and Portugal (1982) observed that an entirely new digital radiography unit would cost $600,000 to $700,000 ($200,000 to $300,000 to upgrade an existing X-ray system).

Turning to CT scanners, Shope and Rudolph (1978) estimated that in 1976 the average price for a head CT unit was $300,000 and for a body CT unit was $500,000. This agrees with Theta Technology Corp.'s (1978) survey of CT prices. Their findings for whole body scanners are presented in Table 3-1. The first thing to note is that, although there is a wide range of prices, higher prices are associated with higher quality, measured in this case by the number of detectors and speed per scan. Secondly, there is a great deal of price variation even within the set of market leaders. Compare, for example, General Electric and EMI's price/quality combinations.

In terms of price changes, one source estimated that the average price of a CT scanner had risen from $200,000 in 1975 to $500,000 in 1980.[3] The problem with such a statement is that a "scanner" was by no means the same product in 1980 as it was in 1975. Recall, for example, that between 1973 and 1978 image reconstruction times for an EMI scanner declined from 16 minutes to less than 15 seconds (Theta Technology Corp., 1978). It is also notable that over time the range of prices appears to be widening, as a larger variety of quality options are offered. For instance, EMI introduced a new line of CT systems in late 1978, with prices ranging from $295,000 to $1 million, depending on the model's capabilities.[4] And, by 1981 both Ohio-Nuclear and Omnimedical were selling scanners priced at less than $150,000, while Pfizer's top-of-the-line whole body scanner was quoted at $1.3 million.[5]

Table 3-1

Comparison of Whole Body CT Scanners, 1977

	Price (approx.)	Detectors (#)	Speed per Scan (sec)
Artronix	$300,000	512	405, 9, 18
American Science & Engineering	$700,000	600	5, 10, or 20
EMI	$450,000	Several	20
General Electric	$595,000	320	4.8 or 9.6
Ohio-Nuclear (a)	$400,000	1	120-150
(b)	$525,000	Several	18-34
Pfizer (a)	$350,000	1	120-140
(b)	$500,000	Several	30
Philips	$570,000	30	27+
Picker	$475,000	60	9
Searle	$500,000+	256	5, 20
Syntex	$400,000	12	60
Varian	$500,000+	Many	6

Derived from: Theta Technology Corp. (1978), pg. IX-14.

Ultrasound equipment exhibits this same pattern of price dispersion, both across products and across firms. As an illustration of the first type of price variation, Frost and Sullivan (1975b) present typical prices for ultrasonic devices that range from less than $500 for a Doppler fetal heart detector to $40,000 or $50,000 for a B-scanner. Price here is clearly related to product capabilities. For cardiac diagnostic equipment in particular, Frost and Sullivan (1980a) quote prices for representative echocardiographs both by product type and by firm (see Table 3-2). The price differentials between the two products stem from quality differentials. An M-mode echocardiograph prints out a graph of the ultrasonic echo on a strip chart, while a two-dimensional echocardiograph displays a cross-sectional image. The price differentials among firms, on the other hand, are largely due to the variety of options included when calculating "product" price--again a form of quality differences.

Like X-ray equipment, innovation in the ultrasound market is often accompanied by substantial price hikes. For example, in 1980 an Australian firm introduced an ultrasonic water path scanner for cycled imaging of the heart. This scanner, which has capabilities not available in other scanners at the time, was priced at $120,000 to $140,000, significantly higher than even other high grade scanners.[6]

Table 3-2

Prices of Representative Echocardiographs, 1980

Firm	M-mode	Two-Dimensional
Advanced Technology Laboratories	$23,000	$64,000
Hoffrell	$19,545	$40,205
IREX International	$16,150	$65,000
Picker	$17,000	$48,500
SmithKline	$14,800	$43,500

Derived from: Frost and Sullivan (1980a), pp. 71-72.

For nuclear scanning equipment, the price of a standard Anger-type scintillation camera (with little scope for quality differentiation) has risen steadily from about $60,000 in 1973 (Frost and Sullivan, 1974b) to approximately $75,000 in 1981.[7] The range of prices is wider for data processing equipment, a primary source of product differentiation in this market. In 1981 nuclear data processing systems ranged from a hard-wired scintiview computer with an average price of $30,000 to a sophisticated multiterminal shared processor typically priced at $85,000.[8] The emission computed tomography scanner, a significant technological advance similar to the CT scanner (except that gamma rays are detected instead of X-rays) put nuclear imaging prices into a whole new realm. Frost and Sullivan (1979) estimated that in 1978 a typical ECAT brain scanner was priced at $300,000.

Discounting

The effective price of a piece of imaging equipment is based not only on the list price, but also on the terms of payment and installation and staff training charges. The present discounted value of all charges is the price which matters to the purchaser. Moreover, although product differentiation inhibits price comparisons, there may be scope for price competition within submarkets composed of roughly homogeneous products. Therefore, it is important to look at discounting practices for particular products.

Frost and Sullivan (1974b) found that in the early 1970's discounting was not prevalent in the nuclear imaging market. However, by 1978 (Frost and Sullivan, 1979) manufacturers were offering significant discounts, particularly on gamma cameras. One firm was allowing hospitals to keep nuclear imaging systems for introductory trial periods of as long as a year without charge, gambling that the hospitals would eventually purchase the units.

Discounting is also frequently used in the CT market (Theta Technology Corp., 1978). One case is cited in this source of two hospitals at a CON review, one of which had been offered a CT scanner list priced at $600,000 for a two-year period without charge and a final price of $340,000. The other hospital was offered a $150,000 discount on a scanner listed at $550,000. The former firm had placed very few of its scan-

ners, and the (steep) discounting was an attempt to break into the market. The other firm, more solidly established in the market, responded by lowering its price, but not as drastically.

Finally, CON regulation can affect pricing practices. Recall that for capital expenditures exceeding $150,000 ($100,000 in some states) CON approval is required. Consequently, medical imaging equipment firms have a strong incentive to price their products at less than $150,000.[9] CT manufacturers Ohio-Nuclear and Omnimedical have developed marketing strategies based on the CON process and have actively promoted their scanners priced at less than $150,000 as a way for small hospitals and private physicians' offices to avoid government red tape.[10] And some firms offer discounts expressly for the purpose of sidestepping CON. For example, in 1981 ADAC Laboratories announced that the base price of its digital subtraction angiography system was $160,000, but that by changing the terms of the contract (e.g., eliminating the one-year warranty) the price could be reduced to less than $150,000.[11]

Leasing

Some firms lease imaging equipment rather than selling it outright. Frost and Sullivan (1975a) estimated that about 35% of 1974 X-ray equipment shipments were made on a lease basis. For nuclear medical equipment, approximately 20% was sold on lease; while about 10% of diagnostic ultrasonic equipment was leased. A few years later, Theta Technology Corp. (1978) found that approximately 25% of nuclear medical equipment was sold on lease, and about 15% of ultrasonic equipment was leased.

One reason that equipment users may prefer a leasing arrangement is that it protects them from obsolescence in a rapidly changing market, i.e., at the end of a few years they are not stuck with out-of-date facilities, but can sign another lease for an upgraded class of equipment. This explanation is not very convincing for medical imaging equipment because it would imply that the more rapidly changing product markets would exhibit more leasing activity. Instead, there is more leasing in the older, more established product markets.

Another argument is that some purchasers may prefer leasing due to the income tax structure (Miller and Upton, 1976). The idea here is that in some cases users receive a lower rental rate because the leasing company can specialize in utilizing tax subsidies for capital equipment. Tax advantages for leasing will be more attractive to private physicians' offices, however, than to most hospitals, due to the tax

benefits of ownership for a non-profit institution.

Lastly, CON regulation may affect the lease/buy decision. Leasing turns a capital equipment cost into an operating cost, and thereby sidesteps the regulatory process (although health systems agencies have become more aware of this ploy over time). As before, this avoidance of government bureaucracy is especially attractive to small hospitals and private physicians' offices.

In conclusion, although price comparisons of medical imaging equipment can be problematical due to the high degree of product differentiation in this market, the picture which emerges is of an industry offering a wide range of product choices, where price is only one of a number of relevant product characteristics. And, as would be expected, price tends to be directly related to the level of quality. Thus, a potential buyer of diagnostic imaging equipment can choose from a product menu ranging from a machine with a low price and limited capabilities to one which embodies state-of-the-art technology and a price to match.

Firms in this industry do compete on the basis of price, often by offering various types of discounts. And, leasing is fairly common, particularly in the more established product markets. Moreover, certain types of discounting and leasing activities are a response to CON regulation.

In the X-ray, ultrasound, and nuclear imaging markets, basic equipment can be purchased at a relatively low price. However, if the buyer ventures into the latest high technology portion of the market, prices skyrocket. The CT market is generally associated with high prices, but over time the range of CT prices has widened, with inexpensive scanners now also being offered. It is interesting that the highly publicized price inflation in this market actually appears to be a <u>quality</u> inflation fueled by the rapid rate of innovation. And, due to the prevalence of third-party payment and the

importance of quality in the demand decision, the providers of medical care furnished a ready market for the new technologies and accompanying equipment.

MARKETING STRATEGIES

Marketing strategies vary greatly within the medical diagnostic imaging equipment industry. Some firms elect to manufacture the equipment and then sell a marketing license to another medical equipment firm. The extent and nature of such distribution agreements in this industry will be examined. The majority of firms, however, choose to do their own marketing. For these latter firms, both selling methods and product promotion activities (including advertising) will be investigated. As we will see, the tiered structure of the industry is quite useful in explaining which strategies are selected.

Distribution Agreements

Some firms manufacture medical imaging equipment and then sell the distribution rights to another firm. The firm purchasing the marketing rights is usually another manufacturer of medical imaging equipment, but in some cases it is a firm selling other types of medical equipment. These distribution agreements are different from technology licensing agreements, in which a firm sells the right to manufacture a given product. The latter type of contracts are discussed as an aspect of innovation.

There are two basic types of distribution agreements. In an international agreement, the contract specifies that the equipment can only be marketed in particular countries. The manufacturer thus gains access to a foreign market without having to set up a local sales organization. These contracts may involve U. S. manufacturers seeking foreign sales, or the converse. For instance, Ohio-Nuclear (a U. S. firm) signed an exclusive distribution agreement with Siemens, good until 1981, for sales and service of its nuclear diagnostic equipment outside the United States, Canada, the United Kingdom, Australia, New Zealand, and Japan (Frost and Sullivan, 1979). An example of a foreign manufacturer using this method to sell in the United States is Aloka Ltd. of Japan. In the late 1970's, Narco Bio-Systems was granted an exclusive license to distribute Aloka's diagnostic ultrasound products in the United States, Canada, and Mexico.[12] After Narco sold its ultrasound

business in 1980, Aloka signed a similar agreement with Pfizer.[13]

In these international agreements the marketing firm is generally granted exclusive distribution rights, while the manufacturer receives the assurance that a specified amount of equipment will be purchased. Consider, for example, the agreement between Omnimedical (a U. S. manufacturer of CT scanners) and the Italian firm Kontron SPA. Under the terms of the contract, Kontron was granted exclusive distribution rights in Italy for three years, while Omnimedical was guaranteed the sale of a minimum of 14 of its Model 4001 scanners.[14]

In the second type of agreement, the medical imaging equipment manufacturer grants general marketing rights to another firm. The distribution rights tend to be nonexclusive, with the benefit to the manufacturer coming from the increased scope for sales. For example, both ADAC Laboratories and Medical Data Systems market nuclear imaging equipment directly, and also have sales arrangements with other nuclear diagnostic equipment manufacturers (Frost and Sullivan, 1979).

An interesting question is why certain firms prefer this marketing technique to selling directly or through a dealer network. One answer lies in the importance of personal selling and service in this market, combined with the diseconomies of operating a sales and service organization at small scale. Theta Technology Corp. (1978) observed that foreign sales depend largely on direct selling and a very strong service

organization. They noted that when firms do not find it profitable to set up a foreign sales and service operation, they then often sign distribution agreements with firms already having such operations in place. It is clear that the argument also holds for domestic firms unable to set up a full-scale sales and service operation.

Consider, for instance, the marketing agreement signed between Baird Corp. and Cordis Corp. in 1978. Under the terms of the contract, Cordis, a supplier of cardiovascular equipment, agreed to distribute Baird's "System Seventy-Seven" scanning gamma camera, which is used primarily for dynamic imaging of the heart. Cordis had an established sales force of about 80, specialized in selling cardiovascular equipment. It was Baird's express purpose to use Cordis' expertise as a means of increasing sales penetration in the hospital market.[15] However, most nuclear imaging equipment is purchased by the Radiology (or Imaging) Department, not by the Cardiology Department. As a result, Cordis' expertise was not as useful as had been anticipated, the marketing agreement was terminated in 1980, and Baird subsequently established its own sales organization.[16]

Recall that all the primary firms have the sales volume to support a full-scale sales and service operation. Consequently, it would be surprising to find primary firms using this marketing strategy. And, in fact, of the agreements referenced in the industry literature, only one involved a primary firm being the seller of marketing rights. And in

that case, the Ohio-Nuclear/Siemens agreement was signed before Technicare, Ohio-Nuclear's parent company, managed to move into the set of primary firms. Moreover, the original distribution agreement specified that Siemens could market Ohio-Nuclear's nuclear diagnostic equipment everywhere except in the United States, Canada, and the United Kingdom. The agreement was modified in 1978 to remove Japan, Australia, and New Zealand from Siemen's marketing territory (Frost and Sullivan, 1979). Thus, as Technicare grew, it found it profitable to retain more and more of the sales territory for itself.

Marketing agreements can also be used as a preparation for entry into a particular market. A classic example of this is General Electric's entry into the nuclear imaging market in 1971 as a distributor of the Israeli firm Elscint's line of nuclear medical equipment. The marketing agreement was then terminated a few years later (Frost and Sullivan, 1979). General Electric subsequently bought the nuclear medical equipment line of Nuclear Data in 1975 and began manufacturing and marketing its own line of nuclear imaging equipment (Frost and Sullivan, 1975a).

Selling Methods

For the manufacturers which also do their own marketing, there are four basic ways in which the product is sold: directly, by a staff of company salesmen; by manufacturers' representatives; through regional dealers and distributors; and direct from the factory. Manufacturers' representatives are independent salesmen who represent one or more medical imaging equipment firm, while dealers are middlemen for a particular type of equipment, most commonly X-ray equipment. Direct factory sales are used primarily by components manufacturers, which have individual arrangements with the firms utilizing their components.

Frost and Sullivan (1974a), in a survey of the selling methods of medical diagnostic equipment suppliers, found that 51% used central or branch sales offices, 28% used manufacturers' representatives, 15% used local distributors, and 6% used other methods. Thus, over half the firms relied on direct selling.

This is consistent with evidence from the diagnostic imaging equipment industry survey, in which firms were asked whether they maintained a staff of route salesmen, i.e., whether they relied primarily on direct selling. The responses to that question are presented in Table 3-3. For all product lines, 65% of the responding firms use route salesmen. Firms selling X-ray equipment are less likely to use staff salesmen, while firms selling CT scanners and ultrasound devices are more likely to use staff salesmen. Thus, direct selling is

Table 3-3

Responses to the Medical Diagnostic Imaging Equipment Industry Questionnaire, Selling Methods Question

Question: Do you maintain a staff of route salesmen for medical diagnostic imaging equipment -- yes or no?

	Number Responding	
	"Yes"	"No"
X-Ray Equipment	8 (53%)	7 (47%)
CT Scanners	5 (83%)	1 (17%)
Ultrasound Devices	11 (85%)	2 (15%)
Nuclear Scanning Equipment	4 (67%)	2 (33%)
For All Companies Responding	17* (65%)	9* (35%)
Multiproduct Firms Only	6 (86%)	1 (14%)

*Rows do not sum to this figure due to multiproduct sellers.

quite prevalent in this industry, especially in the CT and ultrasound market segments.

Note that six of the seven multiproduct firms responding to the survey report using route salesmen. This agrees with Frost and Sullivan's (1975b, 1979) findings that virtually all the leading firms in the diagnostic ultrasonic equipment and nuclear medical equipment markets maintain a staff of imaging equipment salesmen. Moreover, all the primary firms rely primarily on direct selling, as indicated by their extensive sales and service organizations.

This pattern is consistent with the argument that there are diseconomies to operating a sales and service organization at small scale. And, it concurs with Frost and Sullivan's (1975a) observation that for new companies, manufacturers' representatives are a low cost method of establishing a national sales presence, but that, as sales increase, firms begin using a company sales staff. In general, then, the primary firms sell directly, while fringe firms are more likely to use manufacturers' representatives or dealers.

In the diagnostic imaging equipment industry, the salesman often acts as a technical interpreter, explaining what the engineering specifications will mean in practice for the user. The salesman's job is complicated in the hospital by the dual lines of authority; determining exactly who has the power to make the final purchase decision is often problematical, especially since it can vary greatly from hospital to hospital.

And, salesmen must have up-to-date information on regulatory, financing, and tax issues. As a consequence, comprehensive sales training is crucial in this industry: in addition to general selling skills, salesmen must have extensive knowledge about technical product characteristics, the organizational structure of the hospital, and general issues such as financing techniques. Moreover, for more expensive equipment, the supplier often offers assistance with the CON approval process. In the end, the salesman may become a de facto consultant to the purchaser (Frost and Sullivan, 1980b).

Medical imaging equipment firms tend to concentrate their selling efforts in the hospital on the physician because in general the doctors have the final word on which equipment will be purchased. In addition, selling efforts in the hospital tend to spill over to private physicians' offices. The most effective means of influencing the medical community are endorsements by opinion leaders and personal recommendations (National Academy of Engineering, 1971). Teaching hospitals are the primary source of new medical developments and thus serve as the standard of good medical practice. As a consequence, doctors at the teaching hospitals receive special attention from medical imaging equipment firms (International Resource Development, 1978).

