Cancer
Cancer Quackery
and the Cancer Law

Prepared by the Cancer Advisory Council and Staff
Approved by the State Board of Public Health
Submitted by the Director of Public Health
1972
HOUSE RESOLUTION NO. 726
Relative to cancer treatment

WHEREAS, The diagnosis and treatment of cancer is of great public importance; and

WHEREAS, Several forms of cancer can be cured through the application of knowledge now available to medical science; and

WHEREAS, The Assembly of the State of California desires to advance knowledge about cancer diagnosis and treatment while protecting cancer victims and their families from the loss and grief associated with application of worthless cancer diagnostic and treatment methods; now, therefore, be it

RESOLVED BY THE ASSEMBLY OF THE STATE OF CALIFORNIA, That the Assembly Committee on Public Health be directed to study and make recommendations on procedures to assist California citizens in obtaining valuable diagnosis and treatment for cancer and to protect California citizens from the application of agents, methods or devices having no value in the diagnosis or treatment of cancer and to report its findings thereon to the Legislature not later than the fifth legislative day of the 1967 Regular Session of the Legislature.

Resolution read, and referred by the Acting Speaker pro Tempore to the Committee on Rules.

Introduced by Assemblymen
Rumford and Duffy, June 15, 1965
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SUMMARY

This report brings together many of the facts and issues related to cancer, cancer quackery and California's Cancer law. The Cancer Law, its intrinsic value and benefit to the citizens, must be understood in a broad context.

The Cancer Law was difficult to enact. Opposition to the Cancer Law continues to come from many quarters. Opponents are vocal, often anxious and fearful. Proponents of the Cancer Law are no less intent. They believe that the enforcement of the Cancer Law is the only reasonable and substantial means available to repress cancer quackery. Proponents of the Cancer Law are troubled that California citizens are enticed to a form of fraudulence which costs far more than gambled money: it costs human lives and needless suffering because it diverts individuals from effective forms of disease management. Cancer quackery preys on the apprehensions of persons when they are most vulnerable, and robs them of a chance for restoration and prolonged life. If the Cancer law can effectively curtail the numbers of unethical practitioners who delude our citizenry, and ban from use the host of worthless remedies dispensed at great human cost, our citizens can be protected from one form of distressing human waste. The number of Californians affected by cancer are bound to increase. Without strict enforcement of the Cancer Law -- the toll of lives is bound to increase. This report elucidates why.

The Disease:

Cancer is the second leading cause of death in California. It will afflict one out of every five persons in the State. In 1972, more than 22,000 persons will die of cancer in California. This disease now accounts for roughly one-sixth of all deaths in the State.
It is not a hopeless disease, however. About one-third of the individuals who develop cancer are being successfully treated and their lives saved through early diagnosis and proper treatment. This includes some individuals who have suffered metastasis or spread of cancer through the body. The medical challenge is to insure the earliest possible diagnosis and correct treatment.

Diagnosis and Treatment:

The establishment of an accurate diagnosis of cancer requires skill and laboratory examinations.

Mistaken diagnoses of benign or non-malignant lesions as cancer can be the basis for "cures" with any or no treatment.

Proved therapy for cancer varies dependent on the location and character of the cancer. It may include surgery, use of radiation, X-ray, hormones, and certain chemicals.

Establishing Value of New Remedies:

Well accepted procedures exist for establishing the value of any new procedure or drug as a treatment for or diagnosis of cancer.

First the effectiveness and safety of the procedure or drug is determined on animals, and if these studies show value, carefully controlled clinical studies are conducted on humans by qualified clinicians. Initial studies are made on individuals who have a form of cancer that is not responsive to other means of treatment. The proponent of a new treatment or procedure is responsible for conducting these studies in a scientific manner and establishing its value.

"Cancer Quackery":

A cancer "quack" disregards these principles of scientific study and claims "cures" or success in treatment using "secret" drugs. He offers his claims to the public at large and he usually is unwilling to present evidence on his
"treatment to his professional associates in the regular manner for scientific evaluation. Some cancer "quacks" become expert at obscuring this point by claiming bias on the part of the medical-scientific community.

The proponents of unorthodox remedies should be required to present evidence of the same type which is demanded of members of the medical profession to substantiate their claims that they have an agent or agents that are useful in the management of clinical cancer.

Unfortunately, many individuals with cancer, or those who think they have cancer, either through fear or for other reasons accept promises of cure by quacks and find out, only too late, that they have lost the benefits of proper diagnosis and effective early treatment.

Legal Rationale:

There is no constitutional right to offer afflicted persons hope of relief by harmful or ineffective modes of treatment -- anymore than there is a right to offer them hopes of financial rewards through fraud.

The Cancer Law prohibits the use of ineffective remedies as well as those directly harmful. As cited in one review, the State has the obligation to see that the treatment of a completely hopeless case will not be a source for the enrichment of quacks.

Need for California Cancer Law:

California's Cancer Law has served to protect the public from intra-state "quackery" activities not covered by Federal or other State law. Federal law applies only to inter-state activity.
Enforcement:

Administration of the Cancer Law by the State Department of Public Health, with the aid of the Cancer Advisory Council composed of 15 well-qualified physicians, scientists, and laymen has been effective in reducing quackery in California and in substantially curtailing the use of worthless remedies.

Cease and desist orders have been issued involving many different agents including Siccacell, the Harmonizer, and a "grape cure". Complaints are received and investigations are being made continuously.

The State Board of Public Health, on advice of the Cancer Advisory Council adopted regulations prohibiting the use of the following "cancer agents":

- Hoxsey Remedy
- Laetriles
- Koch Synthetic Antitoxins
- Anthrone Diagnostic Test
- Lincoln Staphage Iysate
- Mucorhicin
- Bolen Diagnostic Test
- Krebiozen

Public Hearings:

These regulations were adopted only after extensive investigation and public hearings at which everyone was given ample opportunity to be heard.

Clinical Trials:

Critics have suggested "clinical trials" by the Department before such actions are taken. The law and the regulations permit use of any of these agents by competent investigators in clinical studies or evaluations. The regulations prohibit their misuse and use for profit.

The usual scientific procedure for proving the value of any of these remedies is available to any proponent of a "remedy" just as it is for others introducing any new agent for cancer or any other disease.

It would be impractical for the State to test, and particularly to under-
take to clinically test, all new agents proposed for treatment of cancer (and other diseases). Procedures now exist in medical centers for clinical testing of all new agents proposed for cancer treatment that justify such clinical testing on the basis of animal and other studies. Furthermore, the Cancer Law provides for clinical testing when deemed appropriate by the Cancer Advisory Council. However, mandatory clinical testing would expose human beings affected by cancer to experimentation with agents whose value had not been properly estimated on the basis of animal and other studies -- a clearly unethical procedure.

It is significant that in the past, sponsors of certain agents would not provide samples to the Department for analysis, nor would they provide sufficient amount of the agent to Federal agencies for necessary testing.

Costliness:

The cost of the Cancer Law each year is only a small part of the very small enforcement cost of the Fraud Section of the Bureau of Food and Drug. This expense is modest compared to the estimated $20 million spent by Californians on cancer quackery, the millions spent on cancer research and control, public education or on treatment for cancer, the disease.

Public Education:

The American Cancer Society maintains numerous informational and educational activities to familiarize the public with the hazards of cancer quackery. But education, without an enforceable law such as the Cancer Law, is insufficient to thwart cancer quackery.

Activities of the Fraud Section:

As the activities of the Fraud Section, Bureau of Food and Drug suggest, painstaking investigation, testing, hearing and evaluation can result in restraint of cancer quacks. The process is slow, but gives the quack every opportunity to present evidence and witnesses. Case histories illustrate that the
course of cancer varies -- and so does susceptibility to seek quackery.
The costs of worthless treatments are large -- and the personal waste dis-
tressing.

Against this, the Fraud Section has been able to enforce the Cancer
Law and has reduced some of the human toll from cancer quackery.
CHAPTER 1
INTRODUCTION

This report has been prepared to assist the Interim Study Committee on Public Health of the State Assembly in 1966. It has been revised in a few minor respects for use as a public information item in October 1972. Following hearings on the Cancer Law, and extension of the law through December 1967, the Assembly resolved that its Committee on Public Health be "directed to study and make recommendation on procedures to assist California citizens in obtaining valuable diagnosis and treatment for cancer and to protect California citizens from the application of agents, methods of devices having no value in the diagnosis or "treatment of cancer..."

In particular, the Interim Study Committee wishes to evaluate the procedure of the Cancer Advisory Council by which some cancer remedies are found worthless and subject to prohibition from use in California. The focus of this particular evaluation should be "whether testing of remedies should be required before a remedy is banned." Testing in this sense means clinical testing -- on human beings -- under scientifically sound and controlled procedures. The banning of remedies here refers to the means by which diagnostic and treatment agents found ineffective in the management of cancer may be legally restricted from prescription, administration, sale or other distribution in California.

SCOPE OF STUDY

The scope of study implicit in the Committee directive and in H.R. 726 is broad and detailed. It must embrace not only an appreciation of scientific principles and medical ethics, but also of the human constitution when faced with disease, the particular impact of the disease cancer upon individuals and society at large, the likelihood of some persons to deceive and deprive others of recognized means of therapy, and the legal framework...
created explicitly to curtail fraudulence in the handling of cancer cases. Hence, the title, "Cancer, Cancer Quackery, and the Cancer Law." And, hence the need to draw upon knowledge and opinions outside the State Department of Public Health and from outside California.

One word about the organization of this report. A brief summary prefaces the report. Chapters 2 through 5 contain information directly related to the topic of human clinical testing; Chapters 6 through 9 discuss the Cancer Law, the legal foundation upon which it depends, fiscal considerations, and the application of the Cancer Law to date. Chapter 10 discusses public education about cancer and cancer quackery. Chapter 11 presents proposed revisions of the Cancer Law and means to strengthen it.

Each of the several chapters treats one aspect of the subject under study. Each chapter can stand alone. But, each chapter is also related to all of the others. Central to the report are two questions: that of clinical testing on humans -- the scientific, legal, and above all, humane considerations -- and the effectiveness of a cancer law to control the menace of cancer quackery. The Summary aims to highlight the cogent facts from the chapters and to interrelate them.
CHAPTER 2

A PERSPECTIVE ON CANCER

It is impossible to speak of quack cancer remedies or laws to prohibit them without understanding something about the disease cancer. Anti-quack-ery laws, in fact, are probably the most recent weapon available in man's militant attack upon cancer. With the possible exception of man's dilemma of how to live harmoniously with his knowledge of nuclear fission or how to sustain human life on planets other than Earth, nothing engages the imagination, energy or anxiety of modern man as urgently as the conquest of cancer. This preoccupation -- for many persons, occupation -- has received ever more impetus in recent decades, as technology and understanding provide the cause (etiology) of certain types of cancer and of ways of arresting its progression and as we recognize that cancer is gradually increasing as a cause of death.

