Is the FDA's Intervention in to the Computerized Treatment Planning Used in Oncologic Radiation Therapy a Tool to Restrict Entry or a Mechanism that Establishes Quality Standards?

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TABLE OF CONTENTS

Research Project

Is the FDA's intervention into the Computerized Treatment Planning used in Oncologic Radiation Therapy a tool to restrict entry or a mechanism that establishes quality standards?

INTRODUCTION

Its interesting how governmental intervention into a specific field will affect people, isn't it? Stop and think about what the government can do simply by writing some words down on paper, particularly on health issues. Government identifies a specific problem. It assigns investigative and oversight responsibility to an agency that at one time did not exist. This agency will be expected to perform its function. The result will be the protection of the population at large from this potential problem. The governmental agency mandates solutions that it has established as a predetermined "acceptable" result.

How does the government know when to step in, and then, how far to step in? Are these regulations designed to recognize their impact on the manufacturers in a particular field? Is government creating guidelines or regulations for

the sole purpose of manipulation of supply and demand by restricting entry into the marketplace? Or are regulations used to establish and enforce an acceptable standard of quality be maintained? In their book on the Federal Drug Administration, Silverman and Lee noted that in any consideration of this inevitably controversial subject, two points may well be kept in mind. First, since this country was created, blaming any branch of government for doing the wrong thing in the wrong way at the wrong time has remained one of the most cherished pastimes of Americans. Second, while most of the participants in this controversy proclaim their unswerving devotion to the cause of health, there is at least a slim possibility that some of them may be thinking more, although talking less, about money. As a newspaper columnist advised many years ago, "When you see a lot of folks debating with noble arguments over which policy will do most to benefit the public, you'd better look first and see which policy will do most to benefit whose pocketbook."(Silverman and Lee, 1975; p. 235)

Because of, but not limited to, this train of thought, this research project will be a detailed case study of the effect of a policy. For clarification, case studies "are studies that examine in some depth persons, decisions, programs, or other entities that have a unique characteristic of interest."(O'Sullivan and Rassel, 1989; p. 30) As part of this analysis, I will provide the reader with a historical

background on the Federal Drug Administration. This background should enable the reader to achieve a macro prospective of an agency that has been called upon to oversee two very diverse yet intertwined, complex though often simplistic, industries. What industries can be so ambiguous? The industries of Food and Drugs. The industry of "Drugs" is equated with anything "Health" oriented. The "Food" industry represents consumable entities regardless of complexity. Although I will be giving a brief overview of the agency's dichotomy to compare allocations of federal funds, this paper will be confined to the concepts of regulations within the Drugs/Health field. There has been much research in the area of drug regulation but limited investigation into regulations dealing with medical devices. This is primarily due to the fact that regulations on medical devices is relatively new.

I will identify problems within the area of medical devices that have sparked interest and action by the FDA. These problems have led to the promulgation of regulations. The impact of these regulations on a device manufacturer will be reviewed. To conclude this project, I will suggest what changes and outcomes the FDA regulations might bring to bear on the device manufacturers and the marketplace that they dominate.

To provide the reader with a sharper focus, I have limited my research to a very specialized component within the Radiation Oncologic discipline. Radiation Oncology is a

specialized form of cancer treatment. There has been limited literature published on the FDA regulations of medical devices used in this specialty. I will be offering the reader background into this field. This background will enable the reader to understand why radiation therapy is used. It also offers insight as to how radiation therapy is administered and what devices are used in the administration of this type of treatment. The device examined in detail in this paper is a Computerized Treatment Planning Systems(CTPS).

WHO IS THE FDA, AND WHAT DOES IT DO?

The Federal Drug Administration (FDA) first came into existence with the passage of the Pure Food and Drug Act of 1906. This law prohibited the adulation and mislabeling of food and drugs sold in interstate commerce.(Temin, 1981) As can be imagined, the complexion of the medical and health arena, as well as, the retail sale of drugs and food stuffs was very different from what it is today. Medical education and health care institutions lacked the knowledge, technology and experience of today. The norms for food sales and medical care came most often from within the smaller communities where individuals resided. Commercialism had not taken hold, nor had the concept of economy of scale flourished. Doctors were typically individuals that involved themselves with the births, illness, cures and deaths of a constant population base. It was unthinkable to request a stranger to provide a medical opinion or offer care. Of course, during this time period there were relatively few prescription drugs. In fact, prescription drugs constituted less than one third of all drugs sold.(Wardell and Lasagna, 1975) The remaining two-thirds of the drugs were manufactured and sold completely without constraints or guidelines. It was not until 1912 that an amendment was passed that would address and remedy the patent medicine industry. This industry had abused the marketplace with false and misleading claims on many of their products.

Unfortunately, the 1912 amendment would not be very effective in correcting these wrongs. The Courts restricted the enforcement of the law. The agency's staff was small. Staff chemists were responsible for providing the burden of proof that could demonstrate that fraud had been committed. If proof was established, the FDA removed those products from the market whose contents were incorrectly represented or involved obvious fraud. (Grabowski and Vernon, 1983)

A disaster catapulted the drug regulation question to the forefront of legislation. The time frame was 1937-1938. A new drug, sulfanilamide in an elixir that used diethylene glycol as a solvent was produced by the Messengill Company. The elixir was manufactured and sold without first being tested for toxicity. The tragic result was that more that a hundred children died because the diethylene glycol was found to be a poisonous chemical. This unfortunate yet controllable event resulted in the Congress passing the Food, Drug, and Cosmetic Act of 1938.

The Food, Drug, and Cosmetic Act required that all firms submit, to the FDA, a new drug application (NDA). This application was required prior to the introduction of a new pharmaceutical into interstate commerce. The application required that the intended use of the drug be stated, and evidence be provided demonstrating that it was safe under a recommended set of conditions. The application normally was processed within sixty days unless the Secretary of Agricul-

ture, to whom the FDA was accountable, determined that the drug had not proven to be safe. The law separated pharmaceutics into the two categories as we know them today. Drugs became either ethical or proprietary. The ethical drug could be purchased only by a physician's prescription. The proprietary drug could be obtained "over the counter".

This law addressed the expanding discoveries by the biologists and chemists made in the chemical laboratories. It would establish an application limited to the new chemical entity (NCE). These NCEs were innovations within the ethical drug group. The NCEs were responsible for the introduction and availability of such drugs as penicillin, tetracycline, tranquilizers, diuretics, and insulin. Two noticeable phenomena became apparent. The first was a dramatic increases in money allotted to research and development expenditures by the pharmaceutical firms. This increase of funds to R and D was to meet the requirements of the new regulations. There was a change in the way laboratory tests and clinical trials were performed. There was a standardization. All pharmaceutical firms were instructed how to proceed in their research. These firms also discovered the need for a detail paper trail throughout their research. The second was an increase in the processing time of applications, from the sixty days to an average of seven months. There were more steps to complete prior to submitting applications for approval and also more detailed reports to investigate

once the documents were submitted. (Termin, 1981)

MEDICAL DEVICES

While much of this historical prospective has been on the pharmaceutical industry, this same legislation, the Food, Drug and Cosmetic Act of 1938, also addressed medical devices. In 1938 the medical devices appear crude by today's standards. Most of those devices were instruments where the hazards and defects could easily be determined. The conclusion of World War II brought to medical devices what it brought to many other industries; an overwhelming increase in technology. Our medical devices became more complex. It became more difficult to determine if a device really could do what it claimed. It also became "apparent that a new authority was needed to ensure safety and effectiveness before a product was allowed to be sold."(Drew, 1986) But the focus of the changes would remain on the pharmaceutical industries, largely because of the amount of dollars that were availed to the products.

The amount of dollars spent by manufacturers and consumers on pharmaceutical rose. This came to the attention of Congress. The high profits that were being earned by some prescription drug companies became a major legislative concern. The Kefauver-Harris Amendment of 1962 was a major regulatory bill that amended the Food, Drug, and Cosmetic Act. This bill also came as a result of a drug disaster: from the drug, thalidomide. Thalidomide is a drug that had been used in many European countries to control morning sickness for pregnant women. The drug was responsible for fetal defor-

mities in the mothers that used the drug. The FDA had successfully blocked introduction of this drug into the United States while it as investigating its application.

This bill added two provisions that had not been considered previously. The first was the question of efficacy; was the drug or medical device able to produce the desired effect? The second was the establishment of regulatory controls over the human testing (clinical trials) of new drugs and, to a more limited extent, medical devices. The controls, although modified and upgraded, are in existence today for clinical trials. The question of efficacy is today coming to light. Manufacturers are being asked "Does the medical device do what it was designed to do?"

In 1968 the FDA turned its attention to the increased availability and use of radiologic devices. Diagnostic radiation was demonstrating its benefits to the medical professions. In response to the inevitable questions of how much or how little radiation exposure was "safe", the Radiation Control for Health and Safety Act of 1968 was passed. This act charged the FDA with the responsibility for ensuring that radiation emitting products did not expose people to unnecessary and possibly harmful levels of radiation.(Drew, 1986) The Radiation Control amendment addressed not only the safety of the device, but also the effectiveness. Effectiveness was defined as the device actually doing what it was created to do. Since effi-

cacy and effectiveness mean the same, the product doing what it claimed it would, the terms are used interchangeably.

The medical device industry changed as the technology and the knowledge changed. The complexity of the devices grew. It became apparent the FDA needed a specialized division to oversee the medical device industry. The Medical Device Amendments of 1976 would establish the Center for Devices and Radiological Health. (Stearman, 1987) This division was charged with remaining current in all areas of medical technology. To remain current required the widest possible range of scientific, engineering and medical expertise available.

Medical devices continue to change today. It has been stated that the medical devices of today have been simplified, by means of computers, to the point that fairly naive people can implement complex systems quite easily. (Rosenthal, 1989) There are more than 1,700 types of medical devices being manufactured. Within those types there are estimated to be between 40,000 and 50,000 different models and sizes. The instrumentation and the medical devices have become so much more complex that the Center for Devices and Radiological Health has subdivided into five laboratory divisions. The five laboratories areas are the Division of Mechanics and Materials Laboratory, Biometrics Sciences, Life Sciences, Physical Sciences and Electronics and Computer Sciences.