Diagnostic imaging equipment firms recently have moved toward the use of a product line sales approach, in which a

firm offers to supply all the medical imaging needs of a given hospital (Frost and Sullivan, 1980b). There are cost savings to the firm in such a situation, stemming from more intensive utilization of the sales and service operation. And hospitals find substantial time savings in dealing with only one company's sales and service organization.

Product Promotion

Although the topic of product promotion is related to both product differentiation and nonprice competition, it is discussed here as an aspect of how firms market their products. In the medical imaging equipment industry, product promotion includes not only advertising, but also activities such as trade show exhibits, which are also a form of personal selling.

The classic debate, of course, is whether promotion activities are primarily informative or persuasive. That this question cannot be answered for the economy as a whole is not surprising. It should, however, be possible to come to some conclusion about the role of promotion within a given industry. One point is that purchasers of producer goods tend to be well-informed about objective product qualities and, because they are profit-maximizers rather than utility-maximizers, not particularly susceptible to subjective appeals. Consequently, producer good advertising is primarily informative. This argument applies to medical imaging equipment because it is a producer good, although it should be remembered that the providers of medical care are not, in general, profit-maximizers. Secondly, image as a dimension of differentiation is somewhat superfluous for diagnostic imaging equipment given that there are so many important elements of actual product quality. Lastly, as we will see, the methods of product promotion used in this industry are not those typically associated with "pure" image differentiation, i.e., no catchy jingles and crowds of beautiful people.

Taken as a whole, medical imaging equipment product promotion is expected to be primarily informative in nature.

The survey of diagnostic imaging equipment firms included two questions relating to the nature of product promotion in this industry. The first question asked each firm what percentage of sales was allotted to advertising; the responses are presented in Table 3-4. For all companies responding, the mean advertising-sales ratio was 3.6%. The ratio was least for firms manufacturing X-ray equipment (1.9%), followed by CT suppliers (2.8%), and then nuclear scanning equipment firms (3.6%). Ultrasound manufacturers had the highest advertising-sales ratio (4.4%). And, firms active in more than one product market devote a lower percentage of their sales to advertising (2.5%) than single product firms.

An industry advertising-sales ratio of between 3% and 4% is somewhat higher than would be expected for a producer good. But, the pharmaceutical industry, which also markets primarily to physicians, had an advertising-sales ratio of about 12% in 1972 (Schwartzman, 1976). In general, an advertising-sales ratio of 3% to 4% tends to be associated with consumer durable goods (see, for example, Ornstein, 1977). This finding is explained by the fact that medical imaging equipment is similar to an infrequently purchased, complex durable consumer good for which it is difficult to assess product performance. For such a product, firm reputation can serve as a signal of quality (Nelson, 1974), and firms have an incentive to invest in

Table 3-4

Responses to the Medical Diagnostic Imaging Equipment Industry Questionnaire, Advertising Budget Question I

Question: What percentage of your sales is allotted to advertising?

	Mean (# of Companies Responding)	
X-Ray Equipment	1.9%	(12)
CT Scanners	2.8%	(6)
Ultrasound Devices	4.4%	(12)
Nuclear Scanning Equipment	3.6%	(6)
For All Companies Responding	3.6%	(22)*
Multiproduct Firms Only	2.5%	(7)

*Rows do not sum to this figure due to multiproduct sellers.

firm reputation by advertising. It is also the case, as we will see, that a large portion of the advertising budget is devoted to promotion activities which are technical in nature, as would be expected for a product of this type.

The second question in the survey relating to product promotion asked how the advertising budget was allocated among various types of promotion activities. The responses, shown in Table 3-5, indicate the importance of convention-associated promotion in this industry. For all companies responding, 48% of the advertising budget was devoted to conventions, 32% to magazines, 11% to direct mail, and 9% to other. This pattern is fairly consistent across product market segments, except that there is more "other" advertising than direct mailings in the other cases (one of the firms active in all four market segments indicated that it allocates 50% of its advertising budget to "other").

This emphasis on product promotion at conventions has been noted by other industry observers. For instance, Frost and Sullivan (1980b) commented that major promotional efforts are made at professional meetings and trade shows. A primary characteristic of convention promotional efforts, such as exhibition booths, slide shows, and equipment demonstrations, is that they emphasize the technical aspect of purchasing imaging equipment. In addition, such promotional activities are closely related to personal selling methods, in contrast to, for example, a billboard sign.

Table 3-5

Responses to the Medical Diagnostic Imaging Equipment Industry Questionnaire, Advertising Budget Question II

Question: What percentage of your advertising budget is allotted -- to magazines, to direct mail, to conventions, or other?

	Mean				Number of Companies Responding
	"to magazines"	"to direct mail"	"to conventions"	"other"	
X-Ray Equipment	28%	12%	48%	12%	10
CT Scanners	28%	11%	46%	15%	4
Ultrasound Devices	32%	10%	45%	13%	9
Nuclear Scanning Equipment	22%	14%	42%	22%	5
For All Companies Responding	32%	11%	48%	9%	20*
Multiproduct Firms Only	19%	12%	41%	28%	4

*Rows do not sum to this figure due to multiproduct sellers.

The magazine advertisements for medical imaging equipment appear primarily in the professional journals (such as Radiology) and the trade magazines (e.g., Medical World News) (Theta Technology Corp., 1978). Direct mailings, on the other hand, are used mainly when the firm can pinpoint the desired recipients by purchasing names and addresses of radiologists or other specialists from a medical society or journal.

In addition to those already discussed, another type of promotion frequently used in this industry is the arrangement of seminars for key potential buyers (Frost and Sullivan, 1975a). These seminars are used most often for new, expensive, high technology equipment and, like convention promotions, are a mixture of technical education and personal selling.

In summary, although firms use a variety of strategies to market medical imaging equipment, certain patterns are apparent. In the first place, the primary firms all market their own products directly through a network of sales and service offices. For other firms in the industry, there are disadvantages to operating a sales and service organization at small scale. Therefore, when sales volume is low, firms tend to rely on distribution agreements, manufacturers' representatives, or dealers as marketing outlets.

Direct selling is the key to marketing medical imaging equipment. Purchasers rely on the salesman to interpret technical details and advise on tax and regulatory problems. The pivotal role of personal selling is also demonstrated by the fact that convention activities, in which there is direct customer contact, account for about half of all promotion expenditures. Other product promotions include advertising in magazines, direct mailings, and seminar presentations.

INNOVATION

Innovation is defined as any activity which leads to a new product or production technique (Kamien and Schwartz, 1982). One of the keys to understanding the market for medical diagnostic imaging equipment is the nature of innovation in this industry. Technical change is not only an important aspect of conduct, but also a major influence on market structure and performance. In this section the process by which innovation occurs in this industry is examined in detail.

History

To set the stage for the subsequent analysis, the major technical advances in the field of medical imaging will be described. Some of this material was covered in Chapter 1 and, as was the case for the product descriptions, each type of imaging equipment will be discussed individually.

The industry as a whole has experienced an extremely rapid rate of technical change, particularly in the last ten to fifteen years. For instance, International Resource Development (1978) estimated that two-thirds of the industry's growth over the period 1972 to 1978 had been generated by products introduced after 1972. And the CT scanner provides a striking illustration of this rapid change. One of the first CT scanners installed in the United States was recently placed in the Mayo Clinic Historical Museum, a historical artifact after slightly more than five years of use.[17]

The field of medical imaging has been greatly influenced by technological progress in other areas. After World War II, the development of the television tube and the electronic amplifier led to major changes in imaging technology (International Resource Development, 1978). Then in the 1970's there was a surge of technical change which was closely linked to developments in solid state physics and, more importantly, in computer technology (Portugal, 1982). In particular, micro chips have been widely incorporated in medical imaging technology and there have been major strides in the processing of medical

imaging information as a result of the introduction of fast, inexpensive micro computers.

Discovered in 1895, X-rays have been used for medical imaging since the turn of the century. In the early 1900's various improvements in the X-ray tube were proposed, and in 1913 the prototype of the "hot filament" X-ray tube, still in use, was invented (Hendee et al., 1977). The image intensifier, which increased the resolution of fluoroscopic images, was introduced in the 1950's and there were various improvements in film quality during the 1960's.

Major advances in X-ray technology occurred during the 1970's stemming from various applications of the computer. Most important was the development of digital radiography, a technique in which the information contained in an X-ray image is recorded in a computer. The data can then be manipulated and displayed in various ways. A major use of this capability is digital subtraction, in which the computer electronically subtracts images made before and after injection of contrast material in order to isolate the anatomical structure of interest. Digital radiography can also considerably reduce the patient's exposure to radiation in comparison to conventional X-ray techniques. And, with provision for mass storage, electronic processing eliminates the need for X-ray film and copies.

CT scanning, invented in 1967, was an offshoot of the computer revolution. The computer was a necessary prerequisite

to the development of the CT scanner due to the multitude and complexity of the mathematical computations necessary for image reconstruction. And, rapid advances in computer capabilities were quickly incorporated into CT technology.

Both scanning methods and detectors were made more efficient during the mid- to late-1970's, but the most prominent improvement was drastic reductions in scanning times. EMI's scanner introduced in 1973 required 16 minutes for image reconstruction. By 1978 this had been reduced to an initial reconstruction time of less than 15 seconds and single slice scanning times of less than two seconds (Theta Technology Corp., 1978). As of 1981, state of the art for scan speed was between three and ten seconds.[18]

The direction of future progress is indicated by a joint project between ScienTex and the New York University School of Medicine to adapt CT technology for neurosurgery. The purpose of the project is to develop an instrument which will use CT images to guide a surgical instrument to the desired location within the brain.[19]

The basic principles underlying ultrasound have been known since the early 1900's. However, it was not until the early 1960's that ultrasound was used for medical imaging. Early applications of ultrasound were limited primarily to imaging of the fetus because the amniotic fluid is an ideal medium for the technique. A major advance in ultrasound technology was the development of gray scale imaging in the late 1960's. This

technique increases the information obtainable from an ultrasound scan because the echo amplitudes can be expressed as various shades of gray, rather than as dots of set intensity.

Like other imaging technologies, the advent of fast, inexpensive computers led to major breakthroughs in ultrasound imaging. Analogous to the application of computer capabilities to X-ray equipment, the information in an ultrasound image can be electronically collected, processed, and displayed in a variety of ways. And, it is notable that some data processing equipment is designed to function with fluorographic, ultrasound, and nuclear diagnostic imaging systems.[20]

Computer processing and enhancement has made feasible the use of ultrasound for mammographic imaging, which is desirable since ultrasound is not radioactive. In addition, there have been major advances in cardiac applications of ultrasound, such as phased imaging of the heart. Lastly, there have been recent improvements in real-time imaging capabilities which are particularly useful for obstetric applications.

Nuclear scanning techniques depend on both the equipment and the radiopharmaceutical used for the given procedure. The discussion here refers to major improvements in nuclear scanning equipment, but discoveries of new radiopharmaceuticals are equally as important in this field. Soon after it became practical to produce radioisotopes in quantity in the 1940's, nuclear techniques were first used for imaging of the thyroid gland. And the medical applications of nuclear scanning

increased as new radiopharmaceuticals were discovered.

The rectilinear scanner, the first widely used scanner, was invented in 1951. Then in 1956 Harold Anger developed the scintillation camera which eventually replaced the rectilinear scanner as the workhorse of the nuclear imaging department. The technology of the gamma camera has remained essentially the same since the 1960's, although large field-of-view cameras are now used more frequently than standard field cameras.

The computer has influenced nuclear imaging technology in much the same way as it has affected X-ray and ultrasound imaging techniques. That is, the information contained in a nuclear image can be digitalized, processed, and enhanced in various ways. One development directly attributable to computer capabilities is emission computed tomography (ECT) scanning, a cousin of CT scanning in which image slices are reconstructed from gamma radiation emitted from injected or ingested radiopharmaceuticals. ECT scanning produces images with much less resolution than CT scanning, but has the advantage that it can detect functional, as well as structural, abnormalities.

A totally new type of imaging technology recently developed is nuclear magnetic resonance (NMR). The scientific basis for NMR has been around since the late 1940's, but it was only in the late 1970's that this technology, utilizing magnetic fields and radiowaves, was applied to medical imaging (Portugal, 1982). By 1982 NMR units had been placed at four U. S. hospitals for clinical investigation. A number of companies are actively

engaged in NMR product development, and some firms are said to currently be taking orders for future placements. However, full-scale commercialization of NMR must await FDA premarket approval of the new technology (Delco, 1983).

Since NMR is still in the experimental stage, a great deal of attention is being given to improving system performance. In addition, there are still technical problems with the technology, primarily involving the magnet systems used in the equipment. The trial status of NMR means that it must be demonstrated to be safe for human use. And much of the current research involves determining the full range of clinical uses for NMR.

There are a number of research projects currently investigating the possibilities of positron emission tomography (PET) for diagnostic imaging applications. PET constructs images by detecting positrons emitted from certain radioisotopes. Although very promising as a source of biochemical imaging, PET is still very much in the development stage due to technical problems with the production of appropriate radioisotopes.

At one time, medical imaging and X-ray technology were synonymous. Beginning in the 1950's with the spread of nuclear imaging procedures, however, the domain of medical imaging has periodically expanded to encompass new inventions which make pictures of the human body. Ultrasound was added to the diagnostic imaging repertoire in the 1960's and CT in the

1970's. And, if the predictions of industry observers come true, NMR will be the new imaging technology of the 1980's.

A recurring theme in the chronology of innovation in medical imaging is the crucial role of computer applications in this field. Indeed, the acceleration of technical change is directly related to the advent of fast, inexpensive computers. The computer's data handling capabilities are used in all four types of imaging equipment to collect, process, display, and store information. In addition, micro chips are used as process controllers in some of the more sophisticated equipment.

Public Research Support

To understand the process of innovation in this industry, it is necessary to examine the role of public funding for research activities. This is of interest because many new medical imaging products have resulted from discoveries by academic researchers, for whom the government is a primary source of research support. In particular, of the five major technological breakthroughs in medical imaging, four (X-ray, nuclear medicine, ultrasound, and NMR) were based on work by academic researchers. (It is interesting to note that the fifth major advance, CT, was developed by EMI, a firm outside the diagnostic imaging equipment industry.)

There are three types of research activities. First, there is basic research, the search for very general scientific and engineering principles. Secondly, there is applied research, the use of basic research to solve a specific problem, often resulting in an experimental model of a new product or technique. And lastly, there is product development and commercialization, in which the new product or technique moves from the laboratory to the market.

The fundamental reason that most major advances in medical imaging have originated outside the industry is that the research and development (R&D) budgets of medical imaging equipment firms are devoted almost exclusively to product development or improvement. Basic research in this field is carried on primarily by academic researchers in the teaching hospitals and medical

centers. And the bill for this type of academic research is generally paid by the government (Frost and Sullivan, 1974a, 1975b, 1979).

The Department of Health and Human Services is a frequent source of such research support. For example, in 1979 it awarded a $5.7 million multi-institution grant for a study of the clinical uses of PET technology.[21] In addition to funding research in the universities and medical centers, the government also sometimes awards research contracts directly to medical imaging equipment firms. However, in these cases, the research goal is generally development of a specific product. For instance, American Science & Engineering developed and manufactured a CT scanner under a contract awarded in 1975 by the National Cancer Institute.[22]

Although firms are not actively engaged in basic research in this field, they keep a very close eye on research developments. In some cases firms maintain informal contacts with academic researchers for this purpose. In other cases, firms take advantage of the academic pressure to publish and closely monitor the academic journals and professional meetings (National Academy of Engineering, 1971). Once the results of a research project are considered worth further development, firms use various technology licensing agreements or, in some cases, outright acquisition in order to obtain the development and manufacturing rights to new types of medical imaging equipment.

The subsequent discussion refers exclusively to R&D activities by private medical imaging equipment firms. But it is important to recognize that public funding is an integral part of the research environment in this industry, and that private R&D in general refers only to the final stage in the innovative process.

Innovation Inputs and Outputs

Once the decision is made to invest in R&D, the firm can be thought of as having a production function for innovation, with associated inputs and outputs. R&D expenditures, R&D employees, and scientific and engineering personnel all have been used as measures of inputs to innovation. R&D spending is the most frequently used input variable, but there are problems with this measure. For one thing, expenditures for R&D personnel and facilities are a very imperfect measure of the quality of the innovational effort. There is some evidence, for example, that more talented technical personnel tend to prefer working in a smaller firm, which may offer a lower salary but more autonomy and self-direction (Cooper, 1964).

Evidence on the R&D efforts of medical imaging equipment firms was obtained from the industry survey. Responses to a question about the company's R&D budget are shown in Table 3-6. For all companies responding, the mean R&D budget was 8.9% of sales. CT firms devoted the smallest percentage of sales to R&D (6.7%), followed by nuclear scanning equipment firms (7.6%), and then X-ray equipment firms (8.8%). Ultrasound manufacturers had the largest R&D budget (8.9% of sales). And, firms active in more than one product market devote a lower percentage of their sales to R&D (7.7%) than single product firms.

Thus, medical imaging equipment companies devote a considerable fraction of sales to R&D activities. They certainly fall within the "high technology" category defined

Table 3-6

Responses to the Medical Diagnostic Imaging Equipment Industry Questionnaire, R&D Budget Question

Question: What percentage of your sales is allotted to research and development?