What is cancer?

Why the immense effort to contain it?

Why the universal anxiety?

How does cancer differ from other modern afflictions?

Is cancer hopeless?

These are fundamental questions to be asked about cancer. For the last 30 years especially, physicians, scientists, and others have attempted to answer such questions. A composite of opinions and responses would require volumes and would contribute little of originality.

One of the most lucid discussions of cancer in our times has been written by Dr. Michael B. Shimkin, who has devoted his working career to cancer research. With gratitude to Dr. Shimkin, the next few pages are
excerpted from his book, *Science and Cancer*¹ (1964), in which he wrestles with these vital questions. (Portions in parentheses have been added by the editor, as have unindented portions of the text).

"It is impossible, these days, not to be aware of cancer.... At the level of the common citizen, there are few families in the United States who have not had personal experiences with cancer. This is almost inevitable, because now cancer is the number two scourge of our people, destined during the whole of our lifetime, of 70 years, to afflict one of each five of us, and to send one of each eight of us to the grave....

**WHAT IS CANCER?**

"First of all, cancer is a word in the English language, derived from the Greek word for crab, *karkinos*. Among its many synonyms are malignant tumors and malignant neoplasm (from the Latin for new growth.) Subgroups of cancer, describing the body tissues of origin, include carcinoma, sarcoma, melanoma, lymphoma, and many other related or combined terms. Cancer is a word that stands for a great group of diseases that afflict man and animals. Cancer can arise in any organ or tissue of which the body is composed. Its main characteristics include an abnormal, seemingly unrestricted growth of body cells, with the resultant mass compressing, invading and destroying contiguous normal tissues. Cancer cells then break off or leave the original mass and are carried by the blood or lymph to distant sites of the body. There they set up secondary colonies, or metastases, further invading and destroying the organs that are involved....
"Thus, cancer is a group word that encompasses many different entities that are dissimilar in appearance, in behavior, and undoubtedly in the causative factors as well....

WHY THE IMMENSE EFFORT TO CONTAIN CANCER?

"The diseases grouped together under the general term 'cancer' are second only to diseases of the heart and blood vessels, as killers of the people of the United States. This is also true of European and other countries that have kept pace with modern public health technology, and have reduced tuberculosis, other infectious diseases and malnutrition to relatively less important roles.

"In numbers, among the 180 million people of the United States in 1960, approximately a half million develop cancer during one year, and approximately 280,000 die of cancer during one year.... There has been a steady, striking rise in number of cancer deaths in the United States during the past 50 years. Some of this rise is undoubtedly due to better diagnosis of cancer, and better reporting of cancer cases. But a much more important factor has been the increasingly older population, saved from earlier death from other causes. If aging is taken into consideration, and statistics from different years adjusted to a similar age distribution, relatively little change in the incidence and mortality from cancer remains.

"Immediately, we must specify that this is by no means true of all cancer entities.... (Lung) cancer, relatively rare only 30 years ago, is now among the top three cancer killers of men. Intensive studies relate this tragic rise to environmental

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inhalation of cancer-producing chemicals, derived from tobacco products and from our increasingly contaminated atmosphere.

As interesting and as important as the rise in lung cancer has been the impressive drop in the death rate from cancer of the stomach. During the past 30 years, in women as well as in men, this cancer entity has dropped in occurrence by about 50 percent. We do not understand the reasons for this happy situation in the United States....

"In the United States, the last 30 years also have shown a steady increase in the reported deaths from leukemia and related cancers of the blood and lymphatic systems, and a decrease in mortality from cancer of the uterine cervix in women. Part of the latter effect is due to better treatment. The salvage rate of women with cancer of the uterus and cervix is improving continually, particularly as a greater proportion of the cases is detected at earlier stages by the use of the vaginal smear technic (Pap smear).

"In the United States and many European countries, the common forms of cancer among women are cancers of the breast, the uterus, and the large intestine. Among men, lung, prostate and large intestine are among the most frequent sites in the death statistics. In terms of incidence, skin cancer ranks high among fair-skinned males, but this is not apparent in the death registries because most patients with skin cancer are successfully treated....

WHY THE UNIVERSAL ANXIETY?

"Careful studies going back to the last century show that human
The balance in the reaction may favor the host (here, man), in which case the disease is overcome with or without (sequential change). It may favor the causative stimulus to a degree that results in the death of the organism. Or the process may achieve a constant or undulating balance between the stimulus and the host....

Clinically, cancer is manifested by a great diversity in its course. Some cancers of the breast will grow very rapidly and kill the individual within months after diagnosis, while others, seemingly identical, will progress slowly; some will metastasize widely while the primary tumor is still small, whereas others will remain relatively localized for many years. Some tumors, especially the neuroblastomas of childhood, melanomas of the eye, and breast cancers, demonstrate temporary and even seemingly permanent regressions. One of the possibilities is that these tumors, and perhaps many others at lesser degrees, stimulate a form of an immune response in the patient....

For cancer of the internal organs, the steps between initial suspicion and definite diagnosis may be many and complex. The steps are targeted at three questions a physician must answer in considering a patient's problem. These questions are: what is it? (diagnosis); what should be done? (therapy); and what is the probable outcome? (prognosis). Cancer is always a medical challenge because the life of the patient depends upon the earliest diagnosis and the correct first treatment. (Emphasis added)

The most curable cancers are cancers that have not progressed to
the stage of producing symptoms. For this reason, periodic exam-
inations of individuals without symptoms is well worthwhile for
the earliest clinical detection of some cancers. Such examina-
tions will not detect all cancers, and many procedures that must
be employed in the face of symptoms simply are uneconomical to
consider for symptomless individuals. Economy here is not used
in the monetary sense, but as it relates to the time, discomfort,
and hazard to the patient.

"Under conditions as they exist at present, most cancers are
diagnosed because an individual becomes aware of certain symptoms,
or because a physician suspects that certain symptoms or signs of
a patient may mean that a cancer is present.

For specific sites and types of cancer, a wide variety of labor-
atory procedures are useful in diagnosis and subsequent observa-
tions on patients. Cytologic evidence alone is seldom con-
clusive, however, and should be followed by an actual biopsy for
the definite diagnosis of cancer.

"It is immediately obvious that human error is inevitable. For
some forms of cancer this error is almost negligible, especially
if the lesion is not in its earliest stages. But for other,
rarer cancers, such as bone sarcomas, melanomas and lymphomas,
the margin of error may be considerable, even on such a basic
point as whether it is a malignant tumor at all.

"Here, often is the explanation of the miraculous cure claimed by
a quack. A lesion that is diagnosed as cancer that is not a
cancer is curable by any, or no treatment. (Emphasis added)
"Here is also the tragedy of recurrence and wide spread of a disease that was considered to be a benign one. Fortunately, these occurrences are not frequent, and become less frequent as the training and the experience of physicians and pathologists improve. It is also true that difficulties in diagnosis will increase as patients bring smaller and earlier lesions to the attention of physicians, and as the physicians confront the pathologists with progressively earlier stages of cancer."

It is apparent that generalities should not be made about cancer, especially those which cast a varied and complicated group of diseases into the realm of "hopeless," "fatal," and "futile." It is unfortunate that so much mystery surrounds the causes and progress of cancers, because this mystery is projected upon human behavior. Fear and ignorance, as manifest by imprudent decisions to seek false "cures," deter persons from seeking sound diagnostic advice and pursuing recognized forms of treatment.

Chapter 4 discusses in detail the effectiveness of treatment upon survival from cancer. It suggests that survival is related to many factors, not least of which are efficacious, prompt diagnosis and treatment.
Perhaps more than other diseases which afflict man, cancer exerts tremendous impact on human behavior. In part, because the course of certain types of cancer, especially those which attack inaccessible, vital organs, can induce pain and suffering. In part, because cancer can be fatal. In large part, perhaps, particularly among persons not experiencing cancer but observing second-hand the disease in others, because the term "cancer" evokes the entire gamut of emotions ranging from terror, escape and resistance to informed, rational conduct. It is almost impossible to codify the range of emotions exhibited or suppressed by persons reacting to the term "cancer," to the application of the term on their own states of health, to the total absence of knowledge about cancer or signs of its presence.

To every person, at different stages of his life, cancer can mean different things -- and having it can evoke different types of emotional responses than not having it. Nor is it easy to enumerate the attitudes which influence men who seek the origins of cancer, who attempt to control its course, who concentrate their skills and intelligences on this particularly thorny aspect of human life.

The literature of many disciplines -- medicine, psychiatry, psychology, anthropology -- contains references to the human emotional response to various types of diseases. No less significant throughout man's history are testaments to his adaptation under stress -- his ability to accommodate himself to threats or changes in his environment, his chemistry, his style of existence. It must be affirmed that adaptability is a highly elastic quality, and reflects cultural as well as technological influences. So it is that in some cultures, men will sacrifice themselves to preserve strong
beliefs in a certain ordering of life, where other men will look upon self-sacrifice as unhealthy, the sign of a sick mind. So it is that in a seemingly simple, uncluttered society, disease may be regarded as the just result of having evil thoughts or committing bad deeds, whereas in a highly complex, technological society, the origins of disease and its impact on individuals resides in a host of rational, provable explanations having nothing to do with a person's mores or thoughts.

At the present, the origins of cancer in its many forms still defies man. His need to rationalize its presence is intense. In some individuals, such rationalization can lead to distortion, self-deception, avoidance of existing knowledge. But the challenge is enormous. And bewildering. There are still corners of the world where cancer is not a significant cause of illness or death among men. These pockets of society are spared either because infectious diseases, pestilence, malnutrition, and even wars cut down substantial population before cancer -- or other diseases associated with aging -- has a chance. One price our more "advanced" stage of society must pay is the presence, to a significant degree, of the degenerative diseases and cancer, which is perhaps the most disturbing, though by no means the most common. And much of the disturbance is the degree of knowledge presently available -- and that even when known the complete application of that knowledge among a population.

Unquestionably, the nature of cancer, the inability to identify precisely all of its causes, and its increasing presence in a contemporary Western society, tend to influence how human beings feel about cancer. How they feel determines how they act -- or even whether they act. Here, it is, that quackery can become a vicious yet tempting force.

HUMAN NATURE AND QUACKERY

Doubt, fear and mystery create a hospitable setting in which quackery
can flourish. These qualities prevail whether the deception concerns one's health, one's property, or one's faith. For as long as men have doubted themselves or their immortality, there have been charlatans to tease at the truth, to tempt the unwary.

Who, then, are the opponents in this sick game?