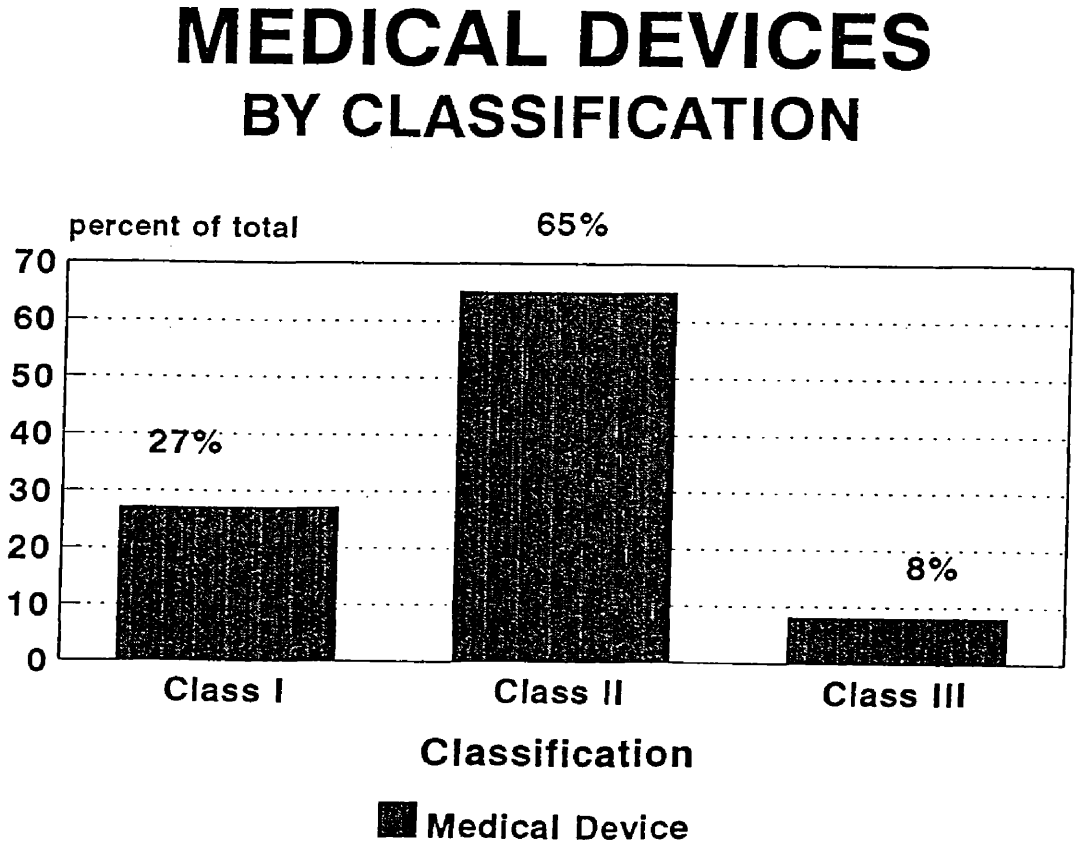
The divisions are responsible for complying, analyzing

and evaluating medical devices. The Biometrics Sciences Laboratory reviews and evaluates medical device statistical data. The Life Sciences Laboratory conducts research on the health effects of radiation and medical devices. The Physical Sciences Laboratory conducts engineering studies related to the safety and effectiveness of medica devices and electronic products. The Electronics and Computer Sciences Laboratory provides electronics and computer science support for the medical device and radiological product programs. The Mechanics and Materials Lab ensures that the best scientific knowledge available is used in the design of each device. This lab evaluates the device performance data that is submitted as part of the new device approval application.

REGULATION OF MEDICAL DEVICES

All medical devices are subject to some level of regulation by the FDA. The more hazardous the device, the more involved the regulation. The intent of the FDA is to protect the users and ultimately the patients, while imposing the least possible regulatory burden on the manufacturers of the devices.(Drew, 1986)

To accomplish this a classification system has evolved resulting in three classes of medical devices. The statistical makeup of medical devices by classification is demonstrated in the graph that follows.



source: Glen Drew
FDA Consumer, 1986

The reader can see that while Class III devices are those which constitute the highest potential risk, they equal 140 device types or only 8 percent of the total. Class I devices account for 460 types devices. This represents 27 percent all devices. The largest component is the Class II device type with 1,100 devices and 65 percent of the total.

The least hazardous, Class I, present risks that can be managed with "general controls". Devices that would fall within this class are adhesive bandages, cotton swabs, tongue depressors and toothbrushes. The manufacturer must register these devices with the FDA. Labels and production practices are reviewed. The firms must also comply with inspections by the FDA at least once every four years.

Class II devices include monitors such as respiratory and cardiac, emergency equipment and defibrillators. These devices are subject to performance standards. The standards demonstrate, if they are met, that the device is considered safe and effective. Usually, the meeting of, these performance standards are a lengthy and difficult process. No procedure exists to shorten this process. As a result of this, the consideration of merging Class I and Class II devices has been raised.(Drew) This merger is estimated to reduce the ultimate number of standards that will be required without compromising on the outcome.

Class III devices are those devices that place patients and users at the greatest risk of injury. Examples of this

type of device includes the artificial heart valves, lithotripter, and the multi-volt linear accelerators. These devices are designed to support or sustain life or have an unknown risk factor. The severity and nature of Class III devices require that they meet the most stringent standards. Devices in this class must pass a three level test: pre-market approval, general controls, and post-marketing research.

One noteworthy point to be stated at this time is that the "newer" devices that are surfacing today, such as the computerized treatment planning systems, are actually hybrids within the FDA's classification structure. These systems and other computerized software do not readily qualify into any of the classes because they are not designed to interact directly with the patient. The software is used to organize, calculate and/or evaluate data. In the case of the treatment planning system for radiation therapy, the end product is a "plan" or a graph that identifies the amount of radiation that is delivered within an area that the physician has specified. The software does not deliver the dose of radiation nor does it specify the area to receive the dose. It provides information to be examined, evaluated and interpreted by a professional. Treatment planning system are not hazardous (Class I), it organizes patient information (Class II), and errors in its "plan" can seriously harm a patient (Class III).

Another reason that the software can be considered a hybrid is because of the question as to what standards it must

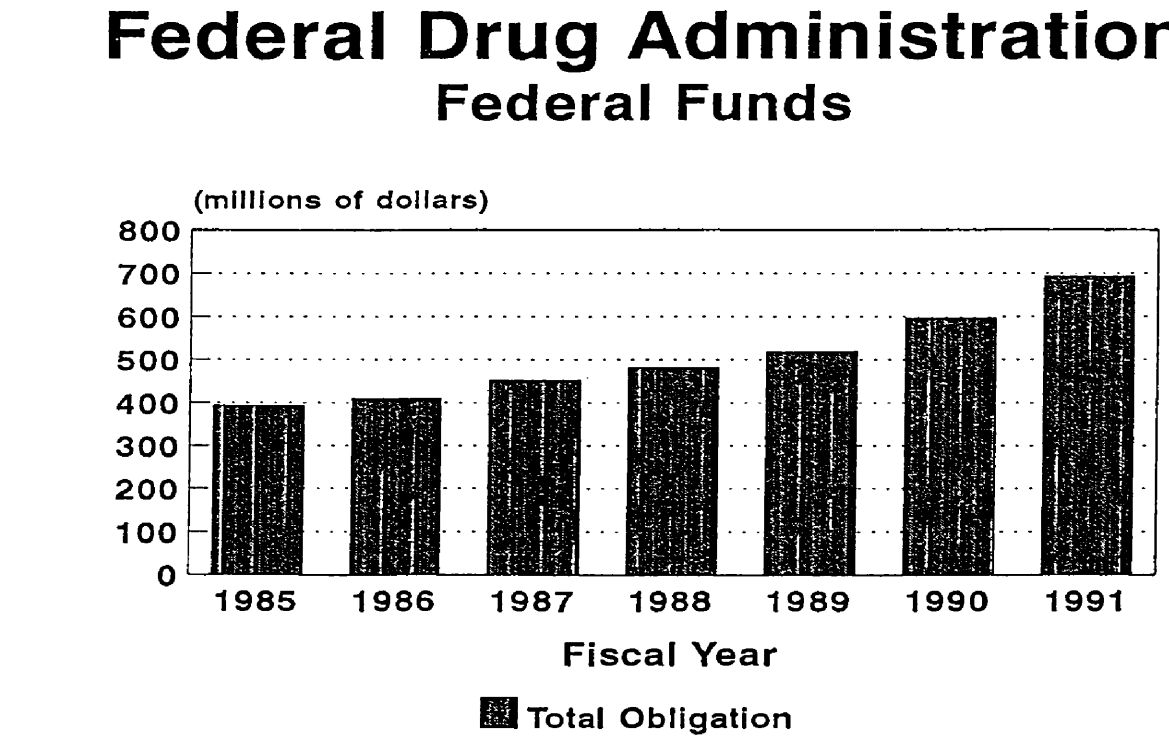
pass prior to acceptance by the FDA. For example should pre-marketing approval be required? Pre-market approval, as well as, general controls are placed on Class III devices, but not Class I or II. This means that FDA approval must be obtained prior to marketing of any device in this class. Pre-marketing approval is achieved only if the manufacturer demonstrates, based on clinical studies or clinical trials, that the device is safe and effective. Safe is defined as the device not presenting any unexpected risk or hazard to the user or the patient. Effective is defined as the device's ability to produce the desired result. It is stressed that approval is obtained only if both conditions are met, safe and effective. How does one acquire clinical trial information? The manufacturer must first seek approval for an investigational device exemption (IDE). This IDE limits distribution under very specific conditions for the purpose of studying the device only.

Post-marketing research is a regulation that was established late in 1984. The post-marketing regulations require that the manufacturers report any deaths or injuries that may be related to the device. It also requires that any malfunction that could result in injury or death be reported. This report must be received by the FDA within 5 days of the malfunction, if reported by phone, or 15 days for written reports.

Upon receipt of the reported accident an investigation

will ensue to determine if the device is safe. If the device is found to be "unsafe", the FDA may ask that the manufacturer to recall its product. The FDA has the power to stop shipment of the identified device without waiting for a court order. Seizure of medical devices, injunction against shipment, and criminal prosecution of the individuals and firms involved are other ways of deterring and ceasing any illegal distribution of medical devices.

Regulations and investigations require that adequate funding is available to the agency held accountable. How does the FDA fair in fund allocation?

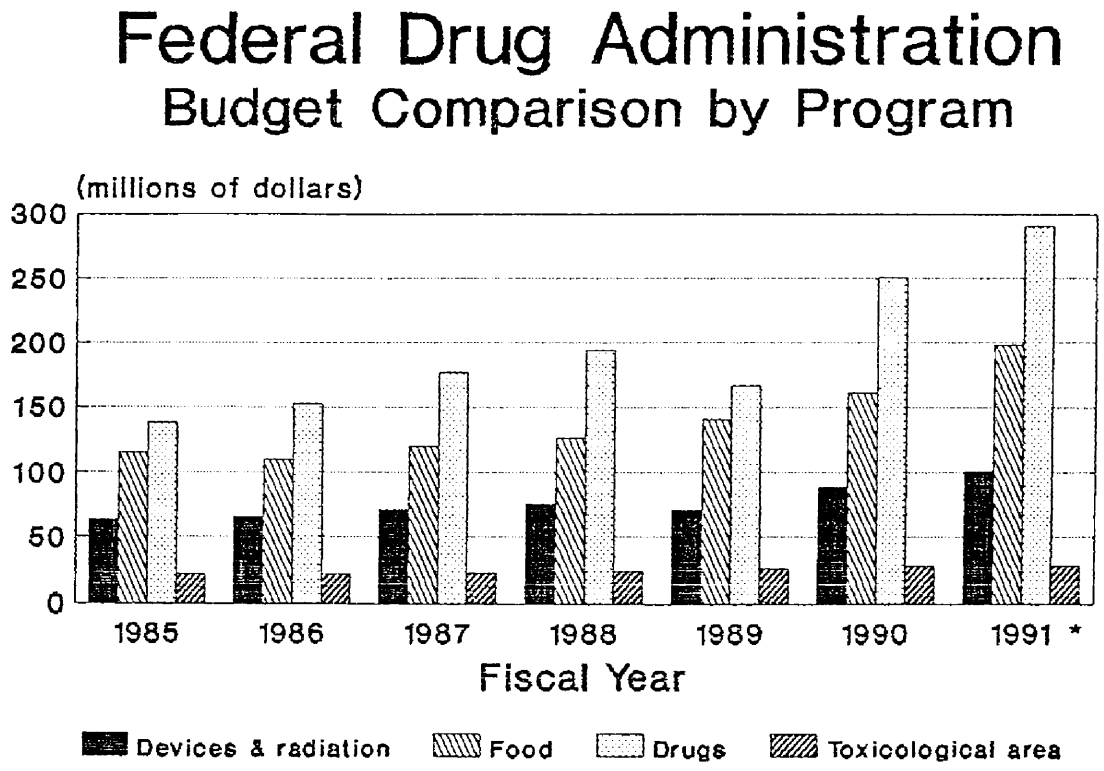


source: United States Budget of the United States

The graph demonstrates that the FDA's budget has continued to grow from 1985 to the present.