	Mean (# of Companies Responding)	
X-Ray Equipment	8.8%	(10)
CT Scanners	6.7%	(5)
Ultrasound Devices	8.9%	(10)
Nuclear Scanning Equipment	7.6%	(6)
For All Companies Responding	8.9%	(20)*
Multiproduct Firms Only	7.7%	(5)

*Rows do not sum to this figure due to multiproduct sellers.

by Grabowski and Vernon (1979) as industries which invest 5% or more of sales in R&D. And the results are consistent with evidence from the National Academy of Engineering (1971) study that biomedical engineering firms (a category encompassing diagnostic imaging equipment) spend about 8-10% of sales on internal R&D.

The end result (output) of innovation has been defined to be a new product (or production technique). Innovational output has been measured by patents awarded, important patents awarded, number of new discoveries, important inventions, and sales of new products (Kamien and Schwartz, 1975). Each of the above variables has certain deficiencies as a measure of innovational output. For example, not all new products are patented and various new products may represent different levels of innovational output.

The use of patents to measure R&D output is inappropriate in this industry because the scientific principles underlying most medical imaging technology are long-established and, in general, unpatentable. And, although specific engineering techniques can be patented, they are often easily circumvented (see Chapter 2). For instance, the scientific phenomenon of nuclear magnetic resonance (NMR) was first discovered in the late 1940's by physicists at Stanford and Harvard Universities and since then numerous papers on the subject have been published in the scientific journals. Consequently, the scientific basis for NMR is not patentable and there are several

companies currently developing NMR units for the medical imaging equipment market.

Evidence on R&D output is available as a byproduct of medical device regulation. The regulatory program administered by the National Center for Devices and Radiological Health requires all medical device firms to submit a premarket notification form (510-K) before introducing a new product. If the manufacturer can provide evidence in the 510-K that the product is substantially equivalent to a device already being sold, then premarket approval is not required and the firm can proceed to market the product. If the product is not equivalent to a device already being sold, premarket approval, contingent upon evidence that the device is both safe and efficacious, is required.

In practice, a firm will not submit a 510-K unless FDA acceptance is a virtual certainty. If the firm believes that it has a truly new product, for which premarket approval will be required, it first submits an Investigational Device Exemption (IDE). If the IDE is approved, the firm can then perform clinical investigations of the product to determine safety and effectiveness.

IDE submissions are not available to the public, but there are few products introduced in the medical imaging equipment market which are so original that extensive premarket testing is necessary. And, although firms are very secretive about

product development plans, it is generally known in the industry that most of the IDE's which have been granted by the FDA are for medical imaging applications of NMR (Delco, 1983).

Information on premarket notifications, on the other hand, is available and the National Center for Devices and Radiological Health provided a list of 510-K submissions for the years 1976 through 1982. The data are collected according to the following product categories: diagnostic X-ray, diagnostic ultrasound, and diagnostic nuclear medicine. This classification differs from the product market definitions used previously in several ways. In the first place, the diagnostic X-ray category includes both conventional X-ray equipment and CT scanners. Secondly, the diagnostic nuclear medicine category includes equipment for <u>in vitro</u> (in glass) diagnostic procedures, as well as equipment for <u>in vivo</u> (in body) procedures. Lastly, equipment used for dental diagnostic procedures is included. Note also that there are no distinctions among the various new products. In other words, a major technical advance such as a sophisticated electronic data processing system is counted as one new product introduction, as is a relatively minor development such as an improved X-ray timer control.

The number of firms which introduced new products and the number of new products over the period 1976 to 1982 are shown in Tables 3-7 and 3-8 (note that a new product here refers to a 510-K acceptance). The pattern which emerges is of an industry in which firms are very active in marketing new

Table 3-7

Number of Firms Introducing New Products, Diagnostic X-Ray, Ultrasound, and Nuclear Medicine Medical Devices, 1976-82

		All Firms (#)	Primary Firms** (#)	Primary Firms** (% of Total)
1976	X-Ray	12	5	42
	Ultrasound	6	1	17
	Nuclear Medicine	1	1	100
	TOTAL	17*	5*	29
1977	X-Ray	19	5	26
	Ultrasound	11	2	18
	Nuclear Medicine	6	2	33
	TOTAL	31*	6*	19
1978	X-Ray	19	5	26
	Ultrasound	13	3	23
	Nuclear Medicine	13	2	15
	TOTAL	39*	6*	15
1979	X-Ray	32	4	13
	Ultrasound	20	6	30
	Nuclear Medicine	5	0	0
	TOTAL	54*	8*	15
1980	X-Ray	28	5	18
	Ultrasound	38	5	13
	Nuclear Medicine	7	2	29
	TOTAL	68*	7*	10
1981	X-Ray	32	5	16
	Ultrasound	39	6	15
	Nuclear Medicine	24	5	21
	TOTAL	84*	8*	10
1982	X-Ray	40	6	15
	Ultrasound	34	5	15
	Nuclear Medicine	6	1	17
	TOTAL	71*	7*	10

* Rows do not sum to this figure due to multiproduct firms.
** Firms with medical imaging equipment sales greater than 5% of total industry sales.

Derived from: Data provided by National Center for Devices and Radiological Health.

Table 3-8

New Product Introductions,
Diagnostic X-Ray, Ultrasound, and Nuclear Medicine
Medical Devices, 1976-82

		All Firms (#)	Primary Firms** (#)	Primary Firms** (% of Total)
1976	X-Ray	20	10	50
	Ultrasound	7	1	14
	Nuclear Medicine	1	1	100
	TOTAL	28	12	43
1977	X-Ray	42	21	50
	Ultrasound	15	2	13
	Nuclear Medicine	10	3	30
	TOTAL	67	26	39
1978	X-Ray	58	28	48
	Ultrasound	16	5	31
	Nuclear Medicine	16	3	19
	TOTAL	90	36	40
1979	X-Ray	60	19	32
	Ultrasound	22	6	27
	Nuclear Medicine	6	0	0
	TOTAL	88	25	28
1980	X-Ray	61	21	34
	Ultrasound	60	10	17
	Nuclear Medicine	12	5	42
	TOTAL	133	36	27
1981	X-Ray	75	40	53
	Ultrasound	55	13	24
	Nuclear Medicine	35	10	29
	TOTAL	165	63	38
1982	X-Ray	64	22	34
	Ultrasound	61	9	15
	Nuclear Medicine	12	5	42
	TOTAL	137	36	26

*Firms with medical imaging equipment sales greater than 5% of total industry sales.

Derived from: Data provided by National Center for Devices and Radiological Health.

products. Since the data classifications differ, it is not possible to be precise, but it appears that between a quarter and a half of the firms in the industry introduce a new product in any given year. Moreover, numerous firms have introduced more than one new product a year (the average number of new products per firm is about two).

For X-ray firms, there was a steady increase in the number of new products introduced over the period 1976 to 1981, with a slight decrease in 1982. Introductions of new ultrasound devices increased slightly over the period 1976 to 1979, increased greatly between 1979 and 1980, and then leveled off during the years 1980 to 1982. And, new product introductions of diagnostic nuclear medicine devices have been erratic over the period 1976 to 1982.

Table 3-8 also presents the number of new products introduced by primary firms over the years 1976 to 1982. Recall that the primary firms collectively account for 75% to 80% of total industry sales in any given year. Thus, it is clear that the number of new product introductions by primary firms is not proportionate to their share of industry sales. The number of new product introductions by large firms (medical imaging equipment sales in excess of $5 million) was also computed and the result was analogous: the proportion of total new product introductions by large firms is not commensurate with their share of industry sales.

In summary, there is a great deal of innovative activity in this industry. Firms allocate considerable resources to R&D activities, as indicated by the average R&D budget of 9% of sales. And, firms producing only one product devote a larger percentage of their sales to R&D than do multiproduct firms. These R&D efforts do lead to innovational outputs, as shown by the large number of new products introduced each year. In any given year, a considerable proportion of firms in the industry introduce at least one new product. And, the primary firms and other large firms account for a relatively small proportion of new product introductions in comparison to their share of total industry sales.

Innovation as a Competitive Strategy

Theoretically, R&D and innovation can either help or hinder entry. For industries in which technical change is an important aspect of competition, the necessity for a minimum R&D capacity may impose a barrier to entry (Kamien and Schwartz, 1975). On the other hand, invention of a new product is often a means of entering a new market, particularly for small firms.

Although no comprehensive data are available, a reading of the industry press makes it clear that there has been a substantial amount of entry into the medical imaging equipment industry on the strength of new product introductions. The classic example is EMI, which with the introduction of the CT scanner, not only entered the market with ease, but also became a primary firm within a few years. There are also numerous examples of small firms which used a new product or, more frequently, a product improvement to pave their way into the market. For instance, Diagnostic Information, Inc. is a small firm which was recently purchased by Xonics. The inventor of an improved fluoroscopic image intensifier founded the company in 1975 to manufacture and market his product.[23]

Thus, in spite of the fact that established firms in this industry both devote considerable resources to R&D activities and are very active in introducing new products, on balance innovation appears to be an aid to entry rather than a barrier. This implies that the minimum level of R&D effort required must be relatively low or small firms would not have been so

successful in developing new products. It is important to note, however, that while innovation has been an avenue of entry into the industry, it has not, with the exception of EMI, promoted entry into the set of primary firms. Entry into this group depends primarily not on innovative efforts, but on the extent of technical service facilities and the possession of a broad product line.

As discussed previously, there is sometimes a product differentiation advantage to being the first to introduce a new product (Bond and Lean, 1977). And, there is some evidence that this has been the case for major medical imaging developments. In particular, most of the primary firms are associated with a pathbreaking new discovery in one area of medical imaging. Siemens and General Electric were two of the original manufacturers of X-ray equipment, Picker was involved with the first scanning systems for both nuclear medicine and ultrasound, Searle developed a production model of the original scintillation camera, and EMI introduced the CT scanner (International Resource Development, 1978). Thus, there are advantages to being a pioneer, but such benefits appear to be substantial only for major technological breakthroughs.

And, it is apparent that other strategies with respect to innovation are also successful. For example, Technicare has a reputation in the industry for "creative copying" (International Resource Development, 1978). By carefully monitoring innovations by others and investing in rapid development for pro-

mising products, the company is able to take advantage of new discoveries without being the pioneering firm. Innovation as a basis for rivalry among medical imaging equipment firms will be discussed further in the section on nonprice competition.

In conclusion, innovation is a major force in the market for medical imaging equipment. In the first place, pathbreaking new technologies have been introduced periodically since the 1950's. As a consequence, medical imaging is no longer synonymous with X-ray technology, but now also encompasses nuclear scanning, ultrasound, and CT techniques. In addition to these major technological breakthroughs, there have been numerous important product improvements, stemming principally from application of the computer to medical imaging technology. And innovation is a constant concern of firms in the industry, as indicated by the amount of resources allocated to R&D efforts and the number of new products introduced each year.

Small firms are particularly active in the area of innovation, as shown by the fact that the proportion of new product introductions by small firms is quite a bit higher than the industry sales share of small firms. The minimum level of R&D effort for effective entry appears to be relatively low and, on balance, innovation has promoted entry into the medical imaging equipment industry.

Finally, although private companies devote a great deal of effort to innovative activities, the R&D undertaken by firms is generally directed at product development or improvement. Most of the basic research in this field is conducted by academic researchers and funded by the federal government.

NONPRICE COMPETITION

In addition to competing on the basis of price, firms in an industry with a high degree of product differentiation often search for other ways in which to vie for customers. The most important bases of nonprice competition among medical imaging equipment firms are product quality attributes, provision of maintenance and repair services, and the introduction of new, technologically prestigious products.

As Lancaster (1966) pointed out, buyers actually demand a combination of characteristics rather than a monolithic product. Consequently, when quality is multi-dimensional, firms can be thought of as positioning themselves in product characteristics space. For a complex product such as medical imaging equipment, there are a number of product quality attributes important to purchasers (see the detailed discussion in Chapter 2). Included are image quality, system throughput rate, data processing, display and storage options, ease of operation, and mobility. There is considerable quality competition in this industry as indicated by the fact that, in the trade press and journal advertisements, firms emphasize these product attributes and point out that they are proof of the quality of their product.

A related topic is competition on the basis of firm reputation. As Nelson (1974) observed, when product performance

is difficult to evaluate, advertising can serve as a signal of quality. Recall that the advertising-sales ratio in the medical imaging equipment industry is higher than would be expected for a producer good and that much of the advertising is technical in nature. This is evidence that firms in this industry invest (via product promotion) in firm reputation as a means of quality competition.

The provision of maintenance and repair services is the second major basis for nonprice competition in this industry. In the first place, the existence of a widespread and reputable service operation is a major factor in the purchase decision (Kreel, 1979; Frost and Sullivan, 1980b). Furthermore, Frost and Sullivan (1980b) presented evidence that in many cases service is more important than technical sophistication as a determinant of demand. Specifically, they found that often a firm with a more reliable service operation but a less technologically sophisticated product was selected over firms with more advanced products but a less dependable service organization.

Medical imaging equipment firms are well aware of this concern on the part of buyers. Consider, for instance, the statement by EMI that a worldwide service organization is essential to satisfy customers and thus gain new sales.[24] Moreover, the importance of service as a basis for competition is repeatedly stressed by industry observers (see, for example, Theta Technology Corp., 1978 or Frost and Sullivan, 1975a).

Finally, innovation is also a basis for nonprice competition in the medical imaging equipment industry. In the first place, firms must innovate simply to survive. The rate of technical change in this industry over the past fifteen years has been so rapid that firms which did not introduce new devices lost market share (Theta Technology Corp., 1978). In response to this pressure to innovate, firms devote considerable resources to R&D activities and many new products are introduced each year. Moreover, product promotion in this industry is frequently devoted to announcing and touting new products. For instance, convention-associated activities, the most important type of promotion, are generally centered around the introduction and demonstration of new, technologically sophisticated medical imaging devices. A final aspect of innovation as nonprice competition is the fact that technical advances have been a primary means of entry into this industry. In these cases, increased competition as a result of entry is a direct consequence of innovation.

One other competitive strategy used by firms in this industry should be mentioned here. Recall that during the 1970's there was a considerable amount of intra-industry entry (i.e., entry by a firm already producing one type of imaging equipment into another market segment). This trend is associated with the use of a full product line sales strategy, particularly by the primary firms. In selling to hospitals, these firms provide a type of "one-stop shopping." The idea is that if

the firm supplies all the medical imaging needs of the hospital, it has a greater incentive to provide reliable service (Frost and Sullivan, 1980b).

Note that this makes it very difficult for a firm to become a primary firm. In order for a firm to expand its market share, it must not only have a high quality product and an extensive service organization, but it also must be able to compete successfully in more than one product market. When buyers prefer multiproduct sellers, competition, especially between fringe firms and primary firms, is inhibited.

SUMMARY

Medical imaging is a complex product and price is only one of several important product characteristics. The firms in this industry offer a wide range of products with an accompanying wide range of prices. Conventional systems are available at a relatively low price, while equipment embodying the latest technological advances is considerably more expensive. Firms in this industry compete on the basis of price, primarily by offering various types of discounts and also on the basis of product quality attributes, the provision of reliable repair and maintenance services, and the introduction of new, technologically sophisticated products.

Direct selling is the cornerstone of marketing in the diagnostic imaging equipment industry. Most firms use a staff of company salesmen to contact potential buyers directly, although for small firms alternatives such as distribution agreements or the use of manufacturers' representatives may be preferable. The importance of personal contact is also indicated by the fact that convention activities are the major element in promotion and advertising campaigns for medical imaging equipment.

Innovation is a driving force in the market for diagnostic imaging equipment. For one thing, the industry has expanded periodically since the 1950's to incorporate the discovery of

new imaging techniques. In addition, advances in computer technology have had a major impact on the industry. Firms allocate considerable resources to R&D efforts, but R&D by private firms is devoted almost exclusively to product development. Basic research in this field depends primarily on public funding. Every year numerous new products are introduced and, on balance, innovation has served to promote entry into the industry.

FOOTNOTES: CHAPTER 3

[1]The "Gray Sheet" (Medical Devices, Diagnostics, and Instrumentation Reports), June 22, 1981 and July 13, 1981.

[2]Ibid., April 27, 1981.

[3]Standard & Poor's Industry Surveys, Health Care, Drugs, and Cosmetics Basic Analysis, January 1, 1981.

[4]The "Gray Sheet," October 2, 1978.

[5]Ibid., February 23, 1981 and March 30, 1981.

[6]Ibid., September 22, 1980 and November 13, 1978.

[7]Changing Medical Markets, 50 (February 1983), pg. 5.

[8]Ibid.

[9]Note, however, that in some states the facility cost, including remodeling expenses and related equipment, is the basis for the expenditure threshold.

[10]The "Gray Sheet," February 23, 1981.

[11]Ibid., May 25, 1981.

[12]Ibid., April 3, 1978.

[13]Ibid., November 3, 1980.

[14]Ibid., February 26, 1979.

[15]Ibid., March 13, 1978.

[16]Ibid., November 24, 1980.

[17]Ibid., November 16, 1981.

[18]Ibid.

[19]Ibid., October 5, 1981.

[20]Ibid., November 23, 1981.

[21]Ibid., November 19, 1979.

[22]American Science & Engineering, Inc. Annual Report for year ending March 31, 1977.

[23]The "Gray Sheet," December 14, 1981.

[24]EMI, Ltd. Annual Report for year ending June 30, 1978.

CHAPTER 4: PERFORMANCE

Summarizing the findings of Chapters 1 through 3, medical imaging equipment, used by doctors as a diagnostic tool, is a highly technologically sophisticated product. Product quality is multidimensional, with salient characteristics including image quality, system throughput rate, reliability, display and storage options, and ease of operation. Both hospitals and private physicians' offices purchase diagnostic imaging equipment and these buyers are relatively insensitive to price due to the prevalence of third-party payment. As a consequence, the purchase decision is determined primarily by perceived quality variations.