The quacks, in this case cancer quacks, are sufficiently numerous and well documented to bear description. Dr. Charles Cameron, among others, has explored this subject. The following ideas are excerpted from his book, *The Cancer Quacks.*

"What are the quacks themselves like? What kind of people are they? It is not easy to describe them, because of the broad range of their mental capacities, their purposes, their emotional quirks, their educational backgrounds, and the degrees and sources of their delusions. It is simple to explain why a stupid, unprincipled, avaricious man latches onto medical quackery as an easy and lucrative livelihood. But to understand how a doctor of medicine becomes a quack -- sometimes after years of respectable, honest professional activity -- would take us into the deep reaches of psychiatry.

There is one thing that all quacks have in common no matter what their intelligence and honesty, no matter what their purpose: they disregard the rules of evidence.

"The scientific method is based on well-established, universally accepted principles of observation and experimentation. These principles are learned through years of disciplined study and intensive experience. And that is the only way they can be learned."
"But the scientific method simply does not exist in the quack mind. He is either ignorant of it, or he disregards it. Therefore, no quack is able to convince thoughtful, competent scientists and doctors of his claims, not because they don't want to be convinced, as the quack charges, but because his observations are faulty, his evidence is unreliable, and because his conclusions are unjustified.

"The quack scoffs at scientific rules in another respect: he does not present his evidence freely to his professional associates for critical evaluation. He offers his claims only to the public at large. This technique is used by no bona fide scientist or physician engaged in an honest search for truth.... The quack chooses to ignore...orthodox methods of disclosing his cancer treatment. He avoids the judgment or scrutiny of those best qualified to evaluate his claims....

"Although the quack bypasses the usual channels of medical communication, he does not dare admit it. His unvarying technique is to cover up his defection by raising a hue and cry to the effect that he can't get a hearing, that the medical profession is a vicious corporation which deliberately obstructs his efforts to save suffering humanity from the scourge of cancer, that doctors actually conspire among themselves to prevent the recognition of new discoveries which would mean loss of income to them....

"If such allegations were not wholly irresponsible, it would follow that "organized medicine" is a good deal better organized than it has been heretofore. After all, it failed to
suppress insulin, sulfa drugs, penicillin, cortisone, polio vaccine, and an impressive list of other agents which effectively combat illness....

"The quack tactic of accusing the medical profession of unfairness, collusion, conspiracy, and avarice strongly suggests that quacks suffer from an emotional disturbance known as the persecution complex.

"And there are likely to be other personality deviations in the classic quack. Dishonesty is one of them. It may be deliberate dishonesty, as when a promise is made to cure cancer with a remedy which the quack knows himself to be 100 percent worthless. Or the dishonesty may stem from a disorder well known to psychiatrists and psychologists: absence of moral sense. (Emphasis added) The person so afflicted cannot distinguish between truth and falsehood. He believes the truth to be what he wants to believe....

"Another quack quality is the one-track mind....Nothing is as good as his method. Most quacks admonish their patients to avoid regular doctors at all costs....(and) the importance of money in quack medical practice makes it essential that the quack maintain a monopoly on his treatment. Therefore, quack medicines and methods compounding them are secrets known only to their promoters....

"Whatever the quack's medicine lacks in the way of actual effect on cancer, he makes up for with his bedside manner. He is the original personality boy. He is long on jocularity and overoptimism, short on candor and caution. He promises to
deliver what no prudent doctor would dare even hope for."

Why, the reader may ask, does the quack succeed in wooing suckers? As Dr. Cameron concludes:

"His warmth and geniality, plus his promise to save the life of the patient who has been told by honest doctors that he cannot get well, plus his denunciation of the doctors who previously treated the patient, binds the quack to the patient and his family with strong ties of affection and loyalty.

"So it is only rarely that the family of the patient will complain of the outrage committed on them. Even rarer is their willingness to testify in court against their great, good quack."

Dr. Cameron has struck at one of the cardinal problems encountered in any legal framework to assault or curb quackery. The painstaking task of routing cancer quacks in California, as permitted under the Cancer Law, must contend with the protective mechanism quackery tends to impose upon its victims. Deception cuts deep, guilt perhaps deeper; many culpable individuals would rather live with their deception than see an end to it -- or prevent others from falling into the same trap. It is a hard matter to admit that you have been duped.

Are there some people more prone to seek quackery, more gullible? Let us briefly examine the characteristics of persons responsive to quackery. Perhaps there are some common threads -- personality traits -- which make them more susceptible to medical chicanery, or other types of fraudulence, for that matter. There is some evidence in the literature, the most current reference an article entitled "Why People Become the Victims of Medical Quackery," by Dr. V.W. Bernard.
The most basic and generic emotional source of vulnerability to quackery is some form of fear, even when this may be deeply hidden from the individual's own awareness and is expressed in disguised and indirect forms. Fears of death and of physical or mental incapacitation and weakness, with corresponding longings for survival, intactness, and strength are universally powerful motivators of human behavior. There is enormous variation among individuals, based on their personality development, as to how they characteristically cope with threatening life situations and how readily they may feel vulnerable in the face of ordinary as well as extraordinary stresses of life. For the susceptible, quackery seems to offer magically potent defenses against their deepest fears.

Among those most receptive to the false appeals of quacks are adults in whom childish forms of magical thinking tend to persist, along with an excessive inner sense of their own vulnerability and a corresponding exaggeration of the power of others to harm or to protect them.

...Susceptibility to the false lures of the quack is intensified by the brevity of contact and impersonality that has come to characterize a good deal of modern medical practice. The personal relationship between doctor and patient provides a potentially strategic opportunity at times of illness for meeting the related emotional needs of the patient and thereby reducing his turning toward quackery.

We should recognize a rather wide spectrum of psychologically different types of people among those who are especially prone to
the illusory appeal of quackery. An intelligent, well-educated and, by and large, well-adjusted individual who contracts a disease for which there is as yet no known scientific cure, or who recognizes that his condition is deteriorating seriously, despite medical care, may seize upon any promise of hope -- no matter how farfetched and no matter how discredited by medical authorities or the basis of scientific evidence. The need to believe in a therapeutic miracle, when medical science is or seems to be failing, can be so strong that it drives one's intelligence into twisting the facts to fit emotional necessity. Thus, faith in the quack, under such conditions, can be maintained without too much offense to reason by mobilizing such arguments as: the quack may have hit upon something of which medical science is still ignorant; the quack is a genius who is too far ahead of his time to be accorded recognition; the quack is a great healer who is the victim of organized medicine's vindictive jealousy or protection of a professional monopoly, and so on. Clearly, the psychological situation is very different for those who turn toward quackery in extremis when medicine is impotent than for the majority of those on whose gullibility and weakness quackery trades."

Dr. Bernard suggests that quackery appeals to emotionally immature personalities, and to persons prone to hopelessness, experiencing isolation or futility in the profound sense. More remarkable, Dr. Bernard observes that "converts" to quackery -- persons crusading unpopular movements -- are very often the same persons who fervently oppose certain health programs under medical auspices. Many of the persons assuming irrational
anxiety over water fluoridation, polio vaccinations and mental health pro-
grams are the same ones attracted to quack medical practices.

"To some individuals who are especially prone to irrational fears, the well-qualified licensed physician may represent a terrifying and malevolent magician armed with mysterious poisons, whereas the quack may be perceived as the counteracting benevolent rescuer who promises to purify, strengthen, and provide immunity against all perils of life." (Emphasis added)

Finally, Dr. Bernard suggests that yet another segment of the population, motivated by intense and long standing "antiestablishment" feelings, tends to champion the quack.

In this most heterogeneous of worlds, there are individuals who are destined to deceive, to live by preying on the human fallibility of others. And, regretably, they can find ample soil on which to forage. It seems likely that there will always be individuals willing to be deceived or unable to help themselves, unable to face unpleasant truths or unsolved mysteries such as the cancer riddle. It seems more reasonable to thwart medical chicanery, to stop the menace which offers false lures. It is also a moral responsibility, as well as more feasible. But, it should be real-
ized that the Cancer Law is a modest beginning against a diffuse, highly successful armada of cancer quacks operating in California.
CHAPTER 4
SURVIVAL FROM CANCER: TREATED AND UNTREATED PATIENTS

One obvious manifestation of cancer is that it can kill. It is this fact which overawes and even intimidates many people. It is this fact which gives the cancer quack his reason for being: he can assume the role of the "rescuer" mentioned by Dr. Bernard.

Critics and opponents of conventional methods of cancer therapy argue that survival from cancer is not possible. They claim that survival figures for cancer patients undergoing conventional treatment are misleading because of the inclusion of skin cancer cases, a large proportion of which are curable. They further claim that conventional treatment does not result in benefit to the cancer patient but may, in fact, be detrimental to him because of the spread of the disease (metastasis) or mutilation due to surgery, "burning" from irradiation therapy and toxic reactions from hormonal treatment or chemotherapy.

In response to the first claim, it should be asserted that survival from cancer, especially when the condition is detected early and submitted to conventional methods of treatment, does occur. In fact, survival from cancer has improved in the past few decades, in particular for accessible sites, where conventional treatment has been applied.

It is indisputable that the numbers of persons who have cancer or may have it are increasing. Cancer has risen in importance: it is now the second leading cause of death in California and in the nation. Much of this increase -- in absolute numbers -- is due to increased population, and the longer life of that population, since many more persons survive the communicable and childhood diseases which took such a heavy toll in times past.
Despite the increase in numbers of persons affected by cancer in the past generation, noticeable changes in death rates from cancer are evident. This information is based on over 110,000 cancer cases reported to the California Tumor Registry. Figure 1 and Table 1 demonstrate that, for men, stomach cancer has declined substantially as a cause of death during the past 35 years, while lung cancer has increased. For women, cancer of the stomach and uterus have also declined; breast cancer increased, but since 1940 has declined. It is believed that early detection, through the Papanicolaou test for example, has appreciably lowered mortality from cervical cancer; improvements in conventional therapy have influenced improvement in breast cancer.

Survival, however, is the key to whether knowledge, early detection and appropriate treatment can make a difference. As shown in Table 2, from 1942 through 1956, the relative five-year survival rates for many sites of cancer indicate survival improvement: even for lung cancer, a condition often fatal by the time it is detected, survival for five years is achievable. Survival improvement is most marked in the accessible sites, where treatment can be effective especially if the cancer is recognized early and brought to orthodox treatment.

Survival is related to the site of the cancer, the stage (whether localized or metastasized,) and to such socioeconomic factors as where care is obtained, social class and health knowledge of the patient and, of course, the willingness to accept treatment. Table 3 shows that, for some sites, the five-year relative survival rate has improved over the 15-year period, 1942-1956, when cancer is localized. Most marked is the improvement for localized cancer of the cervix uteri and corpus uteri, supporting the merits of the Papanicolaou early detection test.
Another way of stating survival improvement is that 33 out of every 100 cancer patients can be expected to survive at least five years after diagnosis. But the range of survival is wide: survival is greatest for the sites of skin, uterus and breast (44-66 percent); somewhat less for bladder, large intestine, rectum, prostate, ovary, Hodgkin's disease and lymphosarcoma (22-32 percent); survival is low for stomach, lung and leukemia (4-8 percent). For localized cases, all sites of cancer combined, the five year survival rate is 59 percent; but for patients with localized breast cancer and localized uterine cervical cancer, the rates are as high as 72 and 73 percent. Five-year survival rates for localized cancers of the stomach (28 percent) and lung (16 percent) are low, but are almost three times higher than five-year survival rates for all stages combined. Surely, when cancer is localized, the chances of survival are greatest.