The distribution of the budgeted funds by program must be

considered to see if there are significant differences. If there are significant differences impact by programs receiving limited funds must be considered. This graph indicates that there does exist significant differences. The Drug budget has continually risen, with the exception of the year 1989, significantly over the other programs.



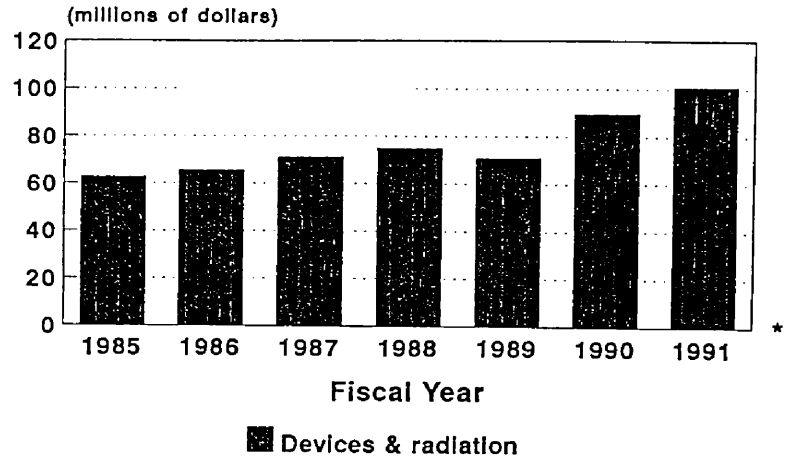
source: United States Budget of the United States

* = estimated

The budget of devices and radiological products has continued to rise since 1985, with the exception of 1989 budget year. What this could mean is that Congress considers this program important. The graph that follows illustrates the growth of this program's budget. But consideration must also be given to the correlation of this program's growth in

contrast to that of the total obligations of the FDA.

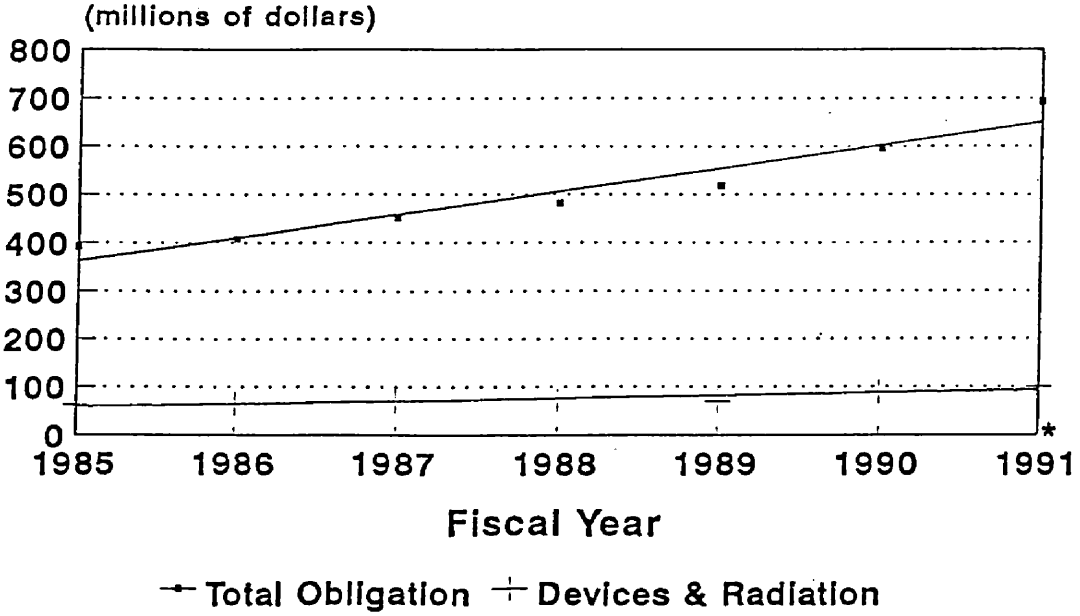
Federal Drug Administration
Budget for Devices & Radiolical products



source: United States Budget of the United States

* = estimated

Federal Drug Administration
Federal Funds



source: United States Budget of the United States

* = estimated

That contrast between the program for Devices and Radiological

Products and the total obligations of the FDA can quickly be identified that there remains the constant positioning of the former.

This total picture suggests that the Devices and Radiological Products Program must consider alternate ways of achieving its objectives. Without additional funding from the government what options are available to this program? How does this program acquire the needed funds?

FDA REGULATIONS AND THEIR IMPACT ON THE MANUFACTURER

The FDA 's intent is to protect the user and patient, while imposing the least possible regulatory burden on producers of devices. In 1986 there were approximately 8,000 firms that were producing medical devices. More than 95 percent of these manufacturers employ less than 500 employees. It should also be noted that at least half of those 95 percent employ fewer than 50 employees.(Drew, 1986)

The technology and knowledge within the medical environment is changing at such a rate that most of the manufacturers of medical devices must constantly be upgrading and modifying their product. This constant development requires the firms to possess immense stores of knowledge in the sciences and technology. All too often these same firms, particularly the smaller firm, find that they have absolutely no knowledge or experience in meeting the regulatory requirements that are in effect. These same small firms may be obligated to spend a larger portion of their financial and human resources for obtaining the regulatory compliance than a larger firm would. A special division was created within the FDA just for this situation. The Division of Small Manufacturers Assistance was established to help the small firm cope with the regulations without impacting significantly on their resources.

This assistance to the smaller manufacturers also helps to deter a power monopoly existence. Albert Kahn has stated,

"All economic regulations involves a limitation or suppression of competition, whether by control of entry or of price rivalry or both. And, in principle, all such regulation has the avowed purpose, among others, of assuring a satisfactory quality of service."(p.172) To combat monopolies, the foresight and planning by the FDA may have assured that quality by the manufacturers is a mainstay. The Division of Small Manufacturers Assistance ensures that a smaller firm continues to compete with those larger firms through governmental assistance. This encourages competition. The questions that must be asked at this point are: "Should there be unrestricted competition? Are there advantages to having fewer providers of a product or service? If so, how does one achieve a optimal number of providers while ensuring that "quality" is also provided?" Albert Kahn addressed these same questions in his text, **The Economics of Regulation.** The focus of chapter five is on destructive competition. In order to have destructive competition there must be economies of scale that are sufficiently limited relative to the extent of the market, and entry sufficiently easy in the absence of governmental restraints as to make competition entirely feasible. But even with these requirements met there remains a need for the consumer to perceive that competition is excessive. How is this requirement met?

J. M. Clark has pointed out that the feasibility and stability of pure competition depends on the circumstances of

increasing marginal costs both in the long and short term. Increased marginal cost in the long run mean that there exists the correct number of firms to be efficient. Short run increased marginal costs mean that provider demand will ordinarily be intersecting a rising provider marginal cost curve at a point that will for the most, or for a sufficiently large number of firms, be at or above their average total costs. This is all well and good. What happens if the providers find the opposite? What happens if there are so many providers that there is an excess product?

This is often the case. To remedy these bleak times, many firms will postpone any expenditures that they think are able to be postponed. One frequently chosen area is that of research and development. Research and development areas are often those same areas that oversee and insure that quality is delivered. If Research and Development areas are cut how is the consumer being protected? The answer to this is that the consumer may not be protected unless the firm finds adequate incentive to maintain quality. This issue makes unrestricted competition particularly injurious to consumers. Consumers limited ability to judge the quality of the product may lead to unacceptable levels being maintained. This may happen regardless of the number of suppliers to choose from.

A good deal of the case of regulation is the importance of assuring that products and services meet acceptable standards. If price competition is very intense, a decline in

price leads to skimping. This skimping may be on safety, reliability or others areas that again are difficult for the consumer to detect. Where does all of this lead? It leads to legally prescribed quality standards.

To answer the first question asked, "Should competition be unchecked?", first lets assume that there are unlimited number of suppliers. Lets also assume that quality standards have been established. Consider that all suppliers must be inspected and rules must be enforced where ever deficiencies are discovered. Finally lets consider that entry is not curtailed. This means that when ever a firm or individual wishes to become a supplier, a supplier they become. This effect will affect again how many suppliers must be inspected and overseen. These circumstances are not manageable because there will be ever changing number of suppliers that an oversight agency must administer.

To be manageable and accountable to an organization such as the FDA, a limited number of firms must exist. This may be achieved with the suppression of competition. This suppression would discourage growing number of suppliers. Inspection and enforcement of established rules is able to be achieved. Entry into the field would be curtailed because there is a valuable commodity in licensure that results from the inspection and adherence to the rules. Licensure becomes more valuable. The regulatory agency, in this case the FDA, can require that the favored licensees assume the

financial burden of the regulatory process. This is accomplished by monetary fees incurred from the license procedure itself. By merely limiting their numbers, the licensed suppliers will reduce their own turnover in the marketplace. This will give the suppliers stronger incentive to take the long view approach to quality. Skimping can no longer be tolerated.

This monetary fee for licensing offers the Program for Devices and Radiological Products with the answer to the question asked earlier, "What alternatives were there for additional funding?"

But how does this relate to this research project?

WHY WOULD THE FDA SELECT COMPUTERIZED TREATMENT PLANNING SYSTEMS AS A TARGET FOR REGULATIONS?

To answer that question lets look first at why computerized treatment planning systems exist. They exist because of cancer, or rather because of a form of treatment against cancer. Cancer, as defined by the American Cancer Society (ACS), is a "large group of diseases characterized by uncontrolled growth and spread of abnormal cells. If the spread is not controlled or checked, it results in death." (Cancer Facts and Figures -1991, p.1) Cancer is treated by surgery, radiation, radioactive substances, chemicals, hormones and immunotherapy.

Everyone is at risk of cancer. This disease is reported to cross all age, ethnic and class barriers. ACS estimates that about 1,100,000 new cases of cancer will be diagnosed in 1991. More children ages 1 through 14 will die of cancer in the U.S. than any other disease.

In the 1980's there were 4.5 millions deaths that were reported linked to cancer. There were almost 9 millions new cases diagnosed during that time frame. It was also reported that there are approximately 12 million people under medical care for cancer.

The future looks bleak. It is estimated that about 76 million Americans now living will eventually develop cancer, or 1 out of every 3 people.(American Cancer Society) Memorial Sloan-Kettering Cancer Center in New York reports that 3,000

new cases of cancer are diagnosed each day. This means that 3 out of every 4 families will be effected by cancer. The following pictogram demonstrate the 1991 estimated sites of cancer by sex.(ACS)

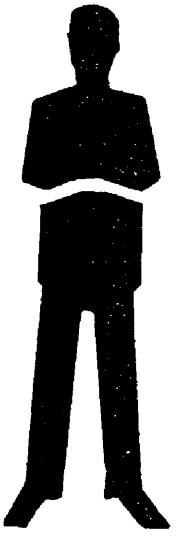
ANALYSIS OF MAJOR CANCER SITES
CANCER INCIDENCE IN FEMALES BY SITE

	USA**
SKIN	3 %
ORAL	2 %
LUNG	11 %
BREAST	29 %
DIGESTIVE	18 %
GENITAL	13 %
URINARY	4 %
LEUKEMIA & LYMPHOMAS	6 %
ALL OTHER	14 %

source: American Cancer Society

ANALYSIS OF MAJOR CANCER SITES
CANCER INCIDENCE IN MALES BY SITE

	USA**
SKIN	3 %
ORAL	4 %
LUNG	20 %
DIGESTIVE	21 %
GENITAL	20 %
URINARY	10 %
LEUKEMIA & LYMPHOMAS	7 %
ALL OTHER	15 %

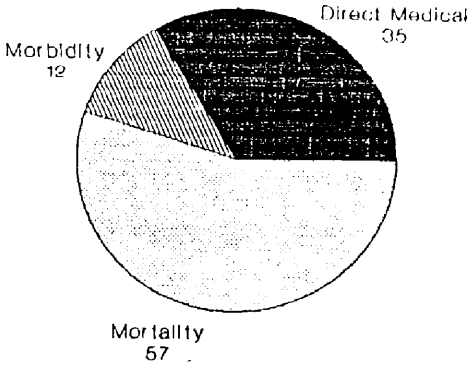


source: American Cancer Society

These site correlations are for reference. Although everyone has heard of cancer of this part of the body or that part of the body without an overall comparison the actual frequency and distribution of incidence can not be realized. These sites are referred to later in this text when identifying modalities of treatments for different types of cancer. Each site becomes important to the reader to establish a baseline knowledge to know which types of cancers have the greatest percentage of occurrence.