The industry composed of the manufacturers of medical imaging equipment has experienced a great deal of change over the last ten to fifteen years. Real sales have grown, there has been a substantial amount of net entry into the industry, and there has been a rapid rate of technical change. The industry is composed of primary firms, which account for at least 5% of industry sales, fringe firms, and firms which manufacture only components. In the aggregate the industry is unconcentrated, but the X-ray, CT, and ultrasound product markets are moderately concentrated, and the nuclear imaging market is highly concentrated. During the period 1971 to 1978 there was substantial entry and little exit, followed by little entry and a significant amount of exit over the years 1979 to 1981.

Innovation is a driving force in this industry. Manufacturers of medical imaging equipment compete with one another not only on the basis of price, but also on the basis of the introduction of new, technologically sophisticated products. Quality competition is also important. And, especially for the primary firms, the provision of reliable repair and maintenance services is a major basis for competition.

This chapter uses these findings to assess performance in the medical diagnostic imaging equipment industry, in particular to determine the extent of competition in this industry. From society's point of view, a competition market is preferred because it avoids the deadweight loss associated with monopoly pricing.

When a firm has market power it can raise its price above that which would be charged under competition. Thus, a measure of market power is the difference between price and marginal cost. However, information on marginal costs generally is unavailable and most empirical studies have used an accounting rate of return as a proxy for the economic rate of return. There are serious problems associated with this approach. In fact, Fisher and McGowan (1983) claim that an examination of accounting rate of return provides no information about the presence or absence of monopoly profits. Other researchers, however, claim that it is appropriate to use adjusted accounting data to measure market power (see Scherer, 1980).

For medical imaging equipment, even accounting data on profit rates is not available for all firms. In the first place, recall that over half of the firms manufacturing diagnostic imaging equipment are also active in one or more other industries (see Chapter 2). These diversified firms tend to use consolidated accounting methods and sales and income data are rarely presented by product line. Secondly, a number of the small firms in this industry are privately held and thus not required to provide detailed accounting information to the public. Nevertheless, some information on profits is available and is subsequently discussed.

Technicare Corporation, a primary firm in the industry after 1976, originally entered the medical imaging equipment market in 1970 by acquiring Ohio-Nuclear, Inc., a supplier of nuclear diagnostic equipment. In 1975 the company began to manufacture CT scanners and then expanded into ultrasound with the purchase of Unirad Corporation in 1976. Technicare was subsequently bought by Johnson & Johnson in 1978.

Information on Technicare's diagnostic imaging equipment net sales and operating income is available for the years 1972 to 1978 and is presented in Table 4-1. The composition of net sales changed greatly over this period, with the percentage of total sales accounted for by diagnostic imaging equipment increasing from 16% in 1972 to 76% in 1978. By 1978 Technicare was primarily an imaging equipment firm. Note that over the years 1973 to 1977 diagnostic imaging equipment's share of total operating income equaled or exceeded its share of sales. Moreover, the firm's after-tax income as a percentage increased steadily from 1972 to 1977. However, 1978 was not a good year for the company and then in 1979, the first year of Johnson & Johnson's ownership, Technicare lost $23,197,000 on sales on $133,633,000.[1] No further information on Technicare's financial performance is available because Johnson & Johnson does not provide accounting data by product line.

Xonics, Inc., which became a primary firm with the 1978 purchase of Litton's X-ray business, also has become mainly

TABLE 4-1

Technicare Corp., Sales and Income,
Fiscal Years 1972-78

Fiscal Year	Diagnostic Imaging Equipment Net Sales (% of Total Net Sales) ($1,000)	Diagnostic Imaging Equipment Operating Income* (% of Total Operating Income) ($1,000)	Total Net Income After Taxes as % of Net Sales
1972	3,800 (16%)	279 (11%)	2.9%
1973	6,100 (17%)	821 (19%)	4.2%
1974	10,565 (24%)	1,152 (24%)	5.4%
1975	18,522 (30%)	2,504 (33%)	5.8%
1976	52,621 (56%)	11,510 (72%)	8.2%
1977	124,952 (76%)	30,321 (92%)	10.0%
1978	142,803 (76%)	8,585 (74%)	1.9%

*Operating income is income before extraordinary items and before allocation of corporate expenses, interest, income taxes, and amortization of goodwill.

Derived from: Technicare Corp. 10-K Report, years ended June 30, 1976 and 1978.

a medical imaging equipment firm. Xonics produces diagnostic X-ray and ultrasound equipment, and as Table 4-2 shows, the share of medical imaging revenues increased from 14% in 1975 to over 90% in 1981. However, the advantages of this move are not yet apparent--the company has lost money every year since 1977. In addition to a general slowdown in the diagnostic imaging market in 1978 and 1979, there were problems associated with changing from a research to a manufacturing orientation and expanding rapidly by acquisition.

Both Technicare and Xonics are active in more than one medical imaging product market. EMI Ltd., on the other hand, sold only CT scanners, from the first commercial scanner placement in 1973 until the firm sold its CT business in 1980. Table 4-3 presents sales and profit data for EMI over the years 1973 to 1979. EMI's CT sales increased dramatically from 321,000£ in 1973 to 93,205,000£ in 1977, with profits increasing more than proportionately. This was followed by an equally dramatic drop in sales in both 1978 and 1979, with the company losing 26,000,000£ on CT sales in these two years. These losses contributed to the sharp drop in the company's after-tax profit rate as a percentage of net sales. In 1980 EMI, deciding to cut its losses, sold its CT business outside North America to General Electric and its North American CT business to Omnimedical.

Baird Corporation is another firm which is active in only one diagnostic imaging market, in this case the nuclear imaging

TABLE 4-2

Xonics, Inc., Revenues and Income,
Fiscal Years 1975-81

Fiscal Year	Medical Imaging Revenues (% of Total Revenues) ($1,000)	Total Revenues ($1,000)	Total Income/Loss After Taxes* ($1,000)
1975	832 (14%)	6,092	326
1976	1,452 (16%)	9,062	211
1977	4,405 (41%)	10,741	-4,466
1978	8,090 (56%)	14,404	-4,207
1979	82,673 (91%)	90,431	-7,320
1980	(> 90%)	70,067	-4,966
1981	(> 90%)	76,981	-1,214

*Before extraordinary items.

Derived from: Xonics, Inc. Annual Report, year ended March 31, 1979; Moody's Industrial Manual, various years.

Table 4-3

EMI Ltd., Sales and Profits, Fiscal Years 1973-79

Fiscal Year	Medical Electronics* Sales (% of Total Sales) (1,000 £)	Medical Electronics* Profits Before Interest and Taxation (% of Total Profits Before Interest and Taxation) (1,000 £)	Profit After Taxes** as % of Net Sales
1973	321 (0.1%)	-67 (-0.2%)	3.4%
1974	5,076 (1%)	1,242 (3%)	3.3%
1975	20,406 (4%)	9,230 (21%)	2.6%
1976	42,104 (6%)	12,502 (19%)	3.6%
1977	93,205 (11%)	14,711 (20%)	3.3%
1978	66,542 (8%)	-13,175 (-35%)	1.0%
1979	43,691 (5%)	-12,788 (-45%)	0.2%

*Medical electronics is mainly CT scanners.

**Before extraordinary items.

Derived from: EMI Ltd. Annual Report, years ended June 30, 1978 and 1979.

equipment market. Baird's sales and income for the years 1978 to 1982 are shown in Table 4-4. Medical diagnostic systems sales accounted for about 10% of total company sales over this period. Operating profits for medical diagnostic systems were off in 1978 and 1979, and then returned to a level commensurate with the share of total sales. The after-tax rate of profit for the firm varied between 1% and 4% over this period.

The last firm for which profit data are available is G. D. Searle & Co., principally a pharmaceutical firm, but also, until 1979, a supplier of CT, ultrasound, and nuclear imaging equipment. Table 4-5 presents sales and earnings information for Searle over the period 1973 to 1978. Diagnostic product sales increased over the period, but in 1976, 1977, and 1978 the company lost money on diagnostic product sales even before the allocation of corporate overhead expenses. And these losses contributed to the reduction in the after-tax profit rate as a percentage of net sales for the period 1976 to 1978 in comparison with the preceding years. In light of these losses, Searle decided in 1979 to divest itself of all diagnostic imaging operations.

Comprehensive profit information is not available for the diagnostic imaging equipment industry. Nevertheless, a look at sales and profits for five imaging equipment manufacturers makes it clear that high profits are <u>not</u> the norm in this industry. Some firms, here EMI and Technicare, did very well in the rapidly expanding markets of the mid-1970's. But 1978 and 1979

Table 4-4

Baird Corp., Sales and Income, Fiscal Years 1978-82

Fiscal Year	Medical Diagnostic Systems* Sales ($1,000) (% of Total Sales)	Medical Diagnostic Systems* Operating Profit** ($1,000) (% of Total Operating Profit)	Total Income After Taxes*** as % of Net Sales
1978	2,835 (9%)	-126 (-2%)	3.0%
1979	3,371 (10%)	259 (4%)	3.4%
1980	4,544 (12%)	845 (12%)	3.8%
1981	4,106 (9%)	735 (9%)	2.7%
1982	3,918 (9%)	509 (9%)	0.8%

*Medical diagnostic systems is mainly gamma cameras.

**Operating profit is profit before allocation of overhead expenses.

***Before extraordinary items.

Derived from: Baird Corp. Annual Report, years ended September 30, 1977, 1978, 1979, and 1982.

Table 4-5

G. D. Searle & Co., Sales and Earnings, Fiscal Years 1973-78

Fiscal Year	Diagnostic Products* as % of Total Net Sales	Total Net Sales ($1000)	Diagnostic Products* as % of Total Operating Profit**	Total Operating Profit** ($1000)	Earnings After Taxes*** as % of Net Sales
1973	10%	425,270	2%	71,806	14%
1974	9%	531,285	5%	88,647	13%
1975	10%	613,367	2%	99,633	14%
1976	10%	660,174	-2%	88,515	10%
1977	10%	749,583	-6%	97,434	5%
1978	9%	848,380	-11%	115,622	9%

*Diagnostic products are ultrasonic scanners, nuclear imaging scintillation cameras and related equipment.

**Exclusive of corporate administrative expenses.

***For continuing operations.

Derived from: G. D. Searle & Co. 10-K Report, years ended December 31, 1977 and 1978.

were bad years for all the firms examined here, and in light of their losses, EMI and Searle decided to exit the industry. Although scanty, the information on profits suggests that the medical imaging equipment industry is competitive.

The competitiveness of an industry can also be assessed by looking at evidence other than profits. For example, free entry and exit is a necessary condition for a competitive market. Recall that in this industry there was substantial net entry over the period 1971 to 1979 (the number of firms doubled over this period), while the years 1979 to 1981 were characterized by a considerable amount of net exit. This is a picture of a responsive, competitive industry. Significant new discoveries and increased demand led to rapid sales growth and large profits for certain highly visible firms (such as EMI) in the early 1970's. In response to these opportunities, a number of firms entered the industry hoping to share in the boom. Then in the late 1970's sales stopped growing so rapidly, there were many firms competing for each sales dollar, and a number of firms decided to cut their losses by leaving the industry. Judging by the substantial numbers of firms moving in and out of the industry, there appear to be minimal barriers to entry (or exit) in this market.

Another point is that firms in this industry compete not only on the basis of price and the provision of repair and maintenance services, but also on the basis of quality and

innovation. This multi-level rivalry combined with the rapid rate of technical change creates an environment in which firm rankings can change very quickly. And in fact, market shares, even of the primary firms, are quite variable--not an outcome to be expected when firms have substantial market power.

Lastly, the level of concentration is important in assessing industry competitiveness. For instance, the level of concentration has long been a focus of antitrust policy because concentration is assumed to affect the likelihood that firms could collude and/or exercise market power (U. S. Department of Justice, 1982). The X-ray and ultrasound markets have many firms and are moderately concentrated, while the CT market is moderately to highly concentrated. Collusion is unlikely in these markets not only because of the number of firms, but also because coordination is very difficult when products are technically complex. Although the nuclear imaging market has fewer firms and is highly concentrated, there appears to have been considerable competition in this market as indicated by the fact that even though Searle was the market leader, it experienced substantial losses and was forced to leave the market.

One other way to assess the extent of competition in an industry is to find out what the firms themselves have to say about it. Self-reporting is not necessarily objective, but any glaring inconsistencies should be exposed by comparing accounts from several sources.

Not surprisingly, firms considering leaving the industry are especially sensitive to competitive pressures. For example, EMI in its 1979 annual report discussed the strong competition in the CT market and then sold its CT business in 1980. Likewise, in 1980 SmithKline commented on the formidable competitive array in the ultrasound market[2] and subsequently sold its medical ultrasound business in 1981. In addition to those feeling the pinch, however, other medical imaging equipment firms also see the industry as competitive. In its 1978 10-K report, Technicare notes that the nuclear diagnostic equipment and ultrasound markets are highly competitive and that pricing and service are the principal competitive factors. It also discusses the intense competition in the CT market, fueled by rapid product innovation. And General Electric, in its 1982 10-K report, described the medical imaging equipment market as being characterized by vigorous competition, especially with respect to price and technical innovation.

In conclusion, medical imaging equipment appears to be sold in a competitive market. An examination of sales and profit data for five manufacturers revealed that high profits are not the norm in this industry. Some firms have made substantial profits in the short run, but such an occurrence was then followed by rapid entry of firms seeking to share in these profits. The numbers of firms moving in and out of the industry suggest that there are minimal barriers to entry in this market, a condition conducive to competition. Overall, the technological complexity of the equipment and the rapid rate of innovation, combined with the ease of entry, promote competition in this industry.

FOOTNOTES: CHAPTER 4

[1]Johnson & Johnson Annual Report, year ended December 30, 1979.

[2]The "Gray Sheet" (Medical Devices, Diagnostics, and Instrumentation Reports), November 17, 1980.

[3]Ibid., November 16, 1981.

CHAPTER 5: POLICY

The government regulations which are relevant for medical diagnostic imaging equipment were described in Chapter 1. This chapter is a consideration of how these regulations have affected the industry. Both radiation safety regulation and medical device regulation directly affect the manufacturers of imaging equipment. The effects of these regulatory programs on market structure and innovation are examined in detail. Then two types of hospital regulation, certificate-of-need and prospective reimbursement, are discussed with respect to the consequences for the suppliers of imaging equipment.

RADIATION CONTROL ACT

Radiation safety regulation, designed to protect the public from the hazards of long-run low-level radiation exposure, operates primarily by means of performance standards which set minimum safety standards for any radiation-emitting electronic product. The regulation applies to the manufacture of X-ray, CT, and ultrasound equipment.

In the case of medical imaging equipment, the purpose of the regulation is to protect both patients undergoing diagnostic imaging tests and operators of the equipment from "unnecessary" radiation exposure. The most important aspects of the regulatory program are: (1) a maximum allowable leakage of radiation per exposure, (2) limitation of the range of the X-ray beam, (3) requirements for reproducibility and consistency of exposure, and (4) positive beam limitation, a system which prevents exposure unless the size of the beam is properly adjusted to the size of the image receptor. Compliance with these requirements is enforced by plant inspections, inspection of products in use, laboratory checks (dissection), and lifetime testing. Other elements of the regulatory program are labeling and safety information requirements, specified quality control procedures, and recordkeeping and reporting requirements (see Chapter 1).

Effects on Market Structure

A regulatory program involving performance standards and reporting requirements can be expected to increase the costs of production (provided that the regulatory constraints are binding). The effect of such regulation on market structure depends on how costs change. If small producers face a higher average cost of regulation and/or there are economies of scale in regulatory compliance, then market concentration is expected to increase. With respect to exit and entry patterns, if costs rise substantially, then alternative investments will be relatively more attractive, leading to a higher exit rate and reduced entry rate after regulation. Thus, the expected effects of product safety regulation on market structure depend on the magnitude and nature of the change in production costs.

In the case of radiation safety regulation, the regulatory constraints were binding, i.e., the regulatory program did change the manufacturers' behavior. For instance, the positive beam limitation system, designed to avoid operator error, was not in general use prior to the implementation of the regulatory program. And, new quality control programs and other design changes were also necessary.

Evidence on how radiation safety regulation has affected production costs is available in a report prepared by the Bureau of Radiological Health (Shope and Rudolph, 1978). The report refers only to diagnostic X-ray equipment, a category encompassing both conventional X-ray equipment and CT scanners;

the radiation hazard of ultrasound devices was not considered to be serious enough to warrant the imposition of performance standards. The report found that, after regulation, the costs of manufacturing diagnostic X-ray equipment increased in the following ways:

(1) The major costs of radiation safety regulation stem from the positive beam limitation requirement for stationary, general-purpose X-ray systems. It is estimated that the added cost per system due to positive beam limitation is about $4000 (in 1976$).

(2) There were start-up costs in 1974 associated with the initiation of the regulatory program. These costs arose from: (a) the need for new administrative capabilities, (b) detailed initial reporting requirements, (c) design changes to comply with the standards, and (d) the need for additional quality control and testing programs. These costs were estimated to be about 10% of annual (product) sales.

(3) Annual costs increased as a result of administrative and quality control requirements and new safety features other than positive beam limitation. These cost increases were estimated at about 5% of annual sales.

Calculations in the report were based on aggregate data. No consideration was given to the possibility of differential cost increases for small and large producers.

These findings indicate that the average cost of radiation safety regulation is approximately the same for small and large producers (e.g., positive beam limitation requirements lead to uniform added per unit costs). There may be some reduction in average cost as output increases due to gains from specialization and indivisibilities (e.g., a large firm could hire a full-time safety engineer). However, any such economies of scale in regulatory compliance are likely to be minimal.