Over the period, 1942-1956, it is possible to observe that the proportions of cancer cases diagnosed at a localized stage have increased. (See Table 4) This is encouraging. With public and professional education, and increased accessibility to diagnostic and treatment services, the next decades should show even greater promise for increasing the rate at which cancers are diagnosed at a localized stage -- when chances for survival are the greatest. When persons are deterred from receiving sound diagnosis and treatment for cancer, survival cannot be expected to improve. Cancer quackery's most flagrant abuse is that persons are deterred from seeking proper diagnosis and treatment -- and that chances for survival are substantially impaired.
Figure 1

AGE-ADJUSTED CANCER DEATH RATES (1)
SELECTED SITES FOR EACH SEX
CALIFORNIA, 1930-64

(1) The indirect method of adjustment was used with United States 1940 rates taken as the standard.

State of California, Department of Public Health, Death Records.
### TABLE 1

**AGE-ADJUSTED CANCER DEATH RATES**

**SELECTED SITES BY SEX**

**CALIFORNIA, 1910-1964**

<table>
<thead>
<tr>
<th>SITE AND SEX</th>
<th>1910</th>
<th>1920</th>
<th>1930</th>
<th>1940</th>
<th>1950</th>
<th>1960</th>
<th>1964</th>
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</thead>
<tbody>
<tr>
<td><strong>All Sites</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>96.7</td>
<td>116.6</td>
<td>123.9</td>
<td>126.1</td>
<td>115.3</td>
<td>116.6</td>
<td>114.0</td>
</tr>
<tr>
<td>Female</td>
<td>71.8</td>
<td>102.3</td>
<td>112.6</td>
<td>124.2</td>
<td>119.6</td>
<td>131.4</td>
<td>129.8</td>
</tr>
<tr>
<td><strong>Buccal Cavity and Pharynx</strong></td>
<td>4.6</td>
<td>4.5</td>
<td>4.9</td>
<td>3.9</td>
<td>2.9</td>
<td>3.0</td>
<td>3.0</td>
</tr>
<tr>
<td>Male</td>
<td>52.3</td>
<td>61.1</td>
<td>60.2</td>
<td>54.4</td>
<td>41.7</td>
<td>38.2</td>
<td>35.8</td>
</tr>
<tr>
<td>Female</td>
<td>42.5</td>
<td>61.7</td>
<td>64.6</td>
<td>62.6</td>
<td>49.1</td>
<td>45.4</td>
<td>41.9</td>
</tr>
<tr>
<td>Stomach</td>
<td>66.1</td>
<td>60.7</td>
<td>55.6</td>
<td>46.6</td>
<td>35.3</td>
<td>32.0</td>
<td>30.2</td>
</tr>
<tr>
<td>Male</td>
<td>b</td>
<td>b</td>
<td>27.3</td>
<td>20.6</td>
<td>12.5</td>
<td>9.0</td>
<td>7.5</td>
</tr>
<tr>
<td>Female</td>
<td>b</td>
<td>b</td>
<td>b</td>
<td>26.4</td>
<td>16.9</td>
<td>11.7</td>
<td>10.0</td>
</tr>
<tr>
<td><strong>Female Genital Organs</strong></td>
<td>30.6</td>
<td>33.4</td>
<td>35.7</td>
<td>34.1</td>
<td>25.8</td>
<td>20.7</td>
<td>15.7</td>
</tr>
<tr>
<td>Uterus</td>
<td>b</td>
<td>30.5</td>
<td>29.5</td>
<td>25.2</td>
<td>17.2</td>
<td>12.3</td>
<td>10.7</td>
</tr>
<tr>
<td><strong>Breast</strong></td>
<td>19.0</td>
<td>23.9</td>
<td>26.5</td>
<td>27.9</td>
<td>25.2</td>
<td>23.1</td>
<td>21.7</td>
</tr>
<tr>
<td>Male</td>
<td>b</td>
<td>b</td>
<td>5.0</td>
<td>8.6</td>
<td>13.3</td>
<td>20.4</td>
<td>23.9</td>
</tr>
<tr>
<td>Female</td>
<td>b</td>
<td>b</td>
<td>7.0</td>
<td>13.3</td>
<td>22.8</td>
<td>36.5</td>
<td>40.6</td>
</tr>
<tr>
<td><strong>Respiratory System</strong></td>
<td>b</td>
<td>b</td>
<td>b</td>
<td>2.8</td>
<td>3.9</td>
<td>4.7</td>
<td>6.0</td>
</tr>
<tr>
<td>Male</td>
<td>b</td>
<td>b</td>
<td>b</td>
<td>6.5</td>
<td>11.7</td>
<td>18.9</td>
<td>22.4</td>
</tr>
<tr>
<td>Female</td>
<td>b</td>
<td>b</td>
<td>b</td>
<td>9.7</td>
<td>19.9</td>
<td>34.2</td>
<td>38.2</td>
</tr>
<tr>
<td><strong>Trachea, bronchus and lung</strong></td>
<td>b</td>
<td>b</td>
<td>b</td>
<td>3.3</td>
<td>4.2</td>
<td>5.6</td>
<td>7.3</td>
</tr>
</tbody>
</table>

1. The Indirect Method of adjustment was used with United States 1940 rates taken as the standard.

2. Excludes Hodgkin's disease and leukemias.

3. Includes a few male deaths.

a. Excludes pancreas, esophagus and unspecified digestive organs.

b. Deaths are not separately classified.

c. Includes duodenum.

d. Projected civilian population in California 1964 used to calculate rates.

**Note:** Rates are per 100,000 total, male or female population.


TABLE 2
TREND IN FIVE-YEAR RELATIVE SURVIVAL RATES
MALE AND FEMALE CANCER CASES, ALL STAGES COMBINED
CALIFORNIA, 1942-1956

<table>
<thead>
<tr>
<th>SITE</th>
<th>FIVE-YEAR RELATIVE SURVIVAL RATE (Percent)</th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Sites</td>
<td>29.2</td>
<td>36.2</td>
<td>32.9</td>
</tr>
<tr>
<td>SELECTED SITES</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lung</td>
<td>2.3</td>
<td>1.4</td>
<td>4.3</td>
</tr>
<tr>
<td>Larynx</td>
<td>36.6</td>
<td>41.2</td>
<td>46.3</td>
</tr>
<tr>
<td>Stomach</td>
<td>7.0</td>
<td>10.7</td>
<td>10.1</td>
</tr>
<tr>
<td>Large intestine</td>
<td>22.8</td>
<td>31.7</td>
<td>38.0</td>
</tr>
<tr>
<td>Rectum</td>
<td>1.4</td>
<td>1.4</td>
<td>1.3</td>
</tr>
<tr>
<td>Pancreas</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Breast</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Cervix uteri</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Corpus uteri</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Ovary</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Prostate</td>
<td>35.4</td>
<td>37.9</td>
<td>39.4</td>
</tr>
<tr>
<td>Kidney</td>
<td>22.7</td>
<td>23.8</td>
<td>25.5</td>
</tr>
<tr>
<td>Bladder</td>
<td>32.6</td>
<td>42.8</td>
<td>48.3</td>
</tr>
<tr>
<td>Skin, other than melanoma</td>
<td>84.8</td>
<td>89.7</td>
<td>81.9</td>
</tr>
<tr>
<td>Leukemia</td>
<td>7.1</td>
<td>5.1</td>
<td>6.7</td>
</tr>
</tbody>
</table>

na Not available.

1 Includes in situ cancer.

Note: Rates were calculated by the actuarial method and have standard errors of less than 10 percent.

<table>
<thead>
<tr>
<th>SITE</th>
<th>Male</th>
<th>Male</th>
<th>Female</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Sites</td>
<td>62.9</td>
<td>68.8</td>
<td>62.9</td>
<td>66.2</td>
</tr>
<tr>
<td>SELECTED SITES</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lung</td>
<td>7.6</td>
<td>15.0</td>
<td>15.4</td>
<td>na</td>
</tr>
<tr>
<td>Larynx</td>
<td>na</td>
<td>na</td>
<td>64.5a</td>
<td>na</td>
</tr>
<tr>
<td>Stomach</td>
<td>19.9</td>
<td>40.2</td>
<td>37.4</td>
<td>20.3</td>
</tr>
<tr>
<td>Large intestine</td>
<td>na</td>
<td>na</td>
<td>na</td>
<td>na</td>
</tr>
<tr>
<td>Rectum</td>
<td>na</td>
<td>na</td>
<td>na</td>
<td>na</td>
</tr>
<tr>
<td>Pancreas</td>
<td>2.6</td>
<td>3.8</td>
<td>3.7</td>
<td>0.0</td>
</tr>
<tr>
<td>Breast</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>75.8</td>
</tr>
<tr>
<td>Cervix uteri</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>60.0</td>
</tr>
<tr>
<td>Corpus uteri</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>70.0</td>
</tr>
<tr>
<td>Ovary</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>62.3</td>
</tr>
<tr>
<td>Prostate</td>
<td>57.0</td>
<td>57.7</td>
<td>56.7</td>
<td>-</td>
</tr>
<tr>
<td>Kidney</td>
<td>41.4</td>
<td>51.6</td>
<td>51.0</td>
<td>55.6</td>
</tr>
<tr>
<td>Bladder</td>
<td>46.3</td>
<td>58.8</td>
<td>65.1</td>
<td>43.9</td>
</tr>
<tr>
<td>Skin, other than melanoma</td>
<td>92.9</td>
<td>91.6</td>
<td>84.3</td>
<td>89.8</td>
</tr>
<tr>
<td>Leukemia</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

na Not available.

Includes situ cancer.

Includes cases 1942-56

Note: Rates were calculated by the actuarial method and have standard errors of less than 10 percent.

<table>
<thead>
<tr>
<th>SITE</th>
<th>1942-46</th>
<th>1947-51</th>
<th>1952-56</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ALL SITES, EXCLUDING SKIN</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Both sexes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accessible sites, excluding skin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inaccessible sites</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>MALE</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All Sites, excluding skin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accessible sites, excluding skin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inaccessible sites</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>FEMALE</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All Sites, excluding skin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accessible sites, excluding skin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inaccessible sites</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Includes in situ.