The National Cancer Institute conducted a study that reported the overall costs of cancer reached $104 billion in 1990.(Brown, 1990) The graph shows that $35 billion was allocated for direct medical costs. The morbidity costs equaled $12 billion. Morbidity costs represent those costs assigned to the cost of lost productivity. The remaining $57 billion was for mortality costs. All of these amounts translate to the fact that cancer accounts for 10 percent of the total cost of all diseases in the United States.

COSTS OF CANCER - 1990
Total Cost Equals $104 billion

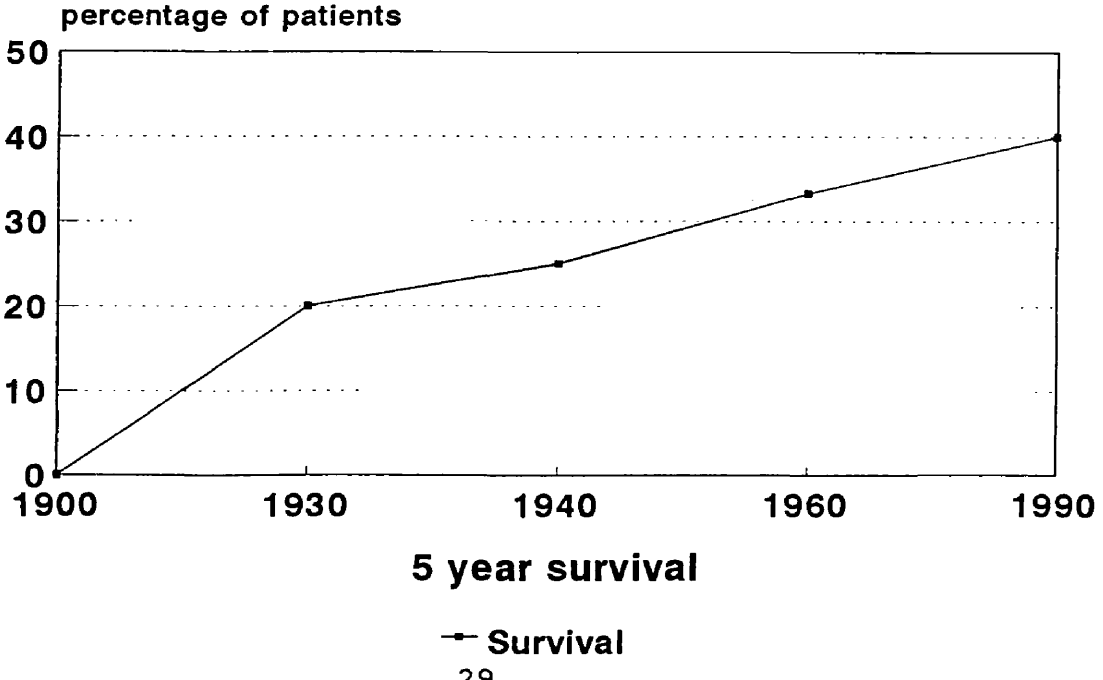


source: NCI

All amounts represent billion dollars

Does this mean that there is no hope for the patient with cancer? No, the survival rates in these patients have been steadily increasing. But survival must first be defined. Cancer survival rates statistics are usually reported as five year relative survival rates. Patients who have a history of cancer but have survived more than 5 years may be considered by their physicians to be "cured". Cure is equated with the prognosis that there is no evidence of the disease and a normal life expectancy is expected. There are an estimated 3 million Americans who are alive today that have had a history of cancer 5 years ago or longer. The following graph depicts the changes in survival since the early 1900s to today.

CANCER OUTCOMES
SURVIVAL RATES



source: ACS

These survival increases are a result of education, early detection and the availability of alternative treatments. The treatment options are surgery, radiation, radioactive substances, chemicals (chemotherapy), hormones, and immunotherapy. The ACS's Cancer Facts and Figures, 1991 chose 11 sites of cancer to discuss. Those cancer sites include lung, prostate, breast, pancreatic, uterine, colon and rectal, oral, bladder, skin, leukemia (blood), and ovarian. Of these 11 sites of cancer only one, leukemia, did not use radiation therapy alone or in combination in the treatment course.

Since there are more cancer diagnoses, there is an increased, demand for treatment. Since radiation therapy is used alone or in combination for almost every type of cancer it seems only too clear that there is an increased demand for this therapy.

WHAT IS RADIATION ONCOLOGY?

Radiation therapy, or radiotherapy, which it is also referred, is the use of an external beam of radiation and the insertion of radioactive isotope into the body. [An area within the body is determined through pathologic findings to be cancerous or at elevated risk of cancer, prior to beginning radiation therapy.] High energy electrons have been used in radiotherapy since the early 1950's. The original beams of radiation, implantation and interstitial devices which have existed only more recently, were produced by low power linear accelerators or Van de Graaf generators. It wasn't until the 1970s that the high energy linear accelerators came into existence. This emergence of technology would coincide with the FDA amendments to the radiologic medical devices.

The principle applications for radiotherapy prior to the 1980s, were: 1) the treatment of skin and lip cancer; 2) chest wall irradiation for breast cancer; 3) administering boost dose to nodes; and 4) the treatment of head and neck cancers. (F. Khan) After the onset of the higher energy, multi-volt linear accelerators of the mid to late 1970s other deeper seated tumor beds could be treated with very good results. The reason for the expansion to other areas is the result of the energy change that the more powerful accelerators could offer. Prior to mid 1980s the average energy rank of the linear accelerator was 4-15 MeV(megavolts). These energy ranges could effectively treat superficial tumors, or those

that were less than 5 cm below the skin surface. The introduction of the higher energy units offered treatment to deeper tumor locations. High energy linear accelerators have the ability to produce photon and multi-energy electron beam capability that today offer better treatment and survival rates for such cancers as prostate and breast.

The electrons produced by the linear accelerator travel through a medium and interact with the atoms they encounter. The basic premise of radiation therapy is that electrons collide with the atoms of the host medium. This collision causes collision and excitation of the nuclei of the host's cells. The excitation of the nuclei causes interference of the nucleic DNA structures in the collided cell. If this cell happens to be a cancer cell, cancer cells are more delicate than healthy cells, the growth process will be interrupted. With the growth cycle impacted on, this cell is less likely to continue its normal growth pattern. Since cancer is defined as the unexplainable, erratic growth of cells, the interruption of this cell's cycle helps to control further introduction of more cancer cells.

The physician must know what type of cell or area is receiving the radiation, how much radiation is being delivered, and if are there any structures (such as spinal cord) or organs that are in the radiation beam's path. To accomplish this the physician and the medical physicist work together. The physicist will provide the physician with a

treatment plan. This plan today is done on a computer.

Computerized Treatment Planning Systems(CTPS) enable the medical physicist to provide for the radiation oncologist information specific to a prescribed course of radiation therapy or any given patient. This information is available with the aid of specialized software programs. The process involves the medical physicist manually imputing, via a computer, information detailing the energy level to be used, and the depth and size of the tumor bed. The product of the CTPS is a plot or drawing of the isodose distribution. (Appendix A.) Each line on the graph illustrates an isodose measurement that is delivered to the area including and surrounding the tumor bed. The radiation oncologist and the medical physicist will review the distribution plot to estimate the appropriateness of the delivery of the radiation dose to the tumor and also to the surrounding radiosensitive "normal" structures.

Today's computers provide many advantages over manually calculated and drawn plans of yesteryear. These computerized treatment planning systems aid in obtaining rapid, accurate and with little effort the isodose distribution for a wide spectrum of irradiation conditions.(Hendee, 1981) These systems are highly interactive so that the user can almost instantly modify, calculate, and examine various plans to select the one that is clinically superior.(F. Kahn, 1984)

WHO CARES IF THERE ARE REGULATIONS IMPOSED ON COMPUTERIZED TREATMENT PLANNING SYSTEMS?

Today there are twenty-three(23) manufacturers of computerized treatment planning systems. An examination of why the government might want to "interfere" with the competition within this particular industry must be conducted. Within the radiation oncology field there have been a number of "malfunctions" of equipment and technology. These malfunctions have resulted in death and/or serious injury to patients. Although no deaths or injuries have been related to any computerized treatment planning system, the FDA had long proven itself to react to catastrophes. It can be assumed that the current restrictions placed on the CTPS manufacturers is a rudimentary step toward establishing accountability by the manufacturers.

The historical evidence of malfunction, by the FDA, within the radiation therapy is first sighted in the **FDA Consumer** dated December 1987. An investigation followed a report to the FDA that there had occurred a possible malfunction of a Therac-25 linear accelerator. The Therac-25 linear accelerator was introduced in 1983 by Atomic Energy of Canada, Ltd.(ACEL). The first reported problem with this model of linear accelerator was in 1985 when a woman being treated for cervical cancer at the Hamilton Clinic in Ontario, Canada received an overdose of radiation. The safety system had fail to engage.

In March 1986, a man being treated for cancer at the East Texas Center in Tyler, Texas complained of an "electric shock" during treatment. The unit was checked by experts at the hospital and by ACEL who found no electrical problem. This same unit malfunctioned again within the month. A woman received what she described as a shock. The shock later turned out to be an overdose of radiation. The study that was to ensue, found that the two patients had received 2000 times more radiation than was intended.

The FDA investigated the Therac-25. The conclusion of their investigation disclosed that a safety switch that was to activate a reversal of operating functions if an edit button were depressed did not engage. During this investigation another incident would be "unofficially" reported. This time a woman at the Kennestone Oncology Center in Marietta, Georgia received a nonfatal dose of radiation during a breast cancer treatment. The time frame was June 1985.

These occurrences led the FDA in November 1986 to conduct a technical assessment of the ACEL Therac-25 linear accelerator. A more thorough investigation to the computer program and how it affected the machine's operation followed. This assessment was performed by the physicists and engineers from the FDA's Center for Devices and Radiological Health. Unfortunately, while this investigation was being conducted another incident on the Therac-25 occurred. In January 1987, in Yakima, Washington, an operator programmed the computer to

administer a radiation dose when the components were not all properly aligned. This time the Therac-25 detected the error. However it failed to prevent the initiation of the treatment which was stopped by the operator. The FDA was informed by ACEL that it had notified all of its Therac-25 users to cease operations until corrective measures could be taken.

These occurrences would be publicized in professional journals such as the American College of Radiology Bulletin in April 1987. The ACR Bulletin would review the technical and computerized software malfunctions thought to be the cause of the overdose incidence. This article would reiterate the process of reporting possible malfunctions of any radiation equipment to the FDA.