Evidence as to the magnitude of the post-regulatory change in production costs is also provided by the survey of firms in the medical imaging equipment industry. One of the questions in the survey asked how radiation safety regulation had affected production costs. The responses, shown in Table 5-1, indicate that radiation regulation did not have a sizeable effect on production costs. Of the 25 companies responding to the question, only 4 (16%) claimed that radiation safety regulation substantially increased the cost of manufacturing imaging equipment. When analyzed by firm size, large producers (medical imaging equipment sales greater than $5 million) were slightly more likely to find a large effect on production costs (2 of 8) than small producers (2 of 17).

Overall, then, radiation safety regulation is expected to have had negligible effects on market structure. There do not appear to be significant economies of scale in compliance for this type of regulation and small firms do not report a greater increase in (average) costs than large firms--the level

Table 5-1

Responses to the Medical Diagnostic Imaging Equipment Industry Questionnaire, Effects of Radiation Safety Regulation Question I

Question: "How has radiation safety regulation by the Bureau of Radiological Health affected your production costs -- a little, some, or a lot?"

	Number of Companies Responding			Total Number of Companies Responding
	"a little"	"some"	"a lot"	
X-Ray Equipment	4 (27%)	7 (47%)	4 (27%)	15
CT Scanners	2 (33%)	2 (33%)	2 (33%)	6
Ultrasound Devices	4 (31%)	7 (54%)	2 (15%)	13
TOTAL	8 (32%)	13 (52%)	4 (16%)	25*
Multiproduct Firms Only	2 (29%)	3 (43%)	2 (29%)	7

*Rows do not sum to this figure due to multiproduct sellers.

of concentration should be unchanged. And the impact on production costs was slight--entry and exit patterns should not be altered after regulation.

Evidence on the level of concentration is contained in Chapter 2. Radiation safety standards went into effect in 1974 and firms would not have instantaneously adjusted to the new environment. Thus, we can examine the effects of radiation safety regulation on the level of concentration by comparing 1974 and 1978 values.

Referring to Table 2-8, we find that in the X-ray market both the four-firm concentration ratio and the Herfindahl index declined, but only slightly, between 1974 and 1978. Thus, concentration in the X-ray market was essentially unchanged after regulation. Note that, since the introduction of the CT scanner coincided with the onset of radiation safety regulation, it is not possible to compare pre- and post-regulatory concentration levels for the CT market. For the industry as a whole, as Table 2-12 shows, both the four-firm concentration ratio and the Herfindahl index decreased, but again, only slightly. Thus, concentration in the medical imaging equipment industry was not changed after regulation.

Chapter 2 also presents evidence on exit and entry patterns for the years 1971 to 1981. Since radiation safety standards went into effect in 1974, the pre-regulatory portion of this data set is 1971 to 1974, the post-regulatory portion 1974 to 1981.

As Table 2-18 shows, one firm exited the X-ray equipment market during the years 1971 to 1974, while six left over the period 1974 to 1981. Table 5-2 presents a contingency table for these data, arraying firm exit behavior against the periods 1971-74 and 1974-81. The entries in the contingency table were used to test the null hypothesis that the qualitative variables firm exit behavior and pre- and post-regulatory periods were independent over the years 1971 to 1981. The chi-square statistic is 3.12; the null hypothesis cannot be rejected.

Exit patterns for the industry as a whole are shown in Table 2-15; one firm exited the industry during the years 1971 to 1974, while fourteen left over the period 1974 to 1981. These data are also presented in Table 5-2 in a contingency table format, and were used to test the null hypothesis that firm exit behavior over the years 1971 to 1981 was independent of the pre- and post-regulatory periods. The chi-square statistic is 10.06; the null hypothesis is rejected at a 1% level of significance.

Note, however, that ten of the fourteen exits in the post-regulatory period occurred in the two-year period 1979 to 1981. The five-year lag between the onset of regulation and this large number of exits is suspicious. Recall also that both the growth rate of industry sales and the rate of entry into the industry slackened considerably in the late 1970's. This suggests that forces other than regulation may have been

Table 5-2

Exit Patterns Before and After
Radiation Safety Regulation

X-Ray Equipment Market

	1971-74	1974-81
Exit	1	6
No Exit	29	29

$X^2(1) = 3.12$

Medical Diagnostic Imaging Equipment Industry

	1971-74	1974-81
Exit	1	14
No Exit	41	40

$X^2(1) = 10.06$

	1971-74	1974-79
Exit	1	4
No Exit	41	50

$X^2(1) = 1.23$

$\chi^2_{.01}(1) = 6.63$

responsible for the high exit rate during 1979 to 1981. Another contingency table is presented in Table 5-2 arraying firm exit behavior against the periods 1971-74 and 1974-79. The entries in the table were used to test the null hypothesis that firm exit behavior over the years 1971 to 1979 was independent of the periods 1971-74 and 1974-79. The chi-square statistic is 1.23; the null hypothesis cannot be rejected.

As to entry patterns, Table 2-18 shows that six firms entered the X-ray equipment market during the years 1971 to 1974, while 22 entered over the period 1974 to 1981. Note that the entry rate is actually higher in the post-regulatory period. Table 5-3 presents a contingency table for these data, arraying firm entry behavior against the periods 1971-74 and 1974-81. The entries in the table were used to test the null hypothesis that firm entry behavior and pre- and post-regulatory periods were independent over the years 1971 to 1981. The chi-square statistic is 4.97; the null hypothesis cannot be rejected.

For the industry as a whole, Table 2-15 shows that 13 firms entered the industry during the years 1971 to 1974, while 39 entered over the period 1974 to 1981, the entry rate again being higher in the post-regulatory period. These data are also presented in Table 5-3 in a contingency table format, and were used to test the null hypothesis that firm entry behavior over the years 1971 to 1981 was independent of the pre- and post-regulatory periods. The chi-square statistic

Table 5-3

Entry Patterns Before and After Radiation Safety Regulation

		1971-74	1974-81
X-Ray Equipment Market	Entrant	6	22
	Existing Firm	30	35

$X^2(1) = 4.97$

		1971-74	1974-81
Medical Diagnostic Imaging Equipment Industry	Entrant	13	39
	Existing Firm	42	54

$X^2(1) = 5.04$

$\chi^2_{.01}(1) = 6.63$

is 5.04; the null hypothesis cannot be rejected.

Overall, there is no evidence that market structure in the diagnostic imaging equipment industry has been significantly affected by radiation safety regulation. The level of concentration, both for the X-ray market and for the industry as a whole, was essentially unchanged after regulation. And, neither exit nor entry patterns for the X-ray market and the industry appear to have been significantly affected by the Radiation Control Act.

The effect of regulation on small firms is an important policy concern. In particular, it is widely believed that government regulation places a disproportionate burden on small firms. For example, Business Week comments: "Regulation has always weighed more heavily on small companies ..."[1] This sentiment is expressed repeatedly in the general press, in the trade literature, and in government publications.[2] The problem was considered to be so serious that Congress passed the Regulatory Flexibility Act of 1980 (P.L. 96-354), which has the express purpose of minimizing the "unnecessary" regulatory burdens on small firms.[3] This concern is especially pertinent in the medical imaging equipment industry since small firms are very active in the innovational process (see Chapter 4).

As noted previously, the effects of regulation on market structure depend on how production costs are affected. With respect to the industry size distribution, small producers are

at a disadvantage after regulation if they face a higher average cost of regulation and/or if there are economies of scale in regulatory compliance. It was shown that concentration was not significantly increased in the period after radiation safety regulation was instituted, one indication that small firms were not adversely affected by this type of regulation.

Another indication of the effect of regulation on small firms is the change in the relative number of small firms. The number of firms by size is reported in Table 5-4 both for the X-ray market and for the industry as a whole over the years 1971 to 1981. In both the X-ray market and the industry, the relative number of small firms increased over the period, evidence that radiation safety regulation did not have the effect of driving small firms from the market. To the contrary, the proportion of small firms increased steadily over the period, there being no perceptible change associated with the onset of the regulatory program.

Thus, in the diagnostic imaging equipment industry, radiation safety regulation does not appear to have had an adverse impact on the relative position of small firms. Regulation has neither affected the level of concentration nor decreased the relative number of small firms. Small firms seem to be especially successful in a dynamic industry such as this, in which there is a high rate of technical change and frequent shifts in relative position within the industry. The ability of small firms to respond very quickly to market changes is a valuable asset in this type of industry.

Table 5-4

Number of Manufacturers of X-Ray and Medical Diagnostic Imaging Equipment, By Firm Size, 1971-81

Year	X-Ray Equipment Market		Medical Diagnostic Imaging Equipment Industry	
	Number of Small* Firms (% of Total)	Number of Large** Firms (% of Total)	Number of Small* Firms (% of Total)	Number of Large** Firms (% of Total)
1971	21 (70%)	9 (30%)	30 (71%)	12 (29%)
1972	24 (73%)	9 (27%)	34 (74%)	12 (26%)
1973	27 (75%)	9 (25%)	38 (76%)	12 (24%)
1974	26 (74%)	9 (26%)	41 (76%)	13 (24%)
1975	30 (77%)	9 (23%)	49 (79%)	13 (21%)
1976	36 (80%)	9 (20%)	58 (82%)	13 (18%)
1977	39 (81%)	9 (19%)	62 (81%)	15 (19%)
1978	42 (81%)	10 (19%)	69 (80%)	17 (20%)
1979	43 (83%)	9 (17%)	70 (80%)	17 (20%)
1980	41 (80%)	10 (20%)	66 (80%)	16 (20%)
1981	41 (80%)	10 (20%)	64 (81%)	15 (19%)

*Small defined as annual medical imaging equipment sales of less than $5 million.

**Large defined as annual medical imaging equipment sales of more than $5 million.

Effects on Innovation

Another major policy concern involves the effect of regulation on innovational activities. The firm's decision to invest in research and development (R&D) is generally analyzed in a capital budgeting framework, in which the firm accepts only projects for which the expected present discounted value is positive. The salient factors in the decision to invest in an R&D project are thus the project cost, length of the development period, net sales, product life span, probability of project success, and discount rate. If regulation affects any of these factors, then the decision to invest in R&D and thus innovation outputs will be affected.

As noted previously, radiation safety regulation can be expected to increase the costs of production, due primarily to the costs of complying with the safety performance standards. However, this type of regulation does not require premarket approval procedures (see the next section on medical device regulation). Consequently, radiation safety regulation is likely to have a negligible effect on innovation.

Firms in the industry agree with this, as indicated by responses to the industry survey. One of the questions in the survey asked how radiation safety regulation had affected the introduction of new products. The responses, shown in Table 5-5, indicate that radiation regulation did not have a sizeable effect on the introduction of new products. Of the 24 companies responding to the question, only 3 (13%) claimed that radiation

Table 5-5

Responses to the Medical Diagnostic Imaging Equipment Industry Questionnaire, Effects of Radiation Safety Regulation Question II

Question: "How has radiation safety regulation by the Bureau of Radiological Health affected introduction of new products -- a little, some, or a lot?"

	Number of Companies Responding			Total Number of Companies Responding
	"a little"	"some"	"a lot"	
X-Ray Equipment	6 (43%)	6 (43%)	2 (14%)	14
CT Scanners	3 (40%)	2 (60%)	0	5
Ultrasound Devices	4 (31%)	8 (62%)	1 (8%)	13
TOTAL	9 (38%)	12 (50%)	3 (13%)	24*
Multiproduct Firms Only	2 (33%)	4 (67%)	0	6

*Rows do not sum to this figure due to multiproduct sellers.

safety regulation significantly affected the introduction of new products.

Since the data series used in Chapter 4 to examine innovation outputs is for the period 1976 to 1982, it is not possible to compare new product introductions before and after regulation. Referring to Table 3-8, however, we can see that radiation safety regulation did not seriously hamper innovational efforts, as indicated by the fact that the number of new product introductions by diagnostic X-ray firms more than tripled over the period 1976 to 1982. And, in general, it appears that radiation safety regulation has not significantly affected innovation in the medical imaging equipment industry.

MEDICAL DEVICE AMENDMENTS

The Medical Device Amendments of 1976 were enacted in order to ensure the safety and efficacy of medical devices intended for human use. All four types of medical imaging equipment fall within the authority of this legislation. Note that radiation safety regulation is aimed at protecting the public from unnecessary radiation exposure, while the scope of medical device regulation is substantially broader--its mandate is safety and efficacy in general.

The provisions of the Medical Device Amendments call for medical devices to be classified into one of the following groups according to the extent of regulatory control: Class I, General Controls; Class II, Performance Standards; and Class III, Premarket Approval. The four primary types of medical imaging equipment are Class II devices, with the radiation safety performance standards for X-ray equipment and CT scanners doubling as the medical device performance standards for those products. NMR, on the other hand, is a Class III device, subject to premarket approval.

All medical devices must comply with the general controls. These include labeling requirements, establishment registration and device listing for manufacturers, premarket notification procedures, and compliance with good manufacturing practice standards (quality control and testing, recordkeeping). All medical device firms are required to submit a premarket notification form (510-K) before introducing a new product. If the

manufacturer can provide evidence in the 510-K that the product is substantially equivalent to a device already being sold, then the firm can proceed to market the product. In practice, a firm will not submit a 510-K unless FDA acceptance is a virtual certainty. If the firm has a truly new product, then its safety and efficacy must be demonstrated before it can be marketed. One frequently used method of securing premarket approval is to first apply for an Investigational Device Exemption (IDE) in order to perform clinical investigations. The results of the investigations can then be used to establish safety and efficacy.

Performance Standards

The performance standards for X-ray equipment and CT scanners originally developed for radiation safety regulation were adopted as the medical device safety standards for those types of equipment. Consequently, the expected effects of these standards on market structure and innovation are the same for both types of regulation, i.e., negligible. Moreover, standards for ultrasound devices and nuclear scanning equipment (not yet published) which involve similar added administrative and quality control requirements can reasonably be assumed to entail cost increases of the same magnitude as those for other types of imaging equipment. Recall that cost increases due to product safety regulation for X-ray equipment and CT scanners were estimated at about 5-10% of annual sales.

Evidence as to the effects of medical device regulation is obtained from the survey of firms in the medical imaging equipment industry. One of the questions in the survey asked how medical device regulation had affected production costs. The responses, shown in Table 5-6, indicate that device regulation did not have a sizeable effect on production costs. Of the 23 companies responding to the question, only 2 (9%) claimed that medical device regulation substantially increased the cost of manufacturing imaging equipment.

Another question in the survey asked how medical device regulation had affected the introduction of new products.

Table 5-6

Responses to the Medical Diagnostic Imaging Equipment Industry Questionnaire, Effects of Medical Device Regulation Question I

Question: "How has medical device regulation by the Food and Drug Administration affected your production costs -- a little, some, or a lot?"

	Number of Companies Responding			Total Number of Companies Responding
	"a little"	"some"	"a lot"	
X-Ray Equipment	4 (31%)	8 (62%)	1 (8%)	13
CT Scanners	1 (17%)	5 (83%)	0	6
Ultrasound Devices	2 (17%)	9 (75%)	1 (8%)	12
Nuclear Scanning Equipment	1 (17%)	5 (83%)	0	6
TOTAL	8 (35%)	13 (57%)	2 (9%)	23*
Multiproduct Firms Only	0	7 (100%)	0	7

*Rows do not sum to this figure due to multiproduct sellers.

Table 5-7 reports the responses; of the 23 companies responding to the question, 5 (22%) claimed that device regulation had substantially affected the introduction of new products. Note that, while still relatively minor, firms report a greater effect of device regulation on the introduction of new products than on production costs. The greater concern with effects on innovation is probably due to the fact that medical device regulation includes premarket approval requirements in addition to performance standards. The provisions for premarket approval also affect innovation and will be discussed further in the next section.

As we have seen, radiation safety performance standards are identical to medical device performance standards for X-ray equipment and CT scanners. In addition, firms in the industry do not report substantially increased production costs or substantially decreased introduction of new products as a result of medical device regulation. Consequently, it is expected that the safety performance standards provisions of device regulation will not materially affect market structure or innovation activities. The data presented in the previous section on the patterns of concentration, exit and entry, and new product introductions are also relevant here--there is no evidence that medical device safety standards have had an adverse impact on market structure or innovation in the diagnostic imaging equipment industry.[4]

Table 5-7

Responses to the Medical Diagnostic Imaging Equipment Industry Questionnaire, Effects of Medical Device Regulation Question II

Question: "How has medical device regulation by the Food and Drug Administration affected introduction of new products -- a little, some, or a lot?"

	Number of Companies Responding			Total Number of Companies Responding
	"a little"	"some"	"a lot"	
X-Ray Equipment	4 (31%)	6 (46%)	3 (23%)	13
CT Scanners	1 (17%)	3 (50%)	2 (33%)	6
Ultrasound Devices	1 (8%)	8 (67%)	3 (25%)	12
Nuclear Scanning Equipment	1 (17%)	3 (50%)	2 (33%)	6
TOTAL	7 (30%)	11 (48%)	5 (22%)	23*
Multiproduct Firms Only	0	5 (71%)	2 (29%)	7

*Rows do not sum to this figure due to multiproduct sellers.

Premarket Approval

The distinguishing characteristic of medical device regulation is the requirement that new devices must be demonstrated to be safe and effective before they can be marketed. While the FDA has not yet published official regulations for premarket approval, it has issued guidelines for premarket approval applications. The clearance process entails well-controlled, but not always clinical, investigations. Although new devices must be shown to be both safe and effective, safety is the primary focus of the legislation. As long as a device is safe, effectiveness is interpreted narrowly in the approval process. Note also that the legislation contains no reference to economic criteria for approval. In other words, cost-effectiveness is not to be considered in the approval decision (National Academy of Sciences, 1979).