1 Excludes malignancies of the lymphatic and hematopoietic tissues.


In response to other claims made by opponents to conventional therapy, considerable data are available. First, tabulations indicate that the inclusion of skin cancer cases in survival calculations does not substantially alter survival rates (See Table 5). Of great importance to the entire issue of cancer quackery -- and choice of therapeutic methods -- is whether treatment can be effective. Table 6 indicates that for all stages of cancer, in
both males and females, treated and untreated cases combined, by selected sites, have a better chance for survival than those which are untreated. Furthermore, as might be expected, localized cases of cancer have better survival rates than cases with regional or greater spread in the body (See Tables 7 and 8). Even with regional spread of the disease, survival is far greater among cases receiving treatment than among those cases which are untreated (See Table 9). Untreated cases and, by the same token, cases treated with useless remedies have a smaller chance of survival than those treated by conventional therapy -- regardless of whether the disease is localized to one site or spread regionally (See Table 10).

The data used in the tables are derived from three sources: the California Tumor Registry, which records and analyzes information on at least one-third of all cancer cases in the State; the paper, "Survival in Untreated and Treated Cancer," by Dr. Michael B. Shimkin; and the report, *End Results and Mortality Trends in Cancer*, issued by the National Cancer Institute. Data for this latter report are based on cases from more than 250 hospitals in the United States.

Table 5 shows that the influence of including survival rates for skin cancer with those for all sites and stages combined is very slight. The observed five-year survival rate is increased from 55.6 percent to 58.6 percent in localized cases when survival from skin cancer is included. For all stages of cancer, the increase is from 29.1 percent to 33.0 percent.
TABLE 5
FIVE-YEAR OBSERVED SURVIVAL RATES
CANCER CASES, ALL STAGES AND LOCALIZED
CALIFORNIA TUMOR REGISTRY 1942-46

<table>
<thead>
<tr>
<th>Site</th>
<th>All Stages</th>
<th></th>
<th>Localized</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>Survival (Percent)</td>
<td>Number</td>
<td>Survival (Percent)</td>
</tr>
<tr>
<td>All sites</td>
<td>110,229</td>
<td>33.0</td>
<td>43,996</td>
<td>58.6</td>
</tr>
<tr>
<td>Excluding skin except melanoma</td>
<td>97,826</td>
<td>29.1</td>
<td>33,008</td>
<td>55.6</td>
</tr>
<tr>
<td>Skin*</td>
<td>12,403</td>
<td>65.1</td>
<td>10,988</td>
<td>67.9</td>
</tr>
</tbody>
</table>

*Data for skin are for skin other than melanoma.


Table 6 shows five-year survival rates for three groups of cancer patients. The first group consists of untreated cases reported by Forber. These are compared to groups of treated and untreated (most were treated) cases reported to state cancer registries in Connecticut and California. Thirteen sites of cancer, not including skin, are shown. Therefore, the rates are unaffected by the relatively favorable survival rates of patients with skin cancer.

Survival rates for untreated cases indicate the proportion of these cases which survived at least five years -- due to natural survival or duration of the disease. For the 13 selected sites an average of 6 percent of untreated cases survived. This compares unfavorably with 27 percent for the entire group reported by Connecticut and 29 percent reported by California, yielding differences of 21 percent and 23 percent respectively.

Among cases reported to the two state registries, five-year survival rates for cancer of several inaccessible sites -- stomach, lung, esophagus
and pancreas -- were less than 8 percent but for the other nine sites ranged from about 21 percent to 52 percent. Without exception, the experience of the untreated cases was very much worse. None of the patients with cancer of the lung, esophagus and pancreas, and fewer than 2 percent of the stomach cancer patients, survived for five years. The highest survival rate among untreated cases occurred for cancer of the breast: 20 percent. But this compares unfavorably with 46 percent and 50 percent of registry cases. These differences are even more striking than shown because the survival of untreated cases dates from the onset of symptoms while registry cases date from time of diagnosis. Shimkin has calculated that this favors the untreated group by 5.3 months. 6 (The cases from the California Tumor Registry represent 65 percent of all cases reported for the period 1942-56 in California or 73 percent if skin cancer except melanoma is excluded.)
TABLE 6

OBSERVED FIVE-YEAR SURVIVAL RATES
COMPARISON OF UNTREATED CANCER PATIENTS WITH THOSE OF REGISTRY CANCER PATIENTS, CONNECTICUT AND CALIFORNIA

<table>
<thead>
<tr>
<th>Organ</th>
<th>Untreated Cases 1928-29*</th>
<th>Number Cases</th>
<th>Percent</th>
<th>Connecticut 1947-51*</th>
<th>Number Cases</th>
<th>Percent</th>
<th>California 1942-56*</th>
<th>Number Cases</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cervix uteri</td>
<td>75</td>
<td>2.7</td>
<td></td>
<td>1,117</td>
<td>52.5</td>
<td></td>
<td>7,814</td>
<td>50.7</td>
<td></td>
</tr>
<tr>
<td>Breast</td>
<td>517</td>
<td>20.1</td>
<td></td>
<td>2,916</td>
<td>46.2</td>
<td></td>
<td>13,925</td>
<td>49.7</td>
<td></td>
</tr>
<tr>
<td>Larynx</td>
<td>26</td>
<td>0.0</td>
<td></td>
<td>227</td>
<td>37.3</td>
<td></td>
<td>1,192</td>
<td>35.2</td>
<td></td>
</tr>
<tr>
<td>Bladder</td>
<td>33</td>
<td>9.1</td>
<td></td>
<td>759</td>
<td>30.2</td>
<td></td>
<td>4,290</td>
<td>32.4</td>
<td></td>
</tr>
<tr>
<td>Large intestine</td>
<td>73</td>
<td>0.0</td>
<td></td>
<td>2,208</td>
<td>29.0</td>
<td></td>
<td>8,094</td>
<td>28.5</td>
<td></td>
</tr>
<tr>
<td>Buccal cavity</td>
<td>91</td>
<td>2.2</td>
<td></td>
<td>666</td>
<td>25.6</td>
<td></td>
<td>5,048</td>
<td>46.6</td>
<td></td>
</tr>
<tr>
<td>Rectum</td>
<td>95</td>
<td>5.3</td>
<td></td>
<td>1,497</td>
<td>25.3</td>
<td></td>
<td>5,762</td>
<td>27.5</td>
<td></td>
</tr>
<tr>
<td>Ovary</td>
<td>26</td>
<td>0.0</td>
<td></td>
<td>629</td>
<td>23.9</td>
<td></td>
<td>2,711</td>
<td>22.4</td>
<td></td>
</tr>
<tr>
<td>Prostate</td>
<td>30</td>
<td>6.7</td>
<td></td>
<td>1,184</td>
<td>20.6</td>
<td></td>
<td>5,848</td>
<td>25.3</td>
<td></td>
</tr>
<tr>
<td>Stomach</td>
<td>228</td>
<td>1.8</td>
<td></td>
<td>1,518</td>
<td>5.7</td>
<td></td>
<td>6,793</td>
<td>7.9</td>
<td></td>
</tr>
<tr>
<td>Lung</td>
<td>45</td>
<td>0.0</td>
<td></td>
<td>1,203</td>
<td>4.1</td>
<td></td>
<td>6,666</td>
<td>4.2</td>
<td></td>
</tr>
<tr>
<td>Esophagus</td>
<td>57</td>
<td>0.0</td>
<td></td>
<td>364</td>
<td>3.0</td>
<td></td>
<td>1,244</td>
<td>1.2</td>
<td></td>
</tr>
<tr>
<td>Pancreas</td>
<td>73</td>
<td>0.0</td>
<td></td>
<td>490</td>
<td>1.4</td>
<td></td>
<td>2,747</td>
<td>1.5</td>
<td></td>
</tr>
<tr>
<td>Survival 13 sites</td>
<td>1,369</td>
<td>6.0**</td>
<td></td>
<td>14,778</td>
<td>27.0</td>
<td></td>
<td>71,734</td>
<td>29.2**</td>
<td></td>
</tr>
</tbody>
</table>

* In the untreated cases survival is measured from date of onset of symptoms rather than date of diagnosis as in the Connecticut and California cases. They, therefore, have a mean survival advantage of 5.3 months over cases observed from date of diagnosis.

** Adjusted to the distribution by site as found in Connecticut. (Weighted average)

Conventional medicine has long recommended frequent physical examination and early diagnosis and treatment of malignant disease. Although localized and early cancer are not necessarily synonymous, Table 7 shows the substantial increase in observed five-year survival rates for malignant disease treated while still localized compared with malignant disease treated after it has spread beyond the localized stage. Even for cancer of the prostate, stomach, esophagus and lung, where survival rates are poor regardless of stage or treatment, there is a marked advantage for treatment begun while still localized.

**TABLE 7**

OBSERVED FIVE-YEAR SURVIVAL RATES, SELECTED SITES
COMPARISON OF CASES LOCALIZED AND REGIONAL STAGES, BY SEX.
END RESULTS GROUP, 1950-57

<table>
<thead>
<tr>
<th>Organ**</th>
<th>Male Localized (Percent)</th>
<th>Male Regional (Percent)</th>
<th>Female Localized (Percent)</th>
<th>Female Regional (Percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cervix uteri*</td>
<td>-</td>
<td>-</td>
<td>74</td>
<td>40</td>
</tr>
<tr>
<td>Breast</td>
<td>-</td>
<td>-</td>
<td>72</td>
<td>42</td>
</tr>
<tr>
<td>Bladder</td>
<td>52</td>
<td>18</td>
<td>55</td>
<td>18</td>
</tr>
<tr>
<td>Large intestine</td>
<td>51</td>
<td>26</td>
<td>61</td>
<td>31</td>
</tr>
<tr>
<td>Rectum</td>
<td>51</td>
<td>21</td>
<td>57</td>
<td>28</td>
</tr>
<tr>
<td>Ovary</td>
<td>-</td>
<td>-</td>
<td>60</td>
<td>24</td>
</tr>
<tr>
<td>Prostate</td>
<td>34</td>
<td>20</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Stomach</td>
<td>30</td>
<td>9</td>
<td>31</td>
<td>10</td>
</tr>
<tr>
<td>Lung</td>
<td>14</td>
<td>4</td>
<td>31</td>
<td>7</td>
</tr>
<tr>
<td>Esophagus</td>
<td>3</td>
<td>2</td>
<td>13</td>
<td>6</td>
</tr>
</tbody>
</table>

*All histological types.
**Buccal cavity, larynx and pancreas not listed in NCI monograph.

-33-
A similar trend in California is shown in Table 8. Using data from the California Tumor Registry, survival is substantially greater in localized cases when compared with all stages, most significantly in the accessible sites, cervix uteri and breast.