Science News reported in its March 12, 1988 edition on the radiation-therapy machine defect. The article was entitled, **A Digital Matter of Life and Death.** This article went on to describe the occurrence surrounding the delivered overdoses. But this article also went on to question who was overseeing the "programmable" medical that patients were exposed to. The major concern cited was that there was a vague concept as to what the FDA was regulating regarding computer products marked for medical use. The FDA policy presented on regulating medical computerized products centered on whether the computerized device was operated with "competent human intervention".(p.170)

Another article appeared in **Lotus** entitled, **When Computers Practice Medicine, Should automated procedures be more closely regulated?** In this article question were asked concerning who and how to regulate computers in medicine. Roger Schneider, former associate director for science at the FDA's Center for Device and Radiological Health was interviewed. He stated, "Microprocessors have made it possible for fairly naive people to implement complex systems quite quickly." (p.20) If the FDA is to regulate all medical software systems then levels must be established to categorized these products and have some latitude in their regulations. The article concluded that this was a problem that was not going to go away. However, it offered no solutions to the problem, either.

IS THIS THE SOLUTION?

But a solution to the problem must be presented by the FDA. If it is going to regulate computerized systems dealing with health issues, it must devise a plan. The plan could be drawing from Albert Kahn. 1) Establish standards and requirements for quality within a provider base, in this case the computerized treatment planning systems. The standards established at present are obtaining 510K certification from the FDA. The standards are not clearly defined nor are they readily available within the radiotherapy field, according to research gathered from manufacturers. 2) Offer licenses to those providers that successfully meet the established criteria. Certification is being offered to suppliers. The process has slowed to almost a stop because of the 23 suppliers only 6 had 510K certification prior to October 15th and it is assumed that the remaining 17 are in the process of applying. It was last reported from a source within the field, that the FDA had promised that if suppliers would apply for their 510K certification, the applications would be processed in 60 days. The process time has been revised and suppliers were advised to proceed as if they had the 510K certification until otherwise notified. 3) Since all of the suppliers have not met the established set of criteria, no implementation of enforcement can be enacted.

HOW THE MANUFACTURERS OF THE COMPUTERIZED TREATMENT PLANNING SYSTEMS VIEW THE FDA'S INTERVENTION:

To understand the FDA's intervention , it was important to obtain information from those suppliers that are currently manufacturing the computerized treatment planning systems. This was accomplished by a three level approach. The first approach was to identify suppliers from advertisements in technical and professional journals. The source that provided most of this information was **Medical Physics**, published for the American Association of Physicists in Medicine by the American Institute of Physics.

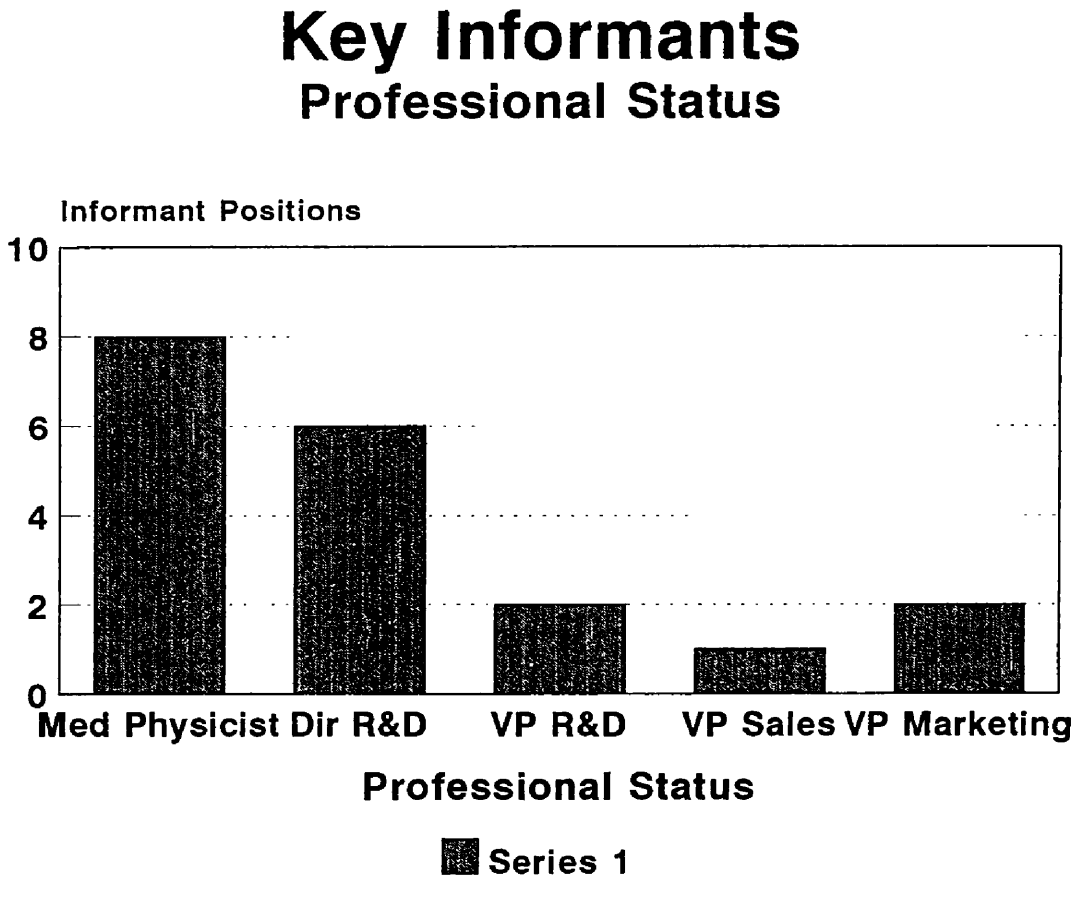
The second approach was to contact various physicists that were identified as key informants by the physicist with whom I work. These physicists offered incite into various systems that were available. Contact was made through conversations with the various suppliers of their resident systems. Other radiotherapy equipment manufacturers were also identified and contacted who were observing, though not yet, responsible for certification to the FDA. These interviews availed the opportunities to contact leaders in research and development and marketing within the computerized treatment planning setting.

The third approach was to present to key individuals, within the field, a questionnaire (sample located in Appendix B) to identify their major concerns stemming from the FDA's intervention into their specific field. These individuals

can be identified as Directors and or Vice Presidents of Research and Development, Marketing and Planning and/or Sales. These questionnaires were distributed two separate times. The first was at the national radiological convention, American Society of Therapeutic Radiation Oncologist,(ASTRO) held in Washington, D.C. from November 1 through November 8, 1991. Limited response was acquired. The second distribution was made the week on December 2 through December 6, 1991. At that time FAX machines were used to expedite the return of the questionnaire. During this second distribution more extensive key informant interviews were conducted.

DATA

From the first level of inquiries, nineteen names of key informants were identified. These individuals were either physicists working with a particular system or company representatives. The following graph presents the key informants professional status.



total: 19 key informants

Next, these individuals were contacted by phone for interviews, using the questionnaire as a guide. The result was that fifteen individuals were available and willing to discuss their opinions and perceptions of the FDA's imposition of the 510K certification. Two individuals was unable to be

reached. Two were contacted that declined the interview opportunity. (Both companies were located outside the United States.)

A composite of the responses to the questions of the questionnaire are presented in the following box and bar charts.

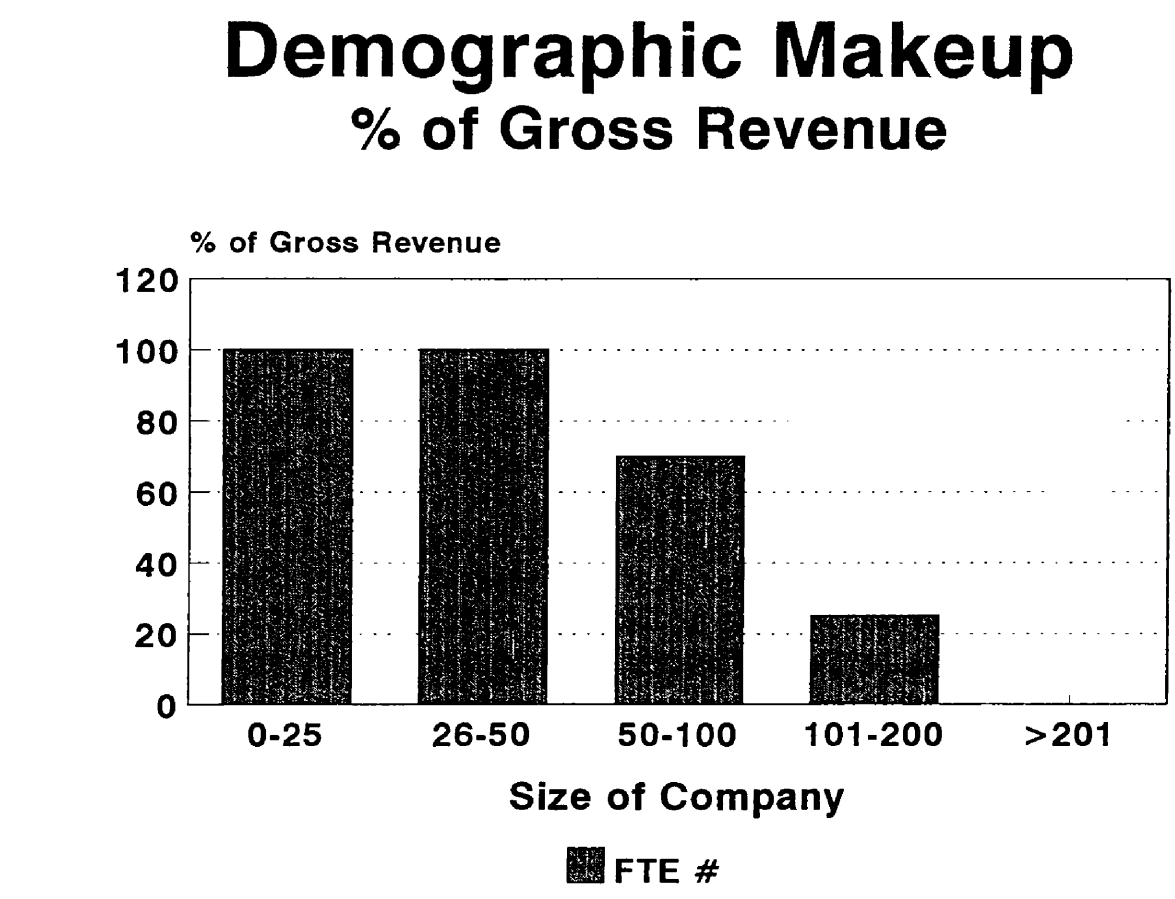
Results of Questionnaire
Agree/Disagree

Question #	Agree	Disagree
3 International Scope	15	0
4 Possess 510K Cert.	7	8
5 510K increase FTE #	15	0
6 510K raise prices	15	0
7 Better system: 510K	4	11
8 Suspect Buy-outs	15	0
10 Test Effectiveness	1	14

total # responses: 15

Response to the question of what percentage of revenue was attributable to the companies from the computerized