Since it applies to new products, a major policy concern is the effect of premarket approval on innovation. Recall that a capital budgeting framework is generally used to analyze the decision to invest in R&D and that the salient factors in the decision to invest in an R&D project are the project cost, length of the development period, net sales, product life span, probability of project success, and discount rate.

Premarket approval requirements affect several of the factors determining the decision to invest in R&D. Reductions in the net present value of a proposed project are likely to result from increased project costs, a lengthened development

period, and the possibility that approval will not be received. The investigations necessary to convince the FDA of the product's safety and efficacy lead to higher project costs and a longer development period. And the possibility that a new product will not prove to be safe enough for human use decreases the probability of project success. Working in the other direction are effects of premarket approval on net sales and product life cycle. Some industry observers argue that once an approved product is released, net sales will be larger because there will be greater market acceptance and less competition. And, it is conjectured that the product life span will lengthen, again because there will be greater market acceptance and because the development period for competing innovations is lengthened (Vanden Brink, 1979; Theta Technology Corp., 1978).

How premarket approval affects R&D investment depends on the relative magnitudes of these effects. With respect to project costs, once premarket approval procedures are well-established, firms can mitigate the increased cost of R&D attributable to safety investigations by performing the safety studies at the same time that the product is in the final stages of development. There is some evidence, for example, that the experimental placements of NMR have been used both to iron out technical problems and to demonstrate patient safety (Delco, 1983). Lengthened development periods may result from additional time for safety studies or from regulatory delays. As to

the latter, by 1981 the average processing time for a medical device premarket approval application was less than eight months.[5]

The aggregate effect of premarket approval on innovation depends not only on the effects on R&D decisions, but also on how frequently premarket clearance is necessary. The most important consideration with regard to medical imaging equipment is that most new product introductions occur within already established product classes and thus do not require premarket approval. Only major new developments, which are rare, require premarket clearance. To date, NMR is the only medical imaging development since medical device regulation was instituted for which premarket approval is relevant. Overall, premarket approval is expected to have only slight effects on innovation in the diagnostic imaging equipment industry primarily because it is necessary in very few cases.

Recall that the industry survey asked a question regarding the effect of medical device regulation on the introduction of new products (see Table 5-7). Less than a quarter of the firms responding to the question claimed that device regulation had substantially affected the introduction of new products. Since device regulation includes both performance standards and premarket approval, this is evidence that firms in the industry do not believe that device regulation, as implemented to date, has had a seriously adverse impact on innovation. The qualification "as implemented" is an important

caveat--if the necessity for premarket approval were interpreted more widely (e.g., to apply also to new diagnostic ultrasound products), then innovation might well be retarded. Another question in the survey asked how the firm would be affected if extensive premarket approval procedures were required. Of the 23 companies responding to this question, 16 (70%) indicated that the effects would be severe.

The primary difficulty in assessing the impact of premarket approval is that NMR is the only medical imaging development to date for which premarket clearance has been an issue. The problems are that firms are very secretive about NMR projects, no FDA approvals have yet been received, and data on Investigational Device Exemption (IDE) applications are not available to the public. Consequently, there is little information on which to base an evaluation and a more complete examination of the effects of premarket approval on this industry must await a later date when more information is available.

One area of particular policy concern has been the impact of medical device regulation on small firms. Small firms have been a major source of innovation in the medical devices field in the past and it was feared that such firms would find the premarket approval process too lengthy, expensive, and uncertain to warrant their participation (see Grabowski and Vernon, 1979; U. S. Department of Commerce, 1979). As mentioned previously, premarket approval has not affected the introduction of new products already classified as one of the four primary

types of imaging equipment. In addition, the relative number of small firms in the industry was constant at approximately 80% over the years 1976 to 1981 (see Table 5-4), the period following the onset of device regulation. And it is interesting to note that of the six companies known to be currently active in the NMR market, a small company, Fonar, is said to be likely to be the first to receive FDA approval (Delco, 1983). In general, medical device regulation does not appear to have put small medical imaging equipment firms at a serious disadvantage.

Lessons From Pharmaceutical Regulation

Under the Food, Drug, and Cosmetic Act of 1938 and the 1962 amendments to the Act, drug manufacturers must demonstrate the safety and efficacy of any new pharmaceutical preparation to the FDA before the drug can be offered for sale. This legislation served as the model for the 1976 Medical Device Amendments. The effects of drug regulation on market structure and innovation have been widely studied and it has been suggested that the findings of these studies are also applicable to the regulation of medical devices (U. S. Department of Commerce, 1979).

The most important component of drug regulation is the premarket approval process in which a new drug must be shown to be safe for human use and therapeutically efficacious. The approval process entails animal toxicity tests and clinical investigations. The major findings as to the impact of premarket approval requirements on the pharmaceutical industry are: (1) increased costs for new product introductions;

(2) reduced rate of new product introductions; and

(3) increased concentration in the supply of new drugs. (See surveys in Grabowski and Vernon, 1979; National Academy of Sciences, 1979; and U. S. Department of Commerce, 1979.)

Because there are similarities between drug and medical device regulation, some observers have argued that the effects of drug regulation are a good predictor of the effects of device regulation (U. S. Department of Commerce, 1979). There

are two problems with this conclusion as it applies to diagnostic imaging equipment. In the first place, every new drug is subject to premarket clearance, so drug regulation affects all new product introductions. For imaging equipment, on the other hand, only infrequently occurring major new developments must receive premarket approval. Secondly, although the Medical Device Amendments were broadly patterned on drug regulation legislation, the authors of the device legislation were aware of the problems associated with drug regulation. As a consequence, medical device regulation differs from drug regulation in several important ways. For one thing, the three-level classification system was designed to differentiate among levels of potential risk and to avoid the over-regulation of devices acknowledged to be clearly safe and effective. Furthermore, in an attempt to encourage flexibility and responsiveness, the legislation provides for the use of advisory committees, composed of experts primarily from the scientific community, to review proposed regulations and applications for premarket approval. Finally, manufacturers of Class III devices can submit a proposed product evaluation procedure to find out beforehand whether the testing program is adequate in the eyes of the FDA (National Academy of Sciences, 1979).

Although superficially similar, there are enough substantive differences between drug and medical device regulation and between the pharmaceutical and diagnostic imaging equipment industries that a priori there is no reason to expect device

regulation to adversely affect the imaging equipment industry. And the indication from the industry survey is that device regulation has not had a seriously negative impact on production costs or the introduction of new products. Overall, it appears that device regulation has not materially affected either market structure or innovation in the medical imaging equipment industry. Thus, the lessons from pharmaceutical regulation are that some of the adverse effects of product safety regulation may be avoided by distinguishing among levels of potential consumer risk and by building responsiveness and adaptability into the regulatory process.

CERTIFICATE-OF-NEED PROGRAMS

Certificate-of-need (CON) programs require hospitals to demonstrate "need" to a health systems agency before making a capital equipment purchase of greater than $100,000 or $150,000 (the threshold varies by state). The purpose of CON review is to restrain hospital cost inflation, but since there are substantial differences among the state CON programs, the methods used to achieve this objective also vary greatly from state to state. With regard to medical imaging equipment, CON regulation has the potential to reduce demand for equipment priced above the CON threshold.

The effect of CON on hospital costs and particular classes of equipment has been the subject of a number of studies. Cromwell et al. (1976) found that CON did not have a significant effect on the adoption of diagnostic nuclear medicine. Likewise, Russell (1978) presented evidence that the diffusion of diagnostic nuclear techniques was not affected by CON. In a broader study, Salkever and Bice (1979) examined the impacts of CON on hospital costs over the years 1968 to 1972. They found that there were no significant savings in hospital costs stemming from CON regulation. Their findings agree with Sloan and Steinwald's (1980) conclusion that CON regulation had little effect on hospital costs over the period 1970 to 1975. Finally, Joskow (1981), using data for the period 1973 to 1979, could find no statistical evidence that CON regulation had affected hospital expenditures. This latter study also included a

case study of CT scanners; the evidence indicated that CON regulation had not affected the supply of CT scanners.

Firms frequently compain about the delay and uncertainty associated with CON regulation. Evidence on regulatory delay is available in a Frost and Sullivan (1980b) study reporting the results of a telephone survey of hospitals which had submitted CON applications to their local health systems agency for approval. The responses, shown in Table 5-8, indicate that, for X-ray equipment, gamma cameras, and ultrasound equipment, the application was processed within six months for over half of the hospitals. CT scanner applications were processed within six months 40% of the time. For all types of imaging equipment, only very rarely (5% or less of the time) did the processing take longer than a year.

Based on these various pieces of evidence, it is unlikely that CON has had a significantly retarding effect on demand for diagnostic imaging equipment. X-ray equipment and ultrasound devices generally are not affected by CON because their prices are usually below the threshold (the exceptions being the latest technological advances, such as digital radiography). As for nuclear scanning equipment, the empirical evidence indicates that CON has not affected the diffusion of nuclear diagnostic techniques or, by implication, demand for the equipment. Finally, the stock of CT scanners does not appear to have been affected by CON regulation. And, for all types of imaging equipment, the regulatory delay due to CON is usually less than six months.

Table 5-8

Responses to Hospital Survey,
Post-Submission Waiting Times For CON

	Number of Months Before Acceptance or Rejection			Total Number of Responses
	<6	6-12	>12	
X-Ray Equipment	192 (61%)	106 (34%)	16 (5%)	314
CT Scanners	25 (40%)	34 (55%)	3 (5%)	62
Gamma Cameras	57 (54%)	49 (46%)	-	106
Ultrasound Equipment	53 (51%)	51 (49%)	-	104

Derived from: Frost and Sullivan (1980b), pg. 118.

With respect to CT scanners, recall that the extremely rapid rate of scanner diffusion in 1975 and 1976 was followed by a sudden decline in the diffusion rate in 1979 and 1980.[6] This resulted in losses for many CT firms and four firms exited the market over the period 1979 to 1981, most notably EMI and Pfizer, two firms which accounted for about 35% of CT sales in 1978. The sentiment in the industry was that CON regulation had contributed largely to a lessening of demand.[7] However, this conclusion has not been supported by the empirical evidence.[8] Moreover, the Office of Technology Assessment released a policy report on CT in 1981 which claimed that firms may have substantially overestimated the potential market for scanners by predicting growth rates on the basis of the first few years of explosive expansion.[9] Overall, the problems in the CT market in the late 1970's appear to be the result of uncertainty about a new product and the ensuing market adjustments rather than the consequence of CON regulation.

REIMBURSEMENT REGULATION

In the past, cost-based retrospective reimbursement was the most common method for determining third-party repayment schedules. Beginning in the 1970's, there was a movement toward prospective reimbursement, in which repayment rates are set in advance. The objective of prospective reimbursement is to restrain hospital cost inflation by imposing a binding budget constraint on the hospital. Rate regulation is not a federal program. Consequently, there is a great deal of variation among the states' approaches to how reimbursement rates should be determined. As of the end of 1980, eight states had mandatory rate regulation programs, four had mandatory rate review programs, and there were private rate regulation programs in 12 states (Joskow, 1981).

The effects of rate regulation are difficult to determine given the lack of uniformity in the rate determination methods, coverage, and organizational structure of the various state programs. Policy Analysis (1980), using data for the years 1970 to 1976 and constructing various indexes to quantify differences among states, found that direct rate regulation did appear to have a significant effect on the rate of growth in hospital expenditures. The empirical evidence in Joskow (1981), based on the years 1973 to 1979, indicates that reimbursement regulation appears to have significantly reduced the growth rate in hospital expenditures, but that the effects were fairly small. This study also pointed out that the

states with the highest hospital costs were the first to institute rate regulation. If there were more scope for initial savings (e.g., from the use of better management techniques) in these states than in states with a less serious hospital cost inflation problem, then the empirical findings may result from the artifact of which states chose to regulate rates, rather than from the method of reimbursement regulation per se.

Given that the effects of rate regulation on hospital expenditures appear to be fairly small, prospective reimbursement is not expected to have had a significant impact on the demand for diagnostic imaging equipment to date. Recall that demand for diagnostic imaging equipment has increased steadily over the past 15 years (see Chapter 1). Although this could be consistent with effective rate regulation, i.e., the growth rate would have been even higher without hospital regulation, it does show that rate regulation has not led to a decrease in the demand for imaging equipment. Note, however, that if more states move to this method of hospital regulation and/or if the financial constraints begin to necessitate difficult choices among input quantities and, more importantly, quality rather than simply forcing the more efficient use of hospital resources, then demand for medical imaging equipment may well be affected. This would be especially true for expensive, state-of-the-art imaging equipment.

SUMMARY

Radiation safety regulation, effective only for X-ray equipment and CT scanner manufacturers, was found to have increased production costs, but only slightly. Firms in the industry did not find that this type of regulation had substantially affected either production costs or the introduction of new products. And, radiation safety regulation does not appear to have significantly increased concentration, driven small firms from the market, or seriously hampered innovation.

Medical device regulation, covering all types of imaging equipment, includes both performance standards and premarket approval. A survey of firms in the industry indicated that device regulation had not substantially affected either production costs or the introduction of new products. Since the four primary types of medical imaging equipment are Class II devices, not subject to premarket approval, the premarket clearance process, although potentially costly and time-consuming, has not been required for most new medical imaging products. And, because medical device regulation differentiates among product risk classes and promotes flexibility, some of the problems associated with drug regulation have been avoided in the case of diagnostic imaging equipment.

Finally, neither certificate-of-need nor reimbursement regulation of hospitals appears to have significantly decreased the demand for medical imaging equipment. The well-publicized problems in the CT market in the late 1970's seem to be the

result of mis-estimation of market potential and intense competition rather than a consequence of hospital regulation. However, reimbursement regulation does have the potential for seriously affecting demand for imaging equipment if stringent budget controls were to be enacted.

FOOTNOTES: CHAPTER 5

[1]Business Week, November 3, 1980, p. 100.

[2]See, for example, Baram (1978) and U. S. Department of Commerce (1979).

[3]U. S. Code Congressional and Administrative News, 96th Congress, 2nd Session, 1980, p. 2788.

[4]Contingency table tests for exit and entry patterns were performed using 1971-76 as the pre-regulatory period and 1976-81 as the post-regulatory period. The resulting chi-square statistics were insufficient to reject the null hypothesis of variable independence.

[5]The "Gray Sheet" (Medical Devices, Diagnostics, and Instrumentation Reports), June 29, 1981.

[6]Ibid., February 23, 1981.

[7]Ibid.

[8]Note that lengthy regulatory delays (e.g., longer than one year) do affect short-run demand; the empirical work cited here refers to the effects of CON over time.

[9]The "Gray Sheet," February 23, 1981.

CONCLUSION

This study has examined the economics of the medical diagnostic imaging equipment industry. First, the basic conditions of the industry were described. Then market structure and conduct were analyzed in detail, followed by an assessment of industry performance. Finally, the effects of various government policies were evaluated. In addition to a variety of other sources, the study utilized two new data sets: a survey of firms in the industry and a constructed data file of industry composition and firm characteristics over the period 1971 to 1981. A summary of results follows.

Medical imaging equipment takes pictures used to diagnose a wide variety of medical conditions, and there are four primary types of imaging equipment: X-ray equipment, CT scanners, ultrasound devices, and nuclear scanning equipment. Quality characteristics are important because the product is technically complex; there are numerous dimensions to product quality, including image quality, speed, reliability, and display and storage options. Both hospitals and private physicians' offices purchase diagnostic imaging equipment and these buyers are relatively insensitive to price due to the prevalence of third-party payment. As a consequence, the purchase decision is often based on perceived quality variations.

There has been a great deal of change in the industry composed of the manufacturers of medical imaging equipment over the past ten to fifteen years. The number of firms in the industry roughly doubled between 1971 and 1981, (real) sales have increased steadily, and there has been a great deal of movement both into and out of the industry. The industry includes primary firms (imaging equipment sales of at least 5% of total industry sales), fringe firms, and firms which manufacture only components. In the aggregate the industry is unconcentrated, but the X-ray, CT, and ultrasound product markets are moderately concentrated, and the nuclear imaging market is highly concentrated. During the period 1971 to 1978 there was substantial entry and little exit, followed by little entry and a considerable amount of exit over the years 1979 to 1981.

Innovation is very important in this industry. Path-breaking new technologies have been introduced roughly every ten years since the 1950's and there have also been numerous important product improvements, many the result of applying computer capabilities to imaging technology. And, firms allocate considerable resources to R&D efforts, although most basic research is funded by the federal government. Firms in this industry compete with one another not only on the basis of price, but also on the basis of product quality, the provision of reliable repair and maintenance services, and the introduction of new, technologically sophisticated products.

Medical imaging equipment appears to be sold in a competitive market. Although firms occasionally have made substantial profits in the short run, other firms have been quick to enter the industry seeking to share in such profits. And, the numbers of firms moving in and out of the industry suggest that there are minimal barriers to entry in this market, a condition conducive to competition.

Radiation safety regulation affects only the manufacturers of X-ray equipment and CT scanners. The program, which operates primarily by means of performance standards, was not found to have substantially affected market structure or innovation in this industry. Medical device regulation, which covers all types of imaging equipment, includes both performance standards and premarket approval procedures. There is no evidence that device safety standards have affected market structure or innovation. And, since premarket approval is required only for a small subset of all new imaging products introduced, innovation has not been seriously hampered by the device premarket clearance process. Finally, neither certificate-of-need nor reimbursement regulation of hospitals appears to have significantly decreased the demand for medical imaging equipment.