**TABLE 8**

OBSERVED FIVE-YEAR SURVIVAL RATES, SELECTED SITES
COMPARISON OF CASES, LOCALIZED AND ALL STAGES*
BOTH SEXES, TREATED AND UNTREATED
CALIFORNIA, 1942-56

<table>
<thead>
<tr>
<th>Organ**</th>
<th>Localized</th>
<th>All Stages*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number Cases</td>
<td>Survival (Percent)</td>
</tr>
<tr>
<td>Cervix uteri</td>
<td>3,828</td>
<td>73.1</td>
</tr>
<tr>
<td>Breast</td>
<td>5,204</td>
<td>72</td>
</tr>
<tr>
<td>Bladder</td>
<td>2,465</td>
<td>46.4</td>
</tr>
<tr>
<td>Large Intestine</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Rectum</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Ovary</td>
<td>672</td>
<td>58.0</td>
</tr>
<tr>
<td>Prostate</td>
<td>2,492</td>
<td>38.1</td>
</tr>
<tr>
<td>Stomach</td>
<td>864</td>
<td>27.9</td>
</tr>
<tr>
<td>Lung</td>
<td>833</td>
<td>15.8</td>
</tr>
<tr>
<td>Esophagus</td>
<td>224</td>
<td>4.0</td>
</tr>
<tr>
<td>Pancreas</td>
<td>316</td>
<td>3.9</td>
</tr>
<tr>
<td>Larynx</td>
<td>516</td>
<td>52.7</td>
</tr>
<tr>
<td>Buccal Cavity</td>
<td>2,005</td>
<td>67.1</td>
</tr>
</tbody>
</table>

*Includes localized.

**Localized disease in large intestine and rectum not tabulated.
Table 9 shows that the five-year survival rates for untreated cases are much smaller than for those who already have a spread of disease beyond the localized stage at time of initial diagnosis and treatment.

**TABLE 9**

**FIVE-YEAR OBSERVED SURVIVAL RATES**  
**CANCER CASES WITH REGIONAL SPREAD OF DISEASE AT TIME OF DIAGNOSIS AND TREATMENT COMPARED WITH END RESULTS GROUP, 1950-57 AND UNTREATED CASES, 1928-29**

| Organ ** | Regional Spread | Number Cases | Survival (Percent) | | Number Cases | Survival (Percent) |
|----------|----------------|--------------|--------------------|----------|------------------|
| Cervix uteri | Male | Female | Male | Female | 75 | 2.7 |
| Breast | Male | Female | Male | Female | 517 | 20.1 |
| Bladder | 972 | 359 | 18 | 18 | 33 | 9.1 |
| Large intestine | 1,800 | 2,221 | 26 | 31 | 73 | 0 |
| Rectum | 1,453 | 1,236 | 21 | 28 | 95 | 5.3 |
| Ovary | - | 825 | - | 24 | 26 | 0 |
| Prostate | 1,489 | - | 20 | - | 30 | 6.7 |
| Stomach | 1,636 | 809 | 9 | 10 | 228 | 1.8 |
| Lung | 2,943 | 452 | 4 | 7 | 45 | 0 |
| Esophagus | 578 | 144 | 2 | 6 | 57 | 0 |

**Buccal cavity, larynx and pancreas not listed in NCI monograph.**  
In Table 10, the survival rates of cancer patients both localized and in all stages treated conventionally by different methods are compared with rates of untreated cases in all stages of the disease. This tabulation shows that, even in the group comprising all stages of malignancy, the survival rate after treatment with either surgery, radiation or both is, in most cases, tremendously increased over that in the untreated group. Among localized cases, the rates are even higher -- in many cases 10 or more times the rates among untreated cases. Not a single site shows a better survival rate for untreated cases than for conventionally treated, localized cases.

This reinforces the importance of modern conventional therapy -- the treatment of localized disease in which the chances of survival are so greatly increased.
TABLE 10
FIVE-YEAR OBSERVED SURVIVAL RATES
UNTREATED AND TREATED CANCER CASES
SELECTED SITES, TREATED CASES BY STAGE

<table>
<thead>
<tr>
<th>Organ</th>
<th>Conventionally Treated</th>
<th></th>
<th>Localized</th>
<th></th>
<th>Untreated</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>All Stages</td>
<td>Localized</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Surgery</td>
<td>Radiation</td>
<td>Surgery</td>
<td>Radiation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Percent)</td>
<td>(Percent)</td>
<td>(Percent)</td>
<td>(Percent)</td>
</tr>
<tr>
<td>Cervix uteri</td>
<td>86.6</td>
<td>46.5</td>
<td>64.3</td>
<td>91.6</td>
<td>65.4</td>
</tr>
<tr>
<td>Breast</td>
<td>60.3</td>
<td>14.8</td>
<td>47.4</td>
<td>75.4</td>
<td>-</td>
</tr>
<tr>
<td>Bladder</td>
<td>42.1</td>
<td>8.9</td>
<td>24.7</td>
<td>51.7</td>
<td>-</td>
</tr>
<tr>
<td>Large intestine</td>
<td>39.7</td>
<td>0.0</td>
<td>12.0</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Rectum</td>
<td>40.4</td>
<td>12.0</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Ovary</td>
<td>37.9</td>
<td>1.3</td>
<td>28.7</td>
<td>60.3</td>
<td>-</td>
</tr>
<tr>
<td>Prostate</td>
<td>33.3</td>
<td>3.1</td>
<td>15.0</td>
<td>40.3</td>
<td>-</td>
</tr>
<tr>
<td>Stomach</td>
<td>18.2</td>
<td>-</td>
<td>-</td>
<td>39.9</td>
<td>-</td>
</tr>
<tr>
<td>Lung</td>
<td>16.7</td>
<td>0.7</td>
<td>2.3</td>
<td>34.1</td>
<td>3.5</td>
</tr>
<tr>
<td>Esophagus</td>
<td>3.5</td>
<td>0.0</td>
<td>-</td>
<td>8.9</td>
<td>0.0</td>
</tr>
<tr>
<td>Larynx</td>
<td>53.9</td>
<td>28.3</td>
<td>-</td>
<td>64.1</td>
<td>46.9</td>
</tr>
<tr>
<td>Pancreas</td>
<td>8.8</td>
<td>0.0</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>


Clearly, survival from cancer for periods of five years -- or longer -- are documented. Let it not be said either that untreated cases (or similarly, those treated by useless methods) fare better than those receiving conventional therapy. Above all, survival is optimum when cancer is localized -- in an accessible site -- but survival is possible, perhaps for shorter periods of
time, when diagnosis is made at a more advanced stage and when known treatment is given. Each cancer — in each person — has its own course. Conformity is not the rule, any more than it is in other bodily dysfunction. This idea alone should deflate the quack who feels confidence in "curing" all cases which come his way.

TREATMENT OF INTERNAL METASTASIZED CANCER

It has been stated by those opposing orthodox forms of therapy (surgery, radium, X-radiation, hormonal or chemotherapy) that there is not one documented case of cured internal metastasized cancer on record where the patient has been treated with so-called orthodox methods. The facts disprove this claim.

The following examples are but a few from existing documentation.

In 1956, Li, Hertz and Spencer reported the effect of methotrexate therapy on the clinical course and urinary excretion of chorionic gonadotropin in two patients with choriocarcinoma and one with chorio-adenoma destruens. The diagnosis had been established histologically; the extent of the disease determined by physical examination and radiological survey. All three cases had pulmonary metastases. A reduction in size of metastatic lesions and a lowering of elevated urinary chorionic gonadotropin to normal levels excited the author's interest and desire for further study.

In 1961, Hertz, Lewis and Lipsett reported on 63 patients who had unequivocal radiological, hormonal, or clinical evidence of metastatic disease due to choriocarcinoma or related trophoblastic tumors among women who had been treated with methotrexate (MTX) (amethopterin) and/or vincaleucoblastine, a derivative of the periwinkle plant. The urinary hormonal level was used as a major guide in clinical evaluation and therapy.

Four tables excerpted from this latter study are shown here: histologic diagnosis on admission, Table I; location of metastatic disease, Table II;
response to therapy, Table III; and duration of remissions (periods free of
disease), Table IV.

Table I. Histological diagnosis on admission
in 63 women with metastatic trophoblastic
disease.

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Choriocarcinoma</td>
<td>44</td>
</tr>
<tr>
<td>Choriocarcinoma destruens</td>
<td>10</td>
</tr>
<tr>
<td>Hydatid mole</td>
<td>5</td>
</tr>
<tr>
<td>Syncytial endometritis</td>
<td>1</td>
</tr>
<tr>
<td>Trophoblastic nodule</td>
<td>1</td>
</tr>
<tr>
<td>Decidual tissue</td>
<td>2</td>
</tr>
</tbody>
</table>

Table II. Findings on admission in 63
women with metastatic trophoblastic
disease.

<table>
<thead>
<tr>
<th>Finding</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulmonary metastases</td>
<td>52</td>
</tr>
<tr>
<td>Pelvic mass</td>
<td>19</td>
</tr>
<tr>
<td>Vaginal metastases</td>
<td>18</td>
</tr>
<tr>
<td>Intracranial metastases</td>
<td>6</td>
</tr>
<tr>
<td>Bowel metastases</td>
<td>3</td>
</tr>
</tbody>
</table>

Table III. Response to chemotherapy in 63
patients with metastatic trophoblastic
disease (1955 to 1960)

<table>
<thead>
<tr>
<th>Response to Therapy</th>
<th>MTX plus MTX</th>
<th>MTX plus VLB</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>No evidence of disease</td>
<td>28</td>
<td>2</td>
<td>30 (47.5%)</td>
</tr>
<tr>
<td>Persistent disease</td>
<td>2</td>
<td>5</td>
<td>7 (11.0%)</td>
</tr>
<tr>
<td>Dead after remission</td>
<td>16</td>
<td>6</td>
<td>22 (35.0%)</td>
</tr>
<tr>
<td>No response</td>
<td>4**</td>
<td>4</td>
<td>4 (6.5%)</td>
</tr>
</tbody>
</table>

*Thirteen MTX-resistant patients received VLB; 5 showed some regression of tumor and, in 2 of these, complete remission was obtained; the remaining 8 showed no response.

**Three died too early during the course of therapy to permit evaluation of response.

Table IV. Duration of 30 complete remissions*

<table>
<thead>
<tr>
<th>Duration</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 to 5 years</td>
<td>3</td>
</tr>
<tr>
<td>3 to 4 years</td>
<td>3</td>
</tr>
<tr>
<td>2 to 3 years</td>
<td>7</td>
</tr>
<tr>
<td>1 to 2 years</td>
<td>13</td>
</tr>
<tr>
<td>&lt; 1 year</td>
<td>4</td>
</tr>
</tbody>
</table>

*The term "complete remission" indicates total absence of evidence of residual disease by physical, radiological, and hormonal examination (Compiled as of Oct. 30, 1960).
These data were compiled on October 30, 1960. As of June 1, 1961, no patient reported with total remission had experienced a relapse.