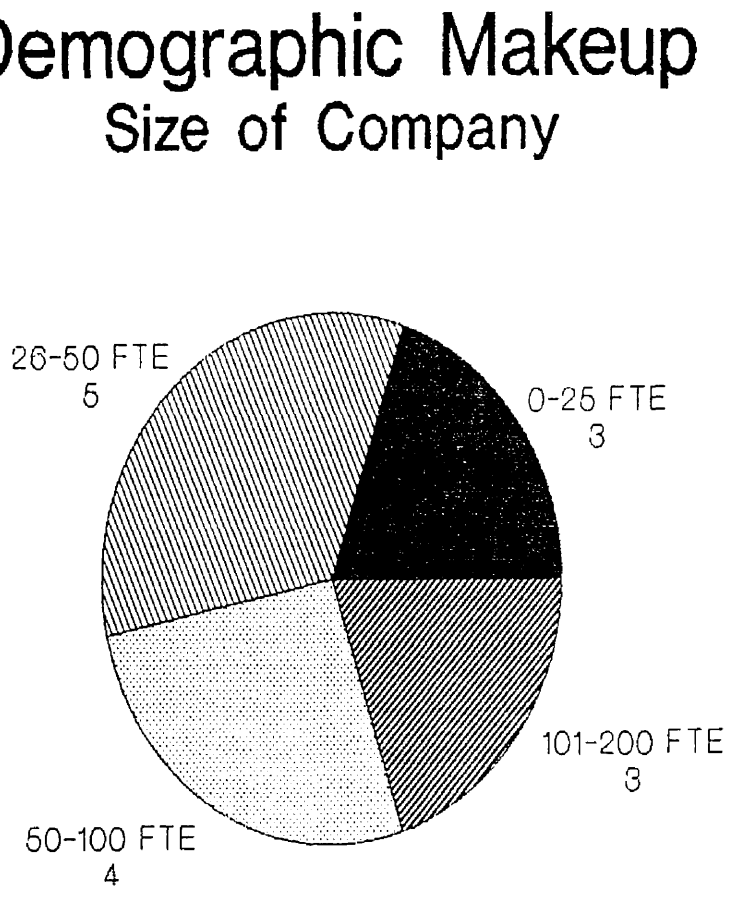
treatment planning system is shown. The graph demonstrates that the smaller the company, size of the company being measured in number of total full time employee (FTE), the more inclined the sole product of the company is to be the computerized treatment planning system.



total # responses: 15

Another point of interest is the number of companies that responded to the questionnaire in terms of their relative

size. Again, relative size is determined by the number of FTE employed by the companies. The pie chart demonstrates the distribution of company size.



total # responses: 15

Conclusion

To answer the questions that were first asked in this research paper: *How does the government know when to step in, and then, how far to step in?* I have suggested that computized radiation therapy treatment planning software regulation is the tip of the iceberg in regulating medical software. This particular area was probably chosen because of its limited number of available systems. The limited number would make it more attractive from a program management stand point for a governmental agency. To interject that government does not know this product well enough to know when or how far to analyze it, implies that this system may have been selected simply for the reason of manageability. It is a system that is often used but whose relative worth in the larger medical software market may not illicit attention by the general population.

Are these regulations designed to recognize their impact on the manufacturers in a particular field? I have presented data that indicates that the manufacturers of the software do not think that the design of the regulation recognizes the impact on the suppliers. Rather they recognize that the impact on them will for a majority be negative. The regulation will lead to increased staffing, increased research and development costs, and delays in new product presentation.

Is government creating guidelines or regulations for the sole purpose of manipulation of supply and demand by

restricting entry into the marketplace? Or are regulations used to establish and enforce an acceptable standard of quality be maintained? Referring back to Albert Kahn's argument on competition, he stated, "All economic regulations involves a limitation or suppression of competition, whether by control of entry or of price rivalry or both. And, in principle, all such regulation has the avowed purpose, among others, of assuring a satisfactory quality of service."(Kahn, 1988, p.172) Again the manufacturers' agree that the regulation will decrease the number of suppliers. As a note of interest, I have been informed by two larger manufacturers that the number of suppliers has been decreased from the twenty-three suppliers identified at the beginning of this project, to twenty-one. Two of the manufacturers have been purchased and/or absorbed by the other existing suppliers.

Addressing the idea of establishing quality through regulations implies that the oversight agency possesses the knowledge base to determine first what "quality" is, and secondly a way to measure that quality. I contend that the FDA is being asked too much in either of these assumptions. The FDA's laboratories can not possibly have the monetary nor FTE (full time equivalent) personnel budget to have experts willing and able to monitor "quality". The field of medical devices in itself is staggering, let alone adding the responsibility for quality assurance of software programs where specialists are required to ascertain the reliability

and the applicability of one set of data over a similar set. What one must conclude then is that the FDA is will be taking responsibility for requiring, acquiring and reviewing documentation of a product's ability to meet the requirements set forth in the regulations. I have included in Appendix C a copy of the American College of Medical Physics Spring conference program to be held in California. This program is devoted to Current Regulatory Issues in Medical Physics. Note that although there are number of separate state issues on the Saturday schedule there is one separate session that is devoted to the FDA requirements Treatment Planning Computer Software.

In closing, what appears most prevalent at the outcome of this research project is:

* Computer software is a hybrid creature new to the classification system by the FDA.
* There exists no proven means to test efficacy of computerized software.
* Competition between the manufacturers is being interfered with to reduce suppliers.
* Suppliers will in essence be policing themselves by means of limited licensure with the licensure fees being used to pay for the policing.
* The policing will result in criteria being established for inspection, verification and standardization of documentation used in the

licensing activity of the suppliers.

* Quality will not been established nor will it be maintained because of the difficulty in measurement.
* One outcome that I expect is that no "better mouse trap" will emerge due to the restriction of entry that will result.

Now what remains to be observed is the final results of these regulations. Do the companies with the best documentation survive? Will "quality" ever be established or just "quality" standards in the documentation process? Will the product improve, suffer or stay the same as a result of the regulation? If the industry is expected to police itself, how comfortable will we as patients be once hospitals start to rely more on computers to assist in diagnosis and setting protocol treatments for the patients? There have been a number of news articles implying to help with decision making and cost containment that these computers may be used in the future. Human error removal, prioritizing and objective evaluation is expected to be the result of this type of system. Who will the ultimate winners be? Hopefully the patient consumer will be the winner, but only time will tell.

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APPENDIX A

PATIENT ID:
PLAN ID: WORKAREA - 1
X-SEC: ABDOMEN SCB
PLAN CALCULATED WITH INHOMOGENEITY, NON-PIXEL, OFF AXIS PLANE IN RECTANGULAR CORRECTION

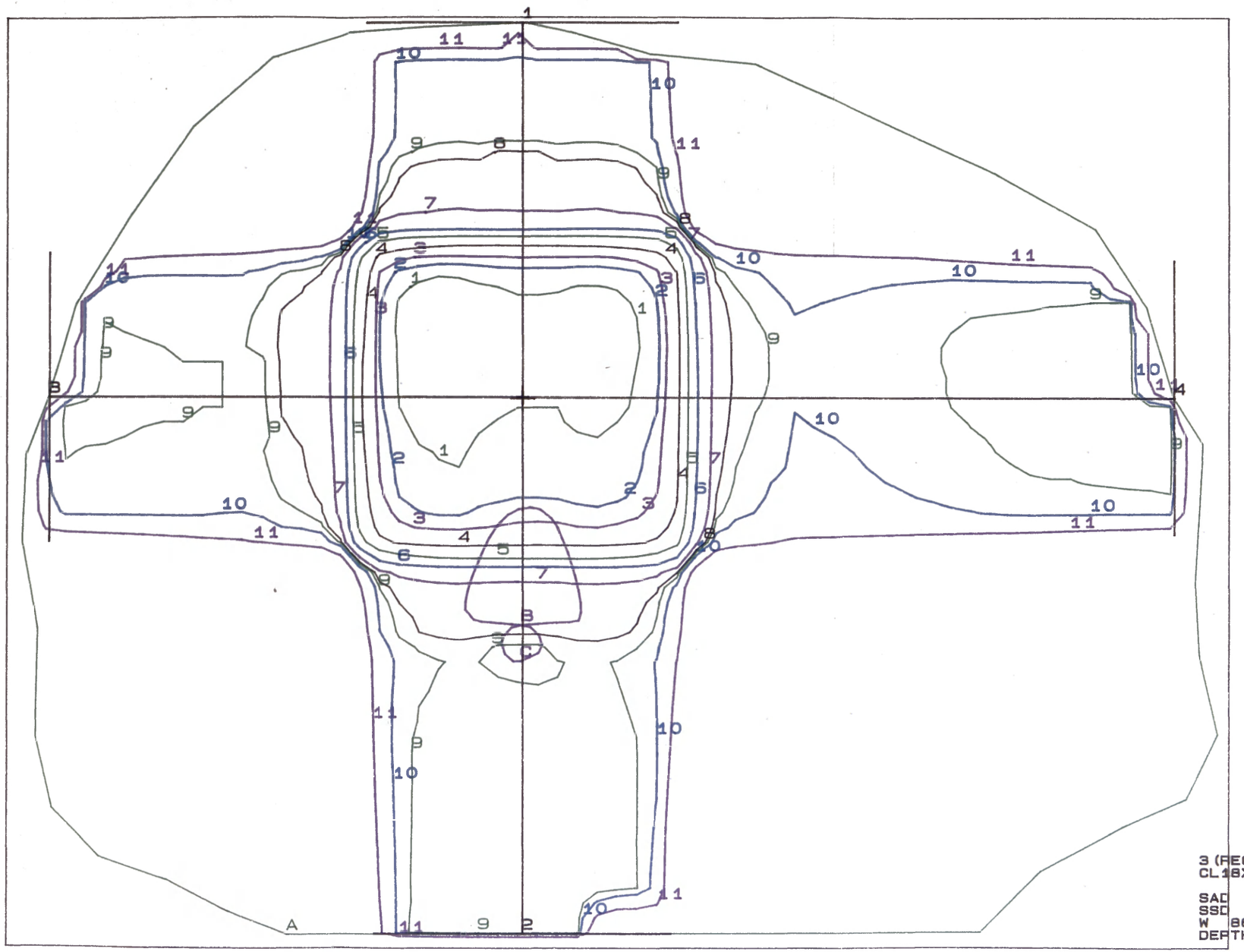
NORMALIZATION: STANDARD (1000)
MAX.IN WINDOW: 1016

16: 27
RTP27500
SCALE
.80

CONTOUR	DENSITY (GM/CC)	DESCRIPTION
A PATIENT	1.00	ABDOMEN
B INTERNAL	1.50	VERT.BODY
C INTERNAL	1.00	CORD

ISODOSES

0	1020
1	1000
2	980
3	960
4	900
5	800
6	700
7	600
8	550
9	530
10	500
11	400



1 (RECT) CL18X
SAD 1000
SSD 902
W 90 L 106
DEPTH 97

2 (RECT) CL18X
SAD 1000
SSD 860
W 90 L 106
DEPTH 139

3 (RECT) CL18X
SAD 1000
SSD 876
W 86 L 106
DEPTH 124

4 (RECT) CL18X
SAD 1000
SSD 829
W 86 L 106
DEPTH 170

GANTRY 180
EQ.DEP 97
TAR .9014

GANTRY 0
EQ.DEP 154
TAR .7938

GANTRY 270
EQ.DEP 124
TAR .8459

GANTRY 90
EQ.DEP 170
TAR .7489

cm

APPENDIX B

THE UNIVERSITY OF MICHIGAN-FLINT
303 E. KEARSLEY STREET
FLINT, MICHIGAN 48502-2186

HEALTH CARE PROGRAMS
(313) 762-3172

FDA POLICY STUDY

November 1, 1991

To: Manufacturers of Computerized Treatment Planning Systems

I am a Graduate Student in the Health Administration program at the University of Michigan - Flint, conducting research in the FDA's intervention into Computerized Software used in Radiation Therapy.

I am asking for your assistance in gathering information for this research. The focus of the questionnaire is on the manufacturers interpretation and perception of the imposed 510K certification ruling from the FDA. I hope to predict what this certification mandate will mean to the industry and the market place. Please complete the attached questionnaire and return it to me in the self addressed envelope.