The results of this study have implications for several topics of public concern. With respect to the problem of hospital cost inflation, the analysis suggests that the issue of quality competition among hospitals must be incorporated

in an effective regulatory program. This would appear to be particularly important for diagnostic imaging equipment and other types of technologically sophisticated medical equipment. Secondly, given that product safety regulation has become much more prevalent over the past 20 years and given that the regulation of drugs has been found to have had adverse impacts on the drug industry, it is interesting that product safety regulation has not affected market structure or innovation in this industry. It appears that some of the negative effects of product safety regulation can be avoided by distinguishing among levels of potential consumer risk and by incorporating the advice of outside experts, such as academic scientists, knowledgeable about the products involved, but not tied to either the government or industry. Finally, the combination of competitiveness and a high rate of technical change in an industry is very likely to be beneficial for the economy as a whole.

One promising area for further research is a broader investigation of medical device regulation. Specifically, it would be interesting to see how device regulation has affected other industries. The policy implications of this topic are extensive. For example, the fact that this type of product safety regulation did not adversely affect the medical imaging equipment industry may be due to the nature of the <u>regulation</u> or to the nature of the <u>industry</u>. The answer to such a question would be very useful to regulators

of product safety. Secondly, the process of innovation is an interesting research topic. Innovations in the medical care sector frequently follow a path from academic researchers to small firms to large firms. It would be useful to investigate the economic interactions among these stages in the course of technical change.

APPENDIX A

In order to collect first-hand information, a questionnaire was mailed to all firms identified as being manufacturers of medical diagnostic imaging equipment as of 1982. Addresses were obtained from Hale and Hale (1978), Medical Device Register (Greenwich, Conn.: Directory Systems, Inc., 1982), Dun & Bradstreet's Million Dollar Directory (Parsippany, N.J.: Dun's Marketing Services, 1982), and Standard & Poor's Register of Corporations, Directors, and Executives (New York: Standard & Poor's Corp., 1982).

The cover letter and questionnaire are shown as Exhibit A-1. A special effort was made to keep the questionnaire short and easy to complete. To this end, the categories "a little," "some," and "a lot" were used instead of numerical scales where appropriate.

MAILING

A total of 73 questionnaires was mailed, with the set of firms to which they were mailed having the following characteristics (as determined using the constructed data file of firms in the industry, see Chapter 2):

(i) 63 (86%) to firms with sales of medical imaging equipment of less than $5 million
10 (14%) to firms with sales of medical imaging equipment of more than $5 million

(ii) 48 (66%) to firms with total firm sales of less than $100 million
25 (34%) to firms with total firm sales of more than $100 million

(iii) 48 (66%) to firms which make only one type of medical imaging equipment
25 (34%) to firms which make more than one type of medical imaging equipment

(iv) 42 (58%) to firms which make X-ray equipment
18 (25%) to firms which make CT scanners
37 (51%) to firms which make ultrasound devices
16 (22%) to firms which make nuclear scanning equipment
(Does not sum to 100% due to multiproduct sellers.)

RESPONSE RATE

Of the 73 questionnaires mailed, six were turned back by the post office as undeliverable and 26 were returned. Thus, the gross response rate was 36% (26 of 73) and the response rate for questionnaires received was 39% (26 of 67). This is a sizeable sample of the industry. As a means of comparison, a portion of the Frost and Sullivan (1980b) study was based on a questionnaire mailed to all hospitals with a medical imaging department. This mailing had a response rate of 6.2%.

ANALYSIS OF RESPONSES

In order to gauge the representativeness of the sample, the characteristics of answering firms are compared to those of the companies to which the questionnaire was mailed:

(i) 6 (23%) from firms with sales of medical imaging equipment of less than $5 million
20 (77%) from firms with sales of medical imaging equipment of more than $5 million

(ii) 18 (69%) from firms with total firm sales of less than $100 million
8 (31%) from firms with total firm sales of more than $100 million

(iii) 19 (73%) from firms which make only one type of medical imaging equipment
7 (27%) from firms which make more than one type of medical imaging equipment

(iv) 15 (58%) from firms which make X-ray equipment
6 (23%) from firms which make CT scanners
13 (50%) from firms which make ultrasound devices
6 (23%) from firms which make nuclear equipment
(Does not sum to 100% due to multiproduct sellers.)

The first thing to note is that 77% of the responding firms claimed sales of medical imaging equipment in excess of $5 million, whereas 14% of the mailed questionnaires were to firms of this size. However, since only 10 questionnaires were mailed to firms in this size range and 20 replying firms claimed sales of this magnitude, it is clear that either imaging equipment sales were overestimated on a systematic basis or the instructions were misunderstood and firms included sales of other medical equipment when answering this question.

In general, the proportion of responding firms by total sales, and number and type of medical imaging equipment sold is similar to that for the firms to which the questionnaire was mailed. The exception is that firms producing only one type of medical imaging equipment appear to be somewhat over-represented in the set of responding firms.

This comparison of responding firms with those to which the questionnaires were mailed utilized questions (1), (8), and (9). Questions (3), (6), (7), (14), (15), and (17) were not answered on a systematic basis and thus have been excluded from the analysis. Answers to part of question (13), part of (18), and (21) and (22) are comments, sometimes lengthy, which are available on request. Finally, replies to the remaining questions are tabulated in this appendix and discussed in the appropriate portion of the text.

Economies of Scale

Question (4): Regarding production, does the cost of one unit of output decrease as volume increases -- a little, some, or a lot? (by product line)

(i) For firms making X-ray equipment (15):

4 (27%)	"a little"
11 (73%)	"some"
0 (0%)	"a lot"

(ii) For firms making CT scanners (6):

1 (17%)	"a little"
4 (67%)	"some"
1 (17%)	"a lot"

(iii) For firms making ultrasound devices (13):

2 (15%)	"a little"
9 (69%)	"some"
2 (15%)	"a lot"

One of these respondents makes only ultrasound components and answered "a lot"; another respondent returned two questionnaires, one for ultrasound systems ("some") and one for ultrasound components ("a lot").

(iv) For firms making nuclear scanning equipment (6):

0 (0%)	"a little"
5 (83%)	"some"
1 (17%)	"a lot"

(v) Overall, for 40 responses (distributed as noted above):

7 (18%)	"a little"
29 (72%)	"some"
4 (10%)	"a lot"

(vi) For the multiproduct firms (total of 21 responses):

5 (24%)	"a little"
16 (76%)	"some"
0 (0%)	"a lot"

Economies of Scope

Question (5): Are there cost savings when this equipment is produced along with other products -- yes or no? (by product line)

(i) For firms making X-ray equipment responding (14):

12 (86%) "yes"
2 (14%) "no"

(ii) For firms making CT scanners responding (5):

3 (60%) "yes"
2 (40%) "no"

(iii) For firms making ultrasound devices responding (12):

6 (50%) "yes"
6 (50%) "no"

One of these respondents makes only ultrasound components and answered "no"; another respondent returned two questionnaires, one for ultrasound systems ("no") and one for ultrasound components ("no").

(iv) For firms making nuclear scanning equipment (6):

3 (50%) "yes"
3 (50%) "no"

(v) Overall, for 37 responses (distributed as noted above):

24 (65%) "yes"
13 (35%) "no"

(vi) For the multiproduct firms responding (6; total of 18 responses):

12 (67%) "yes"
6 (33%) "no"

Distribution of Demand

Question (10): What percentage of your sales are -- to hospitals, to physicians/physicians' offices, to other companies, or other?

(i) Overall, for 25 firms responding, on average:

48% "to hospitals"
27% "to physicians/physicians' offices"
15% "to other companies"
10% "other"

(ii) Excluding two firms which make only components, one firm which sells only for clinical research ("other"), and one firm which sells primarily to consumers ("other"):

55% "to hospitals"
31% "to physicians/physicians' offices"
11% "to other companies"
3% "other"

(iii) For firms making X-ray equipment responding (14):

54% (60%) "to hospitals"
21% (22%) "to physicians/physicians' offices
17% (15%) "to other companies"
8% (3%) "other"

(with exclusions as in (ii))

(iv) For firms making CT scanners responding (5):

67% "to hospitals"
17% "to physicians/physicians' offices"
14% "to other companies"
2% "other"

Note that of the five respondents, one replied "20% to hospitals," while the others replied "70%," "75%," "80%," and "90% to hospitals."

(v) For firms making ultrasound devices (13):

61% (66%) "to hospitals"
29% (31%) "to physicians/physicians/ offices"
7% (1%) "to other companies"
3% (2%) "other"

(with exclusions as in (ii))

(vi) For firms making nuclear equipment responding (5):

51%	(65%)	"to hospitals"
26%	(32%)	"to physicians/physicians' offices"
2%	(2%)	"to other companies"
21%	(1%)	"other"

(with exclusions as in (ii))

(vii) For the multiproduct firms responding (6):

79%	"to hospitals"
17%	"to physicians/physicians' offices"
2%	"to other companies"
2%	"other"

Advertising

Question (11): What percentage of your sales are allotted to advertising?

(i) Overall, for 22 firms responding, on average:

3.6%

(ii) Excluding two firms which make only components:

3.9%

(iii) For firms making X-ray equipment responding (12):

1.9% (2.0% with exclusions as in (ii))

(iv) For firms making CT scanners (6):

2.8%

(v) For firms making ultrasound devices responding (12):

4.4% (4.9% with exclusions as in (ii))

(vi) For firms making nuclear scanning equipment (6):

3.6%

(vii) For the multiproduct firms (7):

2.5%

Question (12): What percentage of your advertising budget is allotted -- to magazines, to direct mail, to conventions, or other?

(i) Overall, for 20 firms responding, on average:

32% "to magazines"
11% "to direct mail"
48% "to conventions"
9% "other"

(ii) Excluding two firms which make only components:

31% "to magazines"
8% "to direct mail"
51% "to conventions"
10% "other"

(iii) For firms making X-ray equipment responding (10):

28%	(31%)	"to magazines"	
12%	(7%)	"to direct mail"	(with exclusions)
48%	(48%)	"to conventions"	
12%	(14%)	"other"	

(iv) For firms making CT scanners responding (4):

28% "to magazines"
11% "to direct mail"
46% "to conventions"
15% "other"

(v) For firms making ultrasound devices responding (9):

32%	(26%)	"to magazines"	
10%	(9%)	"to direct mail"	(with exclusions)
45%	(51%)	"to conventions"	
13%	(14%)	"other"	

(vi) For firms making nuclear equipment responding (5):

22% "to magazines"
14% "to direct mail"
42% "to conventions"
22% "other"

(vii) For the multiproduct firms responding (4):

19% "to magazines"
12% "to direct mail"
41% "to conventions"
28% "other"

Selling Methods

Question (13): Do you maintain a staff of route salesmen for medical diagnostic imaging equipment -- yes or no?

(i) Overall, for all firms (26):

17 (65%) "yes"
9 (35%) "no"

(ii) Excluding two firms which make only components:

16 (67%) "yes"
8 (33%) "no"

(iii) For firms making X-ray equipment (15):

8 (53%) "yes" (7 (50%) with exclusions)
7 (47%) "no" (7 (50%) with exclusions)

(iv) For firms making CT scanners (6):

5 (83%) "yes"
1 (17%) "no"

(v) For firms making ultrasound devices (13):

11 (85%) "yes" (11 (92%) with exclusions)
2 (15%) "no" (1 (8%) with exclusions)

(vi) For firms making nuclear scanning equipment (6):

4 (67%) "yes"
2 (33%) "no"

(vii) For the multiproduct firms (7):

6 (86%) "yes"
1 (14%) "no"

Research and Development

Question (16): What percentage of your sales are allotted to research and development?

(i) Overall, for 20 firms responding, on average:

8.9%

(ii) Excluding two firms which make only components:

9.1%

(iii) For firms making X-ray equipment responding (10):

8.8% (8.6% with exclusions)

(iv) For firms making CT scanners responding (5):

6.7%

(v) For firms making ultrasound devices responding (10):

8.9% (9.3% with exclusions)

(vi) For firms making nuclear scanning equipment (6):

7.6%

(vii) For the multiproduct firms responding (5):

7.7%

Patents

Question (18): Are patents important for medical imaging equipment -- yes or no?

(i) Overall, for 25 firms responding:

13 (52%) "yes"
12 (48%) "no"

(ii) Excluding two firms which make only components:

11 (48%) "yes"
12 (52%) "no"

(iii) For firms making X-ray equipment responding (14):

6 (42%) "yes" (5 (38%) with exclusions)
8 (57%) "no" (8 (62%) with exclusions)

(iv) For firms making CT scanners (6):

3 (50%) "yes"
3 (50%) "no"

(v) For firms making ultrasound devices (13):

8 (62%) "yes" (7 (58%) with exclusions)
5 (38%) "no" (5 (42%) with exclusions)

(vi) For firms making nuclear scanning equipment (6):

4 (67%) "yes"
2 (33%) "no"

(vii) For the multiproduct firms (7):

4 (57%) "yes"
3 (43%) "no"

Effects of Regulation

Question (19a): How has radiation safety regulation by the Bureau of Radiological Health affected your production costs -- a little, some, or a lot?

(i) Overall, for 25 firms responding:

8 (32%)	"a little"
13 (52%)	"some"
4 (16%)	"a lot"

(ii) Excluding two firms which make only components:

7 (30%)	"a little"
12 (52%)	"some"
4 (17%)	"a lot"

(iii) For firms making X-ray equipment (15):

4 (27%)	"a little"	(3 (21%) with exclusions)
7 (47%)	"some"	(7 (50%) with exclusions)
4 (27%)	"a lot"	(4 (29%) with exclusions)

(iv) For firms making CT scanners (6):

2 (33%)	"a little"
2 (33%)	"some"
2 (33%)	"a lot"

(v) For firms making ultrasound devices (13):

4 (31%)	"a little"	(4 (33%) with exclusions)
7 (54%)	"some"	(6 (50%) with exclusions)
2 (15%)	"a lot"	(2 (17%) with exclusions)

(vi) For the multiproduct firms (7):

2 (29%)	"a little"
3 (43%)	"some"
2 (29%)	"a lot"

Question (19b): How has radiation safety regulation by the Bureau of Radiological Health affected introduction of new products -- a little, some, or a lot?

(i) Overall, for 24 firms responding:

9 (38%)	"a little"
12 (50%)	"some"
3 (13%)	"a lot"

(ii) Excluding two firms which make only components:

8 (36%)	"a little"
11 (50%)	"some"
3 (14%)	"a lot"

(iii) For firms making X-ray equipment responding (14):

6 (43%)	"a little"	(5 (38%) with exclusions)
6 (43%)	"some"	(6 (46%) with exclusions)
2 (14%)	"a lot"	(2 (15%) with exclusions)

(iv) For firms making CT scanners responding (5):

2 (40%)	"a little"
3 (60%)	"some"
0 (0%)	"a lot"

(v) For firms making ultrasound devices (13):

4 (31%)	"a little"	(4 (33%) with exclusions)
8 (62%)	"some"	(7 (58%) with exclusions)
1 (8%)	"a lot"	(1 (8%) with exclusions)

(vi) For the multiproduct firms responding (6):

2 (33%)	"a little"
4 (67%)	"some"
0 (0%)	"a lot"

Question (20a): How has medical device regulation by the Food and Drug Administration affected your production costs -- a little, some, or a lot?

(i) Overall, for 23 firms responding:

8 (35%)	"a little"
13 (57%)	"some"
2 (9%)	"a lot"

(ii) Excluding two firms which make only components:

7 (33%)	"a little"
12 (57%)	"some"
2 (10%)	"a lot"

(iii) For firms making X-ray equipment responding (13):

4 (31%)	"a little"	(3 (25%) with exclusions)
8 (62%)	"some"	(8 (67%) with exclusions)
1 (8%)	"a lot"	(1 (8%) with exclusions)

(iv) For firms making CT scanners (6):

1 (17%)	"a little"
5 (83%)	"some"
0 (0%)	"a lot"

(v) For firms making ultrasound devices responding (12):

2 (17%)	"a little"	(2 (18%) with exclusions)
9 (75%)	"some"	(8 (73%) with exclusions)
1 (8%)	"a lot"	(1 (9%) with exclusions)

(vi) For firms making nuclear scanning equipment (6):

1 (17%)	"a little"
5 (83%)	"some"
0 (0%)	"a lot"

(vii) For the multiproduct firms (7):

0 (0%)	"a little"
7 (100%)	"some"
0 (0%)	"a lot"

Question (20b): How has medical device regulation by the Food and Drug Administration affected introduction of new products -- a little, some, or a lot?

(i) Overall, for 23 firms responding:

7 (30%)	"a little"
11 (48%)	"some"
5 (22%)	"a lot"

(ii) Excluding two firms which make only components:

6 (29%)	"a little"
10 (48%)	"some"
5 (24%)	"a lot"

(iii) For firms making X-ray equipment responding (13):

4 (31%)	"a little"	(3 (25%) with exclusions)
6 (46%)	"some"	(6 (50%) with exclusions)
3 (23%)	"a lot"	(3 (25%) with exclusions)

(iv) For firms making CT scanners (6):

1 (17%)	"a little"
3 (50%)	"some"
2 (33%)	"a lot"

(v) For firms making ultrasound devices responding (12):

1 (8%)	"a little"	(1 (9%) with exclusions)
8 (67%)	"some"	(7 (64%) with exclusions)
3 (25%)	"a lot"	(3 (27%) with exclusions)

(vi) For firms making nuclear scanning equipment (6):

1 (17%)	"a little"
3 (50%)	"some"
2 (33%)	"a lot"

(vii) For the multiproduct firms (7):

0 (0%)	"a little"
5 (71%)	"some"
2 (29%)	"a lot"

Exhibit A-1
Cover Letter and Questionnaire

MASSACHUSETTS INSTITUTE OF TECHNOLOGY

DEPARTMENT OF ECONOMICS CAMBRIDGE, MASSACHUSETTS 02139

March 1, 1983

Dear Sir:

I am a doctoral student in the Department of Economics at the Massachusetts Institute of Technology. My dissertation is a study of the medical diagnostic imaging equipment industry; in particular, it is an analysis of market structure and how regulation has affected this industry. As part of my research, I am conducting an industry survey.