Also reported in 1961, Manahan, Benitez and Estralla treated 12 cases of chorioepithelioma by intensive therapy with methotrexate after hysterectomy and bilateral salpingo-oophorectomy.12 Five (41 percent) cases, all with pulmonary metastases, showed complete remission for three years at time of reporting.

In April 1964, Hertz, Ross and Lipsett reported on 111 cases with metastatic disease.13 Of these, 75 had a histologic diagnosis of choriocarcinoma and 36 of chorio-adenoma destruens or other related forms of like origin. All were treated with methotrexate, actinomycin D or vincaleukoblastine, initially or in combination. Complete remissions occurred in 72 cases (64 percent). Six have been in remission for more than five years; 57 for one to four years. These results are tabulated below.

TABLE II

<table>
<thead>
<tr>
<th>Years</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 1</td>
<td>9</td>
</tr>
<tr>
<td>1</td>
<td>12</td>
</tr>
<tr>
<td>2</td>
<td>19</td>
</tr>
<tr>
<td>3</td>
<td>11</td>
</tr>
<tr>
<td>4</td>
<td>15</td>
</tr>
<tr>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>7</td>
<td>2</td>
</tr>
</tbody>
</table>


Manahan, Manuel-Limson and Abad, in 1964, reported on 58 cases of choriocarcinoma seen before methotrexate was available, and 34 cases treated with
methotrexate alone or combined with surgery. In the former group, 16 of
the 58 cases (27.5 percent) treated with hysterectomy were alive after five
or more years. In the group treated with methotrexate alone or combined
with surgery, 22 cases (64.7 percent) were alive two to five years after
treatment. At time of reporting, the death rates were 72.4 percent of the
first group as against 35.2 percent of the methotrexate treated group.

One cannot disregard the known spontaneous clearing of malignant dis-
ease in an unknown number of cancer cases. Neither can one disregard the
regularity of response among patients treated with surgery or a variety
of chemical agents, or in combination, especially considering the minimal
hazard of toxicity. Some internal metastasized malignant disease can be
arrested or cured by conventional (orthodox) means.
CHAPTER 5

CLINICAL TRIALS IN CANCER THERAPY

The Assembly Committee on Public Health in requesting this study, indicated that the "central issue involved is whether testing of remedies should be required before a remedy is banned" under California's Cancer Law.

It should be recognized, at the outset, that "clinical testing" of remedies is not required under the present law. Section 1704 of the Cancer Law dictates that the department (State Department of Public Health) shall:

(c) Secure the investigation and testing of the content, method of preparation, efficacy, or use of drugs, medicines, compounds, or devices proposed to be used, or used, by any individual, person, firm, association, or other entity in the State for the diagnosis, treatment, or cure of cancer, prescribe reasonable regulations with respect to such investigation and testing, and make findings of fact and recommendations upon completion of such investigation and testing.

Sections 1710 and 1711 specify "investigation or testing," and under revisions of the Cancer Law (Chapter 11), these same alternatives are restated. Further sections of the present Cancer Law exempt from investigation and/or testing "any use of any drug, medicine, compound, or device intended solely for legitimate and bona fide investigational purposes by experts qualified by scientific training and experience." Section 1710 states that any testing shall imply neither endorsement of a product's qualifications or value -- nor indictment as useless.
In order to conduct testing, the Department is permitted "as it deems necessary or advisable," to utilize "the facilities and findings of its own laboratories or other appropriate laboratories, clinics, hospitals, and nonprofit cancer research institutes recognized by the National Cancer Institute, within the State or the facilities and findings of the Federal Government, including the National Cancer Institute."

It should be reasserted that prior to the adoption of regulations banning the six remedies so far prohibited for use in cancer management in California, exacting and exhaustive testing by the Cancer Advisory Council and others was considered. Such testing included lengthy tests upon animals, thorough chemical and microbiological analyses and toxicity studies. In the case of Koch Synthetic Antitoxins, the Cancer Advisory Council reviewed carefully a clinical trial conducted in Detroit some years ago by the Wayne County Medical Society. Testing by the Cancer Advisory Council, although sometimes duplicating the work of the Federal Government and other research institutions, did provide additional supportive data of value. Distinguished scientists and countless technicians in California and elsewhere, working under sound scientific procedures, have been involved in meticulous testing of the type required by the Cancer Law.

Opponents to conventional therapy and to the Cancer Law have challenged that clinical trials should be conducted by the Cancer Advisory Council before an agent is banned. Clinical trials -- under the most optimum conditions -- in treatment of any mortal disease are difficult; none more so than those recommended for testing cancer therapy. However, procedures for the testing of potentially useful cancer agents have been evolved by the Cancer Chemotherapy National Services Center (CCNSC)
of the National Cancer Institute. Prior to the initiation of clinical trials, the effectiveness of the agent or drug is determined against a variety of tumors in experimental animals (e.g., mice, rats, hamsters, etc.). Its effectiveness against such an animal screen must be correlated with the toxicity (side effects) and/or physiological action of the compound. Sometimes an agent or drug is additionally tested against cancer cells being grown in tissue culture. In the event that the compound shows promise of potential effectiveness as the result of these types of laboratory studies, the compound is then considered suitable for clinical trials, the basic rules for which have been evolved by the Clinical Branch for Collaborative Research of the CCNSC. Certain standards with reference to the compound, and regulations regarding the people who will use the compound (clinical investigators), are established by the Federal Food and Drug Administration; certification for compliance is required. When these conditions are met, the clinical investigation proceeds in three types of sequential studies (Phase I, II and III), with the understanding that the investigation may be terminated at any given time. This is to insure the welfare of the patient. Phase I studies are concerned with determining the toxicity, if any, of the compound when given to cancer patients; small doses are used initially and gradually increased until signs of toxicity are obtained. The nature and purpose of the study is explained to those patients who agree to participate. Although the patients selected have advanced or disseminated disease -- no longer amenable to conventional means of therapy (e.g., surgery and irradiation) -- it is essential that they be in otherwise fairly good health and not "terminal."
Phase II studies are initiated in the event that the toxic and undesirable effects of the compound have been demonstrated not to be prohibitive. These studies are designed to determine effectiveness of the compound against various types of human cancer. For those compounds with demonstrated anti-tumor effects in patients, Phase III studies may be initiated to compare the effectiveness of a compound with other anti-tumor compounds or modalities of therapy of known efficacy which may be used as standards. Thus, Phase III studies are established preferably on a double blind basis, so that neither the investigator nor the patient knows the identity of the compound administered in any given case until conclusion of the study. Whereas relatively few patients (a minimum of 14) are required in Phase I, many are required in Phase II and III studies. In the instance of patients with certain types of tumors, years may be required before an accurate evaluation can be made — an evaluation which in some cases is based upon survival.

Were this same procedure applied to obviously worthless remedies, a cancer quack could continue to dispense the agent under testing for a number of years; patients used in the test would be deprived of approved, orthodox treatment for cancer; the quack would be given license to flourish; and the Cancer Law greatly weakened in its effectiveness.

The foundation of science lies in observing the rules of evidence. Without a scientific basis for hope, established (in this case) particularly by testing on animals, clinical testing on human beings is unjustifiable. Whenever animal experiments or other means justify expectations of favorable benefit to humans, then testing could be conducted — under strict scientific direction — to ascertain degrees of effectiveness.
This premise governs scientific endeavors in all disciplines. It is the foundation upon which vaccines have been developed and new methods of medical management in the treatment of all manner of human ills. It is the same premise which is applied in space technology and other new frontiers of knowledge.

In considering the merits of clinical testing -- of clearly promising as well as unlikely therapeutic agents -- the following statements by Dr. David Karnofsky are appropriate to cite:

"... A patient entrusts his doctor with his hope for continuing survival, for relief of symptoms and for restoration of good health. Irrespective of the patient's position, economic resources, personality or medical problem, the physician is obligated to do all in his power to accomplish these ends. This is a trust that cannot be violated....

"First, nothing should be taken for granted in reviewing the situation of a patient with advanced cancer. Serious errors affecting the survival of the patient have been made because treatable complications or unrelated disturbances were attributed to disseminated cancer. A careful analysis of the problem can lead to effective treatment.

"Secondly, even in advanced cancer, appropriate treatment, adequately supplied, can produce remarkable results. Any physician experienced in treating cancer can cite moribund patients, beyond reasonable hope of help, who responded miraculously to specific therapy. They occur often enough so that, for this reason alone, aggressive therapy is indicated. (See also Chapter 4 regarding improvement in survival.)
"Third, the vast majority of patients are eager to live and they and their families insist on vigorous and continuous therapeutic efforts. The doctor must maintain a positive therapeutic attitude. To do less may drive the patient, in his desperation, to a quack who will satisfy his need for active treatment with worthless drugs and dishonest promises. (Emphasis added)

"Finally, and perhaps the most important reason for aggressive treatment is to avoid defeatism, which is a major barrier to advances in medical knowledge...If the doctor attacks each problem with vigor and optimism, however discouraging the outlook, he may win great victories and will make far fewer mistakes subsequently than his dispirited colleagues.

"A distinction must be made between the application of established measures and the use of experimental drugs or procedures. The practitioner is only obliged to use conventional treatment and should not be expected to use unproven and possible dangerous experimental procedures. Furthermore, an isolated clinical trial cannot produce meaningful data useful in assessing the value of a method. In appropriate situations, patients should be referred to clinical investigators in specialized hospitals or research centers, where the new procedures, under controlled conditions, can be applied to determine their usefulness in specific clinical situations." (5)"
New methods of treatment for cancer are always being considered and explored. Around the world, thousands of scientists address themselves to this mission. But they are cautious. Here, in California, at our leading research and medical institutions, new methods of surgery, irradiation, chemotherapy and hormonal therapy are being investigated and clinical trials are staged -- under strict scientific rules: the rules of evidence.

Such clinical trials mean designing patient studies so that results measured by completely objective criteria can be compared. Impression, intuition, opinion cannot enter into valid judgments.

Any new agent or method of cancer therapy must be carefully scrutinized. When applied, it must be evaluated according to three determinations: the natural course of the disease (cancer), its site and degree of advancement; 2) the extent to which existing therapeutic means can influence the course, as opposed to giving no treatment at all; and 3) the results obtained when proved, orthodox means of therapy are applied.

In 1964, Dr. Michael Shimkin wrote of the evaluation of anti-cancer treatment: "In cancer, which is fatal unless its course is interrupted by definitive treatment, the most obvious first question in the evaluation of any new treatment is whether it improves the survival of the patient."

Among scientists, clinical testing of worthless remedies is regarded with considerable skepticism, even using animal -- not human -- subjects. In a letter to Dr. Kenneth Ernst dated September 13, 1960, Dr. Alfred Gellhorn, Professor and Medical Director of the Institute of Cancer Research, Columbia University College of Physicians and Surgeons, wrote:
"...It is unwise for professional bodies such as yours to attempt to set up scientific laboratory and clinical testing of what appear to be fake remedies. This position has been reached because of the very real difficulties in the conduct of an evaluation of a bona fide drug, both at the experimental and clinical levels...A comprehensive laboratory evaluation of a compound would require many tumors and many animals, and I believe you would find it increasingly difficult to enlist the aid of competent laboratory groups for this type of scientifically profitless investigation...."

On the matter of employing human subjects for clinical testing of fake remedies, Dr. Gellhorn is even more committed:

"...I completely agree with the proposition...that it is thoroughly indefensible to subject human patients to trials of compounds for which there is neither experimental nor clinical evidence of their usefulness. In short, I believe that it is far wiser to demand of the proponents of unorthodox remedies that they present evidence of the same type which is demanded by members of the medical profession to substantiate their claims that they have an agent or agents that are useful in the treatment of clinical cancer."

(Emphasis added).

Underlying Dr. Gellhorn's statement is this fact: for any agent to be used in the treatment of any disease, the rules of evidence must be observed.

If evidence, collected systematically, according to known and approved methods, can be offered for evaluation, then the treatment can be scrutinized according to scientific standards. To offer inaccurate, incomplete,
let alone implausible, documentation of clinical testing in humans, natu­
urally exposes the fraudulence of an agent. But to extend well-documented,
meticulously gathered data from a clinical trial, designed and conducted
along sound scientific bases, warrants a reasonable hearing.

From many points of view, clinical testing of purported worthless
remedies upon human beings is not in sound judgment. If the proponent of
an agent observes traditional rules of evidence, he can be expected to
have conducted animal tests and possibly proper clinical tests among
volunteer humans. This evidence he should offer as part of that being
reviewed when the agent's efficacy is being challenged.

In summary, the following reasons are given for not requiring that
clinical tests be conducted prior to banning a worthless remedy under the
Cancer Law:

1. **It is the responsibility of a scientist to observe the rules**
   of evidence. The proponent of an agent should be responsible
   for presenting his own clinical experience, just as any
   reputable scientist must do. It is not the responsibility of
   the legally-constituted Cancer Advisory Council to engage in
   clinical research.

2. Proof of efficacy should be required under the Cancer Law as it
   is under the Federal and State Food and Drug regulations.

3. **It is improper to deprive individuals of access to known,**
   proved forms of therapy. Hence, enlisting patients for clin-
   ical studies of untested remedies might not only be unfeasible
   but unethical.

4. In a "profitless investigation," enlisting adequate number of
   subjects would be unlikely; the very requirements of Phase I,

-50-
II and III studies could probably not be realized and hence such studies would be of dubious scientific merit.

5. Enlisting clinical investigators to conduct such studies would be even more improbable. The conduct of clinical medicine is not the province of the State Department of Public Health or the Cancer Advisory Council. While other types of analyses may be contracted for, in compliance with Section 1711 of the Cancer Law, clinical studies of suspected or obviously worthless remedies would be difficult to negotiate with any reputable scientific organization.

6. Clinical testing, especially of material which is designed to extend or salvage human lives, must be time-consuming if it is reliable.

7. The costs of clinical testing are enormous. As indicated later (Chapter 8), clinical tests conducted by the Cancer Chemotherapy National Service Center of materials previously suggesting therapeutic properties cost millions of dollars.

8. Were the practical, ethical and scientific aspects described above resolved, clinical testing would permit the proponent of a worthless remedy to operate during the course of a test. The effectiveness of the Cancer Law would be severely challenged as he could continue his business while the mechanism of the Cancer Law was directed toward him.

9. If the State undertook to conduct clinical testing of agents submitted for the treatment of cancer a precedent would be established for similar testing of all drugs including those prepared for the treatment of other diseases.
To perform clinical tests of worthless remedies on human subjects, the practical, ethical and scientific factors outlined above would have to be seriously weighted, and solutions found. Moreover, the present investigatory body, the Cancer Diagnosis and Therapy Evaluation Unit would have to be enlarged and enriched with greatly increased monies.

At present, justification for clinical testing of suspected quack remedies has not been established.
In November, 1956, the Committee on Cancer Diagnosis and Therapy of the National Academy of Sciences - National Research Council published a statement of criteria by which proposed therapeutic and diagnostic procedures pertaining to human cancer could be evaluated. These criteria -- achievable standards -- would permit scientists and investigators to use a single set of procedures and interpretations in order to compare the results of different evaluation studies. These criteria serve as guidelines and determinations in an area where objective interpretation is of special importance.

Technology, even since 1956, has broadened the scope of cancer therapy. The entire field of chemotherapy, and its benefits on certain types of cancers during varying degrees of severity, has been enlarged since 1956. Therefore the original criteria might, in fact, not be thorough or exact enough. The Council, as a body, reviewed and edited proposed new criteria which at present include only those Criteria for the evaluation of treatment agents. Revisions of Criteria To Evaluate Diagnostic Procedures in Cancer are being contemplated.

This material is provided to define the meticulous analysis which must be undertaken in evaluating any form of cancer therapy. These are the criteria by which bona fide investigators can critically measure whether a form of therapy is beneficial. Using such criteria, an evaluation study can take years of preparation and careful work. Were these criteria applied to evaluate clinical studies of questionable remedies, it is obvious that an equal amount of time and resources would be essential. In the interim, patients given the questionable remedy would have died of their cancers, the quack would maintain his privilege of "business as usual," and the effective enforcement of the Cancer Law would be considerably impaired. Under the existing Cancer Law, a proponent of a suspect cancer therapeutic agent may submit any records of
clinical trials and evaluation studies he has conducted. These trials should, of course, conform to the standards approved by the National Research Council. To date, where clinical records have been supplied for evaluation, they have not conformed to the standards. They have been deficient in detail, objectivity, and reliability.

The term cancer is applied to a group of diseases that arise in different tissues and in many body sites. Much knowledge has been accumulated on the more frequent types of cancer, their general pattern of behavior and the results of various methods of therapy. Although neoplasms from the same location and of similar histologic type generally follow a predictable course, there are individual variations in behavior and survival time. Moreover, other forms of cancer develop different patterns.

Therefore, cancer is an exceedingly variable group of diseases. Neoplasms of different types and sites vary in their rate of growth, their tendency to spread to different tissues and the multiplicity of symptoms to which may give rise. Even in untreated cases the duration of life may show wide range, remissions may occur, and occasional instances of spontaneous regression or even clinical cure have been reported.

The section which follows describes the meticulous criteria and technical analyses essential to evaluate material or a procedure which is therapeutic for cancer. Were clinical studies of unproved cancer remedies feasible and advisable, these criteria would have to be met.
CRITERIA FOR EVALUATION OF CANCER THERAPY IN MAN
ADOPTED BY
CANCER ADVISORY COUNCIL, STATE OF CALIFORNIA, OCTOBER 13, 1965

A. Basic Principles for Evaluation Studies:

In investigating the merit of any new proposal for cancer therapy, many factors must be considered, the following steps are essential:

1. Verification of the Diagnosis of Cancer, together with information on its type, site, and extent. This applies to primary metastatic and recurrent forms of the disease.

2. Observations on the Effects of the Therapy under Study by treatment of a sufficient number of patients with cancer, that the nature and consistency of the results may be known in comparison with a statistically valid control group.

   The number of patients and the period of therapy cannot be determined until results of preliminary trials are available.

3. Assessment of the Results of the Treatment for each case in relation to previous or concomitant other therapy and in comparison with the natural course of the disease and the response observed following other usual methods of treatment.

   It is essential that the clinical investigators be experienced in the observation and treatment of the disease. Their clinical judgment, objectivity and integrity are important in the conduct of evaluation studies.

   The following general criteria have been adopted.

B. Criteria for Diagnosis:

1. Diagnosis of Cancer. Histologic verification of the tumor is essential and the slides (and preferably tissue blocks or tissue must be available for review.) The diagnosis should include information on the type of neoplasm, its site and the extent or stage of the disease.

2. Other Criteria, such as X-ray studies, Papanicolaou smears and gross appearance of the neoplasm, are helpful both in diagnosis and in following the course of the disease.

   These criteria may be acceptable for observing the progress of a previously biopsied cancer, the course of which is consistent with the known natural history of the given lesion.

3. Chemical, Blood and Other Ancillary Studies may be of assistance in specific forms of cancer; they are not recognized as a valid sole basis for diagnosis, or for determining the extent or prognosis of the disease.
Certain studies in steroid metabolism, or certain constituents in blood, such as acid phosphatase levels, are recognized as important indicators of specific types of neoplasms in man but alone are not adequate.

C. Criteria for Response to Therapy:

There are two aspects which determine the response to treatment: the criteria used in measuring response and the simple method of determining whether the treatment was beneficial to patient.

Before any patient with the diagnosis of cancer or leukemia should be studied on a new and unproved method of therapy, certain criteria should be fulfilled in addition to the diagnosis of cancer. All prior therapy should be listed with date, amount, anti-tumor effect and toxicity noted in both qualitative and quantitative terms as well as duration of any anti-tumor effect of the chemotherapeutic agent. Lesions which have been the site of radiotherapy may be not used to evaluate a new agent unless these lesions have shown an increase of 50 percent in the sums of the products of two major diameters of the lesions being measured. In this case, where a lesion has increased in size following previous radiotherapy, this lesion can be used to assess the results of chemotherapy.

No patient can be entered on a study until three weeks after discontinuance of any previous cancer chemotherapy and then only if there is no evidence of continuing toxicity from the previous treatment. The patient who has had a response to previous therapy must have objective evidence of relapse, by which is meant a 50 percent or more increase in the sum of the products of the two major diameters being measured, or the appearance of a new lesion, before the patient may be given a new cancer chemotherapeutic drug. Patients with mammary carcinoma who have previously had a remission or regression of tumor while on additive estrogen or androgen therapy may not be studied with a new cancer chemotherapeutic agent until two months
after the patient has been taken off the hormone which originally induced a regression in order to avoid "rebound regression" seen in approximately 10 percent of the patients who originally have had remissions while on steroid therapy, or 6 months following ablative androgen or estrogen therapy. The patient must be on no known concomitant anti-tumor therapy at the time the new drug is being tested. Radiotherapy, hormonal therapy with androgens, estrogens, corticosteroids, ablative hormonal operations and procedures, or chemotherapy are all considered anti-tumor therapy for particular tumor types.

In the evaluation of an anti-tumor effect only objective decrease in the size of measurable lesions (also see criteria below for evaluating patients with acute leukemia) can be accepted as demonstrating anti-tumor effect by the compound under study. Subjective effects such as pain relief, increased appetite, weight gain, increased activities and other symptomatic improvements should be noted and recorded but in themselves are not evidence of an anti-cancer effect. It is important and should be emphasized that there is not always one to one correlation between subjective benefit and objective shrinkage of tumor. An accurate estimate of benefit