I would be happy to share any or all of my research with you on completion of the thesis. If you have any questions, please feel free to contact me.

Thank you in advance for assisting in this research.

Sincerely,

Roxanne L Clark

Roxanne L. Clark
home: (313) 653-4165
Work: (313) 234-2273

FDA POLICY STUDY
Computerized Treatment Planning System Questionnaire

1. The computerized treatment planning system component of my company's business responsible for:

_____ 0-25% of company's gross revenue

_____ 26-50% of company's gross revenue

_____ 51-75% of company's gross revenue

_____ 76-100% of company's gross revenue

2. My company employs a total of:

_____ 0-25 FTEs (full time equivalent)

_____ 26-50 FTEs

_____ 50-100 FTEs

_____ 101-200 FTEs

_____ more than 201 FTEs

3. I would characterize the geographic scope of my company as:

_____ local

_____ regional

_____ national

_____ international

4. My company currently possesses the 510K certification.

_____ yes _____ no

5. The FDA 510K certification will require that my company _____

_____ increase

_____ decrease

_____ hold constant

the personnel that will be dedicated to quality assurance and product line research and development.

6. The FDA 510K certification requirement will mean that the price of our new computerized treatment planning system will

_____ increase dramatically

_____ increase moderately (>10% but <25%)

_____ increase slightly (< 10%)

_____ remain unchanged

_____ be lowered

7. From your experience will the 510k certification result in a better computerized treatment planning system?

_____ yes _____ no

8. Do you expect to see "buy-outs" of smaller companies with larger organizations?

_____ yes _____ no

9. I predict as a result of the 510K certification that within the next _____ years there will be a total of

_____ 0-6 Computerized Treatment Planning System manufacturers

_____ 7-15 manufacturers

_____ 16-20 manufacturers

_____ the same number of manufacturers

10. Do you expect the 510K certification will "effectively" test the efficacy of the computerized treatment planning system?

_____ yes _____ no

11. Are there are other issues that you see as important components as a result of the 510k certification requirement? (Please expound in what ever detail you feel appropriate.)

Thank you for your time and responses!

APPENDIX C

CURRENT REGULATORY ISSUES IN

An American College of Medical Physic

April 9 - 11, 1992

Hotel Del Coronado, Coronado

Program Directors:

Melissa C. Martin, M.S.
St. Joseph Hospital
Orange, CA

James B. Smathers, Ph.D.
UCLA Medical Center
Los Angeles, CA

Faculty:

Edgar Bailey, Chief
Radiologic Health Branch
Sacramento, CA

Norman Baily, Ph.D.
University of California
San Diego, CA

Stafford Chenery, Ph.D.
Radiation Oncology Center
Sacramento, CA

Robert Chu, Ph.D.
VA Medical Center
Oklahoma City, Oklahoma

Michael Gillin, Ph.D.
Medical College of Wisconsin
Milwaukee, Wisconsin

John Glenn, Ph.D.
U.S. Nuclear Regulatory Commission
Washington, D.C.

Dave Hall
Theratronics International
Ottawa, Canada

Philip Heintz, Ph.D.
Enloe Hospital
Chico, CA

Edward Hendrick, Ph.D.
University of Colorado
Denver, CO

Michael Odlaug, M.P.H.
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Robert Morton, Jr., M.S.
Siemens Medical Labs, Inc.
Concord, CA

Larry Rothenberg, Ph.D.
Memorial Hospital, MKSCC
New York, NY

Robert Shalek, Ph.D., J.D.
M.D. Anderson Cancer Center
Houston, TX

Donald Tolbert, Ph.D.
Trippler Army Medical Center
Honolulu, HI

Anthony Tse, Ph.D.
U.S. Nuclear Regulatory Commission
Washington, D.C.

Robert Wren, Director
Office of Coverage and Eligibility Policy
Health Care Financing Administration
Baltimore, MD

Ann Wright, Ph.D.
Radiological Physics & Engineering Co.
Houston, TX

Course Description and Objectives

This course is designed for clinical medical physicists, radiology
strators, and radiation safety professionals. After attending this cou
participants will have acquired an understanding of the basis for new reg
requirements, become familiar with the new requirements in all a
medical physics, and be able to organize and support a program f
institution to comply with applicable regulations in their state.

Accreditation

**Continuing education units from the American Board of H
Physics are pending.**

Co-Sponsoring Organizations

UCLA Dept. of Radiation Oncology
American Association of Physicists in Medicine
Society for Radiation Oncology Administrators
Health Physics Society

ATORY ISSUES IN MEDICAL PHYSICS

rican College of Medical Physics Workshop

April 9 - 11, 1992

Coronado, Coronado (San Diego), CA

Robert Morton, Jr., M.S.
Siemens Medical Labs, Inc.
Concord, CA

Larry Rothenberg, Ph.D.
Memorial Hospital, MKSCC
New York, NY

Robert Shalek, Ph.D., J.D.
M.D. Anderson Cancer Center
Houston, TX

Donald Tolbert, Ph.D.
Trippler Army Medical Center
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Radiological Physics & Engineering Co.
Houston, TX

Course Description and Objectives

This course is designed for clinical medical physicists, radiology administrators, and radiation safety professionals. After attending this course, the participants will have acquired an understanding of the basis for new regulatory requirements, become familiar with the new requirements in all areas of medical physics, and be able to organize and support a program for their institution to comply with applicable regulations in their state.

Accreditation

Continuing education units from the American Board of Health Physics are pending.

Co-Sponsoring Organizations

UCLA Dept. of Radiation Oncology
American Association of Physicists in Medicine
Society for Radiation Oncology Administrators
Health Physics Society

American College of Medical Physics Works

P·R·O·G·R·A·M

Wednesday, April 8

6:00-8:00 p.m. Registration - *Crystal Room*
Reception - *Garden Patio*

Thursday, April 9

7:30-12:00 p.m. Registration - *Crystal Room*
8:00 *Continental Breakfast with Exhibits - Ballroom*
8:30 *Welcome and Introductory Remarks - Ballroc*

Session 1
Suggested State Regulations for Radiation Therapy

8:35 Rationale for SSR's for Radiation Therapy
Edgar Bailey
9:20 Implementation of SSR's in a Large Oncology Ce
Stafford Chenery, Ph.D.
9:40 Implementation of SSR's by the Consulting Phys
Philip Heintz, Ph.D.
10:00 *Questions and Discussion*
10:15 *Coffee Break*

Session 2
Suggested State Regulations for Diagnostic Radiology

10:45 Rationale for SSR's for Diagnostic Radiology
Michael Odlaug, M.P.H.
11:30 Implementation of SSR's in a Diagnostic Radi
Dept.
Larry Rothenberg, Ph.D.
12:00 *Questions and Discussion*
12:30 *Lunch*

Session 3
Licensure of Medical Physicists

1:30 A Case for Deregulation of Radiation Therapy
Robert Shalek, J.D., Ph.D.
2:15 Benefits and Difficulties of Licensure of Me
Physicists: Texas Experience
Ann Wright, Ph.D.
3:00 Progress in New York for Licensure of Me
Physicists
Larry Rothenberg, Ph.D.
3:15 Progress in Calif. for Licensure of Medical Physi
Norman Baily, Ph.D.
3:30 *Questions and Discussion*
4:00 *Adjourn*
6:30 DINNER - BY THE BEACH - *Promenade Dec*

Friday, April 10

8:00 *Continental Breakfast with Exhibits - Ballroom*

Session 4
"Quality Management Program and Misadministrations in Nuclear Medicine"

8:30 Rationale and Goals of the QMP for Nuclear Medicine
Anthony Tse, Ph.D.

9:15 Compliance with the QMP in a Nuclear Medicine Department
Robert Chu, Ph.D.

9:45 *Questions and Discussion*

10:15 *Coffee Break*

Session 5
"Quality Management Program and Misadministrations in Brachtherapy and Teletherapy"

10:45 Rationale and Objectives of the QMP for Brachytherapy and Teletherapy
Anthony Tse, Ph.D.

11:30 Compliance with the QMP in a Brachytherapy Program
Michael Gillin, Ph.D.

12:00 *Questions and Discussion*

12:30 *Lunch*

Session 6
New 10CFR20 Radiation Exposure Limits for Personnel and the Public

1:30 Rationale for New Guidelines
John Glenn, Ph.D.

2:15 Economic Impact on Institutions to Comply with 10CFR20 Regulations
Don Tolbert, Ph.D.

3:00 *Questions and Discussion*

3:30 *Adjourn*

4:00 OPTIONAL TOUR TO TIJUANA, MEXICO

Saturday, April 11

8:00 *Continental Breakfast with Exhibits - Ballroom*

Session 7
Mammography Equipment Performance Requirements

8:30 HCFA Requirements for Medicare Reimbursement of Mammography
Robert Wren

9:15 ACR Accreditation Program Requirements
Edward Hendrick, Ph.D.

9:45 *Questions and Discussion*

10:15 *Coffee Break*

Session 8
Equipment and Software Requirements for Radiation Oncology

10:45 IEC, NEMA and FDA Requirements for Computer Controlled Linear Accelerators
Robert Morton, M.S.

11:30 FDA Requirements for Treatment Planning Computer Software
Dave Hall

12:15 *Questions and Discussion*

12:30 *Adjourn*

1:30 OPTIONAL BEHIND THE SCENES TOUR - SAN DIEGO ZOO

Fees, Registration, and Refunds

FEES: The fee for the Current Regulatory Issues in Medical P (Wednesday - Saturday) is $400.00, if the registration is recei March 25, 1992. Companion (over age 6) is $150.00 each. Fee received after March 25, is $450.00. Registration fees include reception, 3 continental breakfasts, 2 lunches, Thursday dinner refreshment breaks.

REFUNDS: Full refunds, less $50 administrative service charg made to those supplying Ryals & Associates written cancelation by 25, 1992. After that date, no refunds will be made.

REGISTRATION: Registration check-in will be Wednesday, 1992, 6:00 - 8:30 p.m. in the Crystal Room of the Hotel del Coronad

Social Events

- Guest Hospitality Room, Thursday 8 a.m. - Noon - *Hanover*
- Dinner by the Beach, Thursday 6:30 p.m. - *Promenade Deck*

Rental Cars - Hertz #3145

Hertz has been appointed our official rental car supplier. Special ra have been negotiated to reduce the travel costs. To rent a car during dates, call the Hertz Convention Control Center at 800-654-2240 and this meeting.

For Information

Please contact Dawne Ryals, Ryals & Associates, P.O. Box 1925, Ro GA 30077-1925; telephone (404) 641-9773; FAX (404) 552-9859.

San Diego: "America's Finest City"

San Diego has truly earned its name as "America's Finest City!" balmy Mediterranean climate, it is pleasant all year round. Days are wa sunny, evenings are cool and a light coat or sweater is comfortable. San is home to some prime resort attractions and the Hotel Del Coron conveniently located near them all. The San Diego Zoo is minutes awa World is only 15 minutes north on I-5. The Wild Animal Park is within hour's drive. And historic Balboa Park, located next to the Zoo, is fill theatres, museums, sculpture, art and exhibitions of all kinds.

Just across the Bay Bridge you may visit downtown's newly re Gaslamp Quarter, and the brand new multitiered art deco Horton Plaza is a trendsetter in redevelopment and a shopping and eating delight. A lesser known delight is a hike in the pine covered mountains only 30 mi of San Diego or a visit to the vast desert reserve of Anza Borrego provides such a contrast as one descends eastward from the crest o mountains.

Of course, you may sun, surf, and swim along San Diego's seventy m white sandy beaches or take to the sea for a sail or to deep-sea fish for marlin.

Shopping excursions in and around San Diego are diverse and excitin can visit beautiful La Jolla with its lovely boutiques and specialty shop can wander through Old Town San Diego and enjoy its distinctive M flavor, but if you crave the "real thing," then head south of the border in California and sample color, excitement, and *free port* of Tijuana Mexico.

Optional Events

"VIP Tour of the San Diego Zoo"
Saturday, April 11, 1992

It's a whole new perspective on observing these exotic animals! Through special arrangements, we'll take you on a special VIP tour of the world's rarest collection of mammals, birds and reptiles.

Your private bus will be waiting for you inside the park for your exclusive tour. We'll take you on the other side of the enclosures -- to areas closed off to the general public. You'll learn more about the zoo's breeding efforts with endangered species, find out what the animals eat and how the animals are treated for ailments. Afterwards, there will be time to roam the zoo at your leisure. This tour is a fascinating way to see how the world's most famous zoo operates on a day-to-day basis.

Depart Hotel del Coronado: 1:30 p.m.
Return Hotel del Coronado: 5:30 p.m.
Cost: $38.00 per person

"Tijuana Shopping with Dinner"
Friday, April 10, 1992

Bienvenidos Amigos! A city of cosmopolitan size and tastes, Tijuana is a showcase in fascinating contrasts -- with sleek, new shopping plazas settled comfortably among the quaint side streets of "Old Mexico." Select from name brands like Christian Dior and Ralph Lauren or haggle over leather goods, pottery and handwrought jewelry. From jostling open-air bazaars to some of Mexico's most exclusive boutiques, you can't help but find that perfect "something."

Afterwards, enjoy a traditional Mexican dinner, served in one of Tijuana's finest restaurants complete with a frothy Margarita cocktail! This will be a wonderful shopping adventure!

Note: All U.S. and Canadian citizens should carry identification. All others must have correct documentation to re-enter the United States (i.e. Green Card or Multi-Entry Visa).

Depart Hotel del Coronado: 4:00 p.m.
Return Hotel del Coronado: 9:30 p.m.
Cost: $38.00 per person

Optional Events Registration Form

Current Regulatory Issues In
Medical Physics
April 9 - 11, 1992

Payment Policy: Full payment must be received no later than 15 days prior to your event. After that date, **NO REFUNDS** will be made. Please mail your check and a self addressed stamped envelope to the address listed below. Your tickets will be mailed back to you. If Enjoy California Enterprises must cancel the tour due to lack of participants, a full refund will be made. Our tour escort will check your name off the sign up list as you board the coach. Any available seats will be sold on a first come, first serve basis.

Please send the completed form together with payment in full to:
ENJOY CALIFORNIA
1094 Cudahy Place
Suite 201
San Diego, CA 92110
(619) 275-3830

FRIDAY, APRIL 10, 1992
"Tijuana Shopping with Dinner"
4:00 p.m. to 9:30 p.m. _____ Tickets at $38.00 each = $_____

SATURDAY, APRIL 11, 1992
"VIP Tour at The San Diego Zoo"
1:30 p.m. to 5:30 p.m. _____ Tickets at $38.00 each = $_____

TOTAL = _____

Name _____

Phone ( ) _____

Address _____

Convention Airline Discounts

DELTA

Delta Airlines Special Meeting Network of Atlanta is pleas
the opportunity to work with you on your upcoming meeting. Prov
been made to allow a 5% bonus off most Delta domestic publi
providing all rules and conditions of the fares are met.

Be sure to inquire about Super Saver Fares with discounts up to
passengers not qualifying for published discounts, a 45% discou
offered on Delta's domestic system for travel to the meeting.

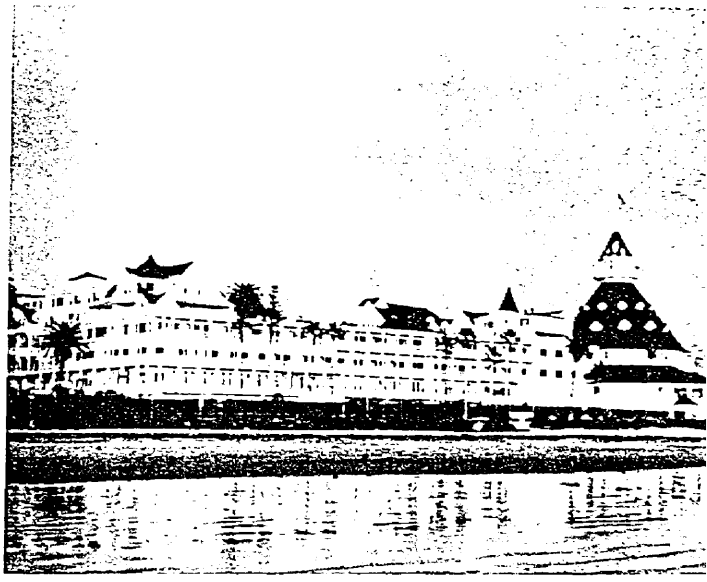
Call Delta at 1-800-241-6760, ask for Special Meetings Net
refer to file #H0511

AmericanAirlines
*Something special in the air.*SM

American Airlines in cooperation with this meeting, offers
discounts of 45% off the full coach fare (tickets must be purchase
advance) or 5% off the lowest applicable airfare at the time of t
All fares and restrictions apply. For all your travel arrangements pleas
American Airlines Meeting Services Desk at its 24-hour number:

In the Continental U.S.A. 1-800-433-1790

Please ask for Star File #S02Z2HC listed under Ryals Grou
calling for reservations.



Hotel Del Coronado

The Hotel Del Coronado has reigned as monarch of the Pacif
resort hotels for nearly a century. Since opening in the late 1800
been admired as an architectural masterpiece, yet this majesti
lishment has never been more alluring than it is today. As a ha
relaxation and wonderfully varied resort activities, it has no peer. T
Del Coronado epitomizes the grand manner in a superb setting surr
by stately trees and framed between the blue Pacific and sparkling C
Bay.

The Hotel's private grounds feature championship caliber illu
tennis courts, a heated pool with poolside terraces, the ever-b
garden courtyard, and acres of California's finest white sandy b
Supervised activities are available for children.

Naturally, the Hotel Del Coronado offers a wide variety of dir
lounge options highlighted by the main dining room and a g
restaurant.

HOTEL ROOM RATES: Special Group Convention Rates are inc
part of this course package and will be available until March 1, 1992. A
that date, reservations will be made on a space available basis only
telephone the hotel for reservations identify yourself with this confe
obtain the special rate. You may mail your reservation to the hotel be u
"Hotel Reservation Request" form included in this brochure.

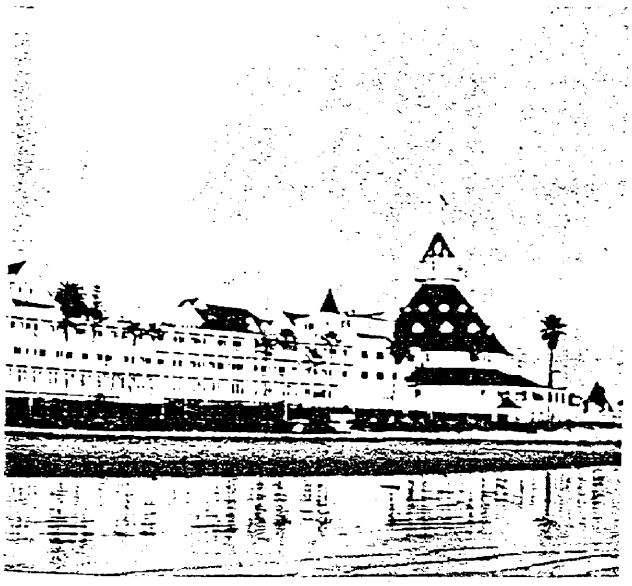
Airline Discounts

DELTA
We Love To Fly And It Shows

s Special Meeting Network of Atlanta is pleased to have o work with you on your upcoming meeting. Provisions have llow a 5% bonus off most Delta domestic published fares s and conditions of the fares are met.
uire about Super Saver Fares with discounts up to 70%. For qualifying for published discounts, a 45% discount will be 's domestic system for travel to the meeting.
1-800-241-6760, ask for Special Meetings Network, and 511

AmericanAirlines
Something special in the air.℠

irlines in cooperation with this meeting, offers exclusive % off the full coach fare (tickets must be purchased 7 days in off the lowest applicable airfare at the time of ticketing. rictions apply. For all your travel arrangements please contact es Meeting Services Desk at its 24-hour number:
the Continental U.S.A. 1-800-433-1790
or Star File #S02Z2HC listed under Ryals Groups, when vations.



Coronado

el Coronado has reigned as monarch of the Pacific Coast r nearly a century. Since opening in the late 1800's, it has as an architectural masterpiece, yet this majestic estab- ever been more alluring than it is today. As a haven for vonderfully varied resort activities, it has no peer. The Hotel pitomizes the grand manner in a superb setting surrounded and framed between the blue Pacific and sparkling Glorietta

rivate grounds feature championship caliber illuminated a heated pool with poolside terraces, the ever-blooming rd, and acres of California's finest white sandy beaches. ities are available for children.
Hotel Del Coronado offers a wide variety of dining and highlighted by the main dining room and a gourmet

M RATES: Special Group Convention Rates are included as e package and will be available until March 1, 1992. After that ations will be made on a space available basis only. If you tel for reservations identify yourself with this conference to rate. You may mail your reservation to the hotel be using the on Request" form included in this brochure.

Course Registration

Current Regulatory Issues in Medical Physics
An American College of Medical Physics Workshop
April 9-11, 1992
Hotel del Coronado, Coronado, CA

OFFICE USE ONLY
Rec. on _____
Amt. $ _____
Chk. # _____
Conf. _____

Mail to: Carleton R. Ryals, Ryals & Associates, P. O. Box 1925, Roswell, GA 30077-1925, Tel. (404) 641-9773, FAX (404) 552-9859. **Make checks payable to: ACMP Workshop.**

☐ $400 before March 25
☐ $450 after March 25
☐ $150 Companion

Name _____

Address _____

City, State & ZIP _____

Telephone Hm. _____ Off. _____

FAX _____

Hotel Reservations at _____

Airline Used _____ Rental Car _____

Hotel Reservation Request

Current Regulatory Issues in Medical Physics
An American College of Medical Physics Workshop
April 9-11, 1992
Hotel del Coronado, Coronado, CA

Your reservations request must be received at the hotel by March 1, 1992. After that date, rooms will be secured on a space available basis only and rack rates may apply. WE URGE YOU TO MAKE RESERVATIONS EARLY.
Mail this form directly to preferred hotel to receive group rates.

Hotel Del Coronado, 1500 Orange Avenue, Coronado, CA 92118; Telephone (800) 522-3088, (619) 435-6611, FAX (619) 522-8238.

☐ Single or Double (Main Building) - $129
☐ Single or Double (Ocean Tower/Poolside - $129
☐ Lanai Suite - $295
☐ Suite - $395

Glorietta Bay Inn, 1630 Glorietta Blvd., Coronado, CA 92118; Telephone (619) 435-3101; FAX (619) 435-6182.

Garden	Lanai	Bay View
☐ Single - $79.00	☐ Single - $89.00	☐ Single - $99.00
☐ Double - $79.00	☐ Double - $89.00	☐ Double - $99.00

Name _____

Address _____

City, State & ZIP _____

Telephones: Hm. _____ Off. _____

FAX _____

Arrival Date _____ Departure _____

Credit Card _____ Account # _____

Signature _____ Exp. Date _____

A deposit for your first night's lodging must accompany this reservation request. All rates are subject to 7% Room Tax.