Enclosed you will find a questionnaire regarding your firm's activities in various areas. I would greatly appreciate it if you would take the time to answer these questions. Please note that confidentiality is assured: you are not asked to name your firm, the data will be used only for this academic purpose, and in no case will information on individual firms be made public.

If you do not feel free to answer certain questions, please return the survey anyway--a partial response is much more valuable than no response at all. Your cooperation would be greatly appreciated.

Sincerely yours,

Niccie L. McKay

Niccie L. McKay

INDUSTRY QUESTIONNAIRE

Please return to: Niccie L. McKay, Dept. of Economics
Mass. Institute of Tech., Cambridge, MA 02139

	X-ray equipment	CAT scanners	Ultrasound devices	Nuclear scanning equipment
(1) Which of these types of medical diagnostic imaging equipment do you produce?				
(2) Do you produce	__systems __components	__systems __components	__systems __components	__systems __components
(3) When did you first enter this market?				
(4) Regarding production, does the cost of one unit of output decrease as volume increases	__a little __some __a lot	__a little __some __a lot	__a little __some __a lot	__a little __some __a lot
(5) Are there cost savings when this equipment is produced along with other products?	__yes __no	__yes __no	__yes __no	__yes __no
(6) What was your company's market share for this product in 1980?				
____ in 1975?				
____ in 1970?				

(7) What types of products other than medical diagnostic imaging equipment do you produce?

(8) Are your firm's total sales ___greater than, or ___less than $100 million annually?

(9) Are your firm's sales in the medical diagnostic imaging equipment market ___greater than, or ___less than $5 million annually?

(10) What percentage of your sales are to ___hospitals, ___physicians/physicians' offices, ___other companies, or ___other?

(11) What percentage of your sales are allotted to advertising?

(12) What percentage of your advertising budget is allotted to ___magazines, ___direct mail, ___conventions, or ___other?

(13) Do you maintain a staff of route salesmen for medical diagnostic imaging equipment?
___yes ___no

Is this the way most sales are made? ___yes ___no

If no: How do you sell your products?

(14) What is the primary way in which you differentiate your products from those of other firms?
___product characteristics ___maintenance and service ___firm reputation

(15) If you sell more than one product, is your profit margin on medical diagnostic imaging equipment ___less than, or ___more than for your other products?

(16) What percentage of your sales are allotted to research and development?

(17) Has your firm been the first to introduce any new products in this market? ___yes ___no

If yes: What were they?

(18) Are patents important for medical imaging equipment? ___yes ___no

If no: Why not?

(19) How has radiation safety regulation by the Bureau of Radiological Health affected:

Your production costs? ___a little ___some ___a lot

Introduction of new products? ___a little ___some ___a lot

(20) How has medical device regulation by the Food and Drug Administration affected:

Your production costs? ___a little ___some ___a lot

Introduction of new products? ___a little ___some ___a lot

(21) If extensive premarket approval procedures were implemented as part of medical device regulation, how would your firm be affected?

(22) How does regulation of hospitals (for example, certificate-of-need programs or reimbursement regulation) affect your firm?

REFERENCES

Bain, Joe S. Barriers to New Competition. Cambridge, Mass.: Harvard University Press, 1956.

Banta, H. David and Sanes, Joshua R. "How the CAT Got Out of the Bag," in R. H. Egdahl and P. M. Gertman, Eds., Technology and the Quality of Health Care. Germantown, Md.: Aspen Systems Corp., 1978, pp. 175-189.

Baram, Michael S. "Medical Device Legislation and the Development and Diffusion of Health Technology," in R. H. Egdahl and P. M. Gertman, Eds., Technology and the Quality of Health Care. Germantown, Md.: Aspen Systems Corp., 1978, pp. 191-197.

Bleich, Alan R. The Story of X-Rays from Rontgen to Isotopes. New York: Dover Publications, Inc., 1960.

Bond, Ronald S. and Lean, David F. Sales, Promotion, and Product Differentiation in Two Prescription Drug Markets. Federal Trade Commission Staff Report, February 1977.

Bradburd, Ralph M. and Over, Jr., A. Mead. "Organizational Costs, 'Sticky Equilibria,' and Critical Levels of Concentration," Review of Economics and Statistics, 64 (February 1982), 50-58.

Brody, Jane E. "Magnetic Device Lifts Hopes For Diagnosis Without X-Ray," New York Times, November 28, 1982.

Brownell, Gordon L., Budinger, Thomas F., Lauterbur, Paul C., and McGeer, Patrick L. "Positron Tomography and Nuclear Magnetic Resonance Imaging," Science, 215 (February 5, 1982), 619-626.

Caves, R. E. and Porter, M. E. "From Entry Barriers to Mobility Barriers: Conjectural Decisions and Contrived Deterrence to New Competition," Quarterly Journal of Economics, 91 (May 1977), 241-261.

Clarkson, Kenneth W. and Miller, Roger L. Industrial Organization. New York: McGraw-Hill Book Co., 1982.

Cooper, Arnold C. "R&D Is More Efficient in Small Companies," Harvard Business Review, May/June 1964, 75-83.

Cromwell, Jerry, Ginsburg, Paul, Hamilton, Diane, and Sumner, Michael. "Incentives and Decisions Underlying Hospitals' Adoption and Utilization of Major Capital Equipment," ABT Associates, Inc., 1976.

Dansby, R. E. and Willig, R. D. "Industry Performance Gradient Indices," American Economic Review, 69 (June 1979), 249-260.

Davis, Karen. "Relationship of Hospital Prices to Costs," Applied Economics, 4 (June 1971), 115-125.

Delco, Steven P. "Market Growth of Diagnostic Imaging Systems," Medical Device and Diagnostic Industry, 5 (April 1983), 57-59.

Dewing, Stephen B. Modern Radiology in Historical Perspective. Springfield, Ill.: Charles C. Thomas, 1962.

Dixit, Avinash. "A Model of Duopoly Suggesting a Theory of Entry Barriers," Bell Journal of Economics, 10 (Spring 1979), 20-32.

Dowling, William L., Ed. Prospective Rate Setting. Germantown, Md.: Aspen Systems Corp., 1977.

Duetsch, Larry L. "Structure, Performance, and the Net Rate of Entry into Manufacturing Industries," Southern Economic Journal, 41 (January 1975), 450-456.

Epstein, Samuel S. and Grundy, Richard B. Consumer Health and Product Hazards--Chemicals, Electronic Products, Radiation. Cambridge, Mass.: The MIT Press, 1974.

Feldstein, Paul J. Health Care Economics. New York: John Wiley & Sons, Inc., 1979.

Fisher, Franklin M. and McGowan, John J. "On the Misuse of Accounting Rates of Return to Infer Monopoly Profits," American Economic Review, 73 (March 1983), 82-97.

Fleischer, Arthur C. and James, Jr., A. Everette. Introduction to Diagnostic Sonography. New York: John Wiley & Sons, Inc., 1980.

Frost and Sullivan, Inc. "Advanced Medical Imaging Equipment Market," Report #252, May 1975a.

_____. "Cardiac Diagnostic Equipment, Supplies and Services Market," Report #A702, June 1980a.

_____. "Medical Diagnostic Equipment Market," Report #208, January 1974a.

_____. "The Nuclear Medical Market," Report #293, November 1974b.

_____. "The Nuclear Medical Market," Report #640, April 1979.

_____. "Strategies for Selling to Hospital Imaging Departments," Report #724, June 1980b.

_____. "The Ultrasonic Medical Market," Report #347, June 1975b.

Gorecki, Paul K. "The Determinants of Entry by New and Diversifying Enterprises in the U.K. Manufacturing Sector 1958-1963: Some Tentative Results," Applied Economics, 7 (June 1975), 139-147.

Grabowski, Henry G. and Vernon, John M. The Impact of Regulation on Industrial Innovation. Washington, D.C.: National Academy of Sciences, 1979.

Hale, Adeline, B. and Hale, Arthur B., Eds. The Medical and Healthcare Marketplace Guide. Acton, Mass.: International Bio-Medical Information Service, Inc., 1975.

_____. The Medical and Healthcare Marketplace Guide. Miami, Fla.: International Bio-Medical Information Service, Inc., 1978.

Harris, Jeffrey E. "The Internal Organization of Hospitals: Some Economic Implications," Bell Journal of Economics, 8 (Autumn 1977), 467-482.

_____. "Regulation and Internal Control in Hospitals," Bulletin of the New York Academy of Medicine, 55 (January 1979), 88-103.

Heflebower, Richard B. "Corporate Mergers: Policy and Economic Analysis," Quarterly Journal of Economics, 77 (November 1963), 537-558.

Hendee, William R., Chaney, Edward L., and Rossi, Raymond P. Radiologic Physics, Equipment and Quality Control. Chicago: Year Book Medical Publishers, Inc., 1977.

Hicks, John. The Theory of Wages, 2nd Ed. London: Macmillan and Co., Ltd., 1963.

Hines, Howard H. "Effectiveness of 'Entry' by Already Established Firms," Quarterly Journal of Economics, 71 (February 1957), 132-150.

Hounsfield, G. N. "Computed Tomography--Past, Present and Future," in Louis Kreel, Ed., Medical Imaging. Chicago: Year Book Medical Publishers, Inc., 1979, pp. 1-9.

International Resource Development Inc. "Medical Imaging: The State of the Industry; The State of the Art," August 1978.

Jacobs, Philip. "A Survey of Economic Models of Hospitals," Inquiry, 11 (June 1974), 83-97.

Joskow, Paul L. Controlling Hospital Costs: The Role of Government Regulation. Cambridge, Mass.: The MIT Press, 1981.

_____. "The Effects of Competition and Regulation on Hospital Bed Supply and the Reservation Quality of the Hospital," Bell Journal of Economics, 11 (Autumn 1980), 421-447.

Kamien, Morton I. and Schwartz, Nancy L. Market Structure and Innovation. Cambridge: Cambridge University Press, 1982.

_____. "Market Structure and Innovation: A Survey," Journal of Economic Literature, 8 (March 1975), 1-37.

Kottke, Frank J. "Market Entry and the Character of Competition," Western Economic Journal, 5 (December 1966), 24-43.

Kreel, Louis, Ed. Medical Imaging. Chicago: Year Book Medical Publishers, Inc., 1979.

Kreel, L. and Meire, H. B. "Computed Tomography and Ultrasound--A Comparison," in Louis Kreel, Ed., Medical Imaging. Chicago: Year Book Medical Publishers, Inc., 1979, pp. 236-240.

Kwoka, Jr., John E. Market Shares, Concentration, and Competition in Manufacturing Industries. Washington, D.C.: Federal Trade Commission, 1978.

Lancaster, Kelvin J. "A New Approach to Consumer Theory," Journal of Political Economy, 74 (April 1966), 132-157.

Landes, William M. and Posner, Richard A. "Market Power in Antitrust Cases," Harvard Law Review, 94 (March 1981), 937-996.

Lange, Robert C. Nuclear Medicine for Technicians. Chicago: Year Book Medical Publishers, Inc., 1973.

Little, Arthur D., Inc. Analysis of New Technologies: A Guidebook for Health Planning Agencies. U. S. Department of Health and Human Services, Publication No. (HRA) 80-14014, 1976.

McNeil, Barbara J. "Lessons from Technology Assessments," in E. B. Roberts, R. I. Levy, S. N. Finkelstein, J. Moskowitz and E. J. Sondik, Eds., Biomedical Innovation. Cambridge, Mass.: The MIT Press, 1981, pp. 255-274.

Medical Device Register, 1982. Greenwich, Conn.: Directory Systems, Inc., 1982.

Meire, H. B. "Ultrasound in Liver and Pancreas," in Louis Kreel, Ed., Medical Imaging. Chicago: Year Book Medical Publishers, Inc., 1979, pp. 201-206.

Michela, William A. "Trends in the Volumes of Services Utilized," Hospitals, 50 (September 1, 1976), 55.

Miller, L. A. Report of State and Local Radiological Health Programs. DHEW Publication (FDA) 77-8034, August 1977.

Miller, Merton H. and Upton, Charles W. "Leasing, Buying, and the Cost of Capital Services," Journal of Finance, 31 (June 1976), 761-786.

Miller, Wallace T. Introduction to Clinical Radiology. New York: Macmillan Publishing Co., Inc., 1982.

Mueller, Dennis C. "A Theory of Conglomerate Mergers," Quarterly Journal of Economics, 84 (November 1969), 643-659.

National Academy of Engineering. An Assessment of Industrial Activity in the Field of Biomedical Engineering. Washington, D.C.: National Academy of Engineering, 1971.

National Academy of Sciences. Medical Technology and the Health Care System: A Study of the Diffusion of Equipment-Embodied Technology. Washington, D.C.: National Academy of Sciences, 1979.

Needham, Douglas. The Economics of Industrial Structure Conduct and Performance. New York: St. Martin's Press, 1978.

Nelson, Phillip. "Advertising as Information," Journal of Political Economy, 82 (July/August 1974), 729-754.

Newhouse, Joseph P. "A Model of Physician Pricing," Southern Economic Journal, 37 (October 1970), 174-183.

Ornstein, Stanley I. Industrial Concentration and Advertising Intensity. Washington, D.C.: American Enterprise Institute for Public Policy Research, 1977.

Orr, Dale. "The Determinants of Entry: A Study of the Canadian Manufacturing Industries," Review of Economics and Statistics, 56 (February 1974), 58-66.

Panzar, John C. and Willig, Robert D. "Economies of Scale in Multi-Output Production," Quarterly Journal of Economics, 91 (August 1977), 481-494.

Pauly, M. V. and Redisch, M. "The Not-for-Profit Hospital as a Physicians' Cooperative," American Economic Review, 63 (March 1973), 87-100.

Policy Analysis, Inc. Evaluation of the Effects of Certificate-of-Need Programs, Vol. 3 (processed), 1980.

Portugal, Franklin H. "Medical Imaging: The Technology of Body Art," High Technology, 2 (November/December 1982), 75-82.

Robinson, P. J. "Clinical Uses of Isotope Imaging," in Louis Kreel, Ed., Medical Imaging. Chicago: Year Book Medical Publishers, Inc., 1979, pp. 228-235.

Russell, Louise B. Technology in Hospitals: Medical Advances and Their Diffusion. Washington, D.C.: The Brookings Institution, May 1978.

Salkever, David S. and Bice, Thomas W. Hospital Certificate-of-Need Controls. Washington, D.C.: American Enterprise Institute for Public Policy Research, 1979.

Scherer, F. M. Industrial Market Structure and Economic Performance, 2nd Ed. Chicago: Rand McNally College Publishing Co., 1980.

Schmalensee, Richard. "Another Look at Market Power," Harvard Law Review, 95 (June 1982), 1789-1816.

_____. "Economies of Scale and Barriers to Entry," Journal of Political Economy," 89 (December 1981), 1228-1238.

_____. "Using the H-Index of Concentration with Published Data," Review of Economics and Statistics, 59 (May 1977), 186-193.

Schwartzman, David. Innovation in the Pharmaceutical Industry. Baltimore: The Johns Hopkins University Press, 1976.

Shope, Thomas B. and Rudolph, Harvey. "A Second Look at the Costs and Benefits Associated with the Diagnostic X-Ray Equipment Performance Standard and Policy on Assembly and Reassembly," FDA, Bureau of Radiological Health, Draft Report #3, November 1978.

Sloan, Frank A. and Steinwald, Bruce. "Effects of Regulation on Hospital Costs and Input Use," Journal of Law and Economics, 23 (1980), 81-110.

Spence, A. Michael. "Entry, Capacity, Investment and Oligopolistic Pricing," Bell Journal of Economics, 8 (Autumn 1977), 534-544.

Spencer, J. D. "Isotope Scanning Equipment and Radiopharmaceuticals," in Louis Kreel, Ed., Medical Imaging. Chicago: Year Book Medical Publishers, Inc., 1979, pp. 33-37.

Steiner, Peter O. Mergers: Motives, Effects, Policies. Ann Arbor: University of Michigan Press, 1975.

Sutton, David, Ed. A Textbook of Radiology and Imaging, 3rd E. Edinburgh: Churchill Livingstone, 1980.

Theta Technology Corp. "The Market for Medical Imaging Systems," Report #730, February 1978.

Thompson, Thomas T. A Practical Approach to Modern X-Ray Equipment. Boston: Little, Brown & Co., 1978.

U. S. Department of Commerce. Final Report of the Advisory Committee on Industrial Innovation. Washington, D.C.: U. S. Government Printing Office, 1979.

U. S. Department of Justice. "Merger Guidelines," (mimeographed), June 1982.

Vanden Brink, John A. "How to Develop the New Marketing Opportunities Created by Government Regulation," Technology Marketing Group Ltd., June 1979.

Walmsley, B. "Computed Tomography--Equipment," in Louis Kreel, Ed., Medical Imaging. Chicago: Year Book Medical Publishers, Inc., 1979, pp. 15-22.

Wells, P. N. T. "Theory of Ultrasound," in Louis Kreel, Ed., Medical Imaging. Chicago: Year Book Medical Publishers, Inc., 1979a, pp. 23-26.

_____. "Ultrasound Limits, Resolution, and Equipment," in Louis Kreel, Ed., Medical Imaging. Chicago: Year Book Medical Publishers, Inc., 1979b, pp. 27-32.

Zweifel, Peter. "'Supplier-Induced Demand' in a Model of Physician Behavior," in J. van der Gaag and M. Perlman, Eds., Health, Economics, and Health Economics. Amsterdam: North-Holland Publishing Co., 1981, pp. 245-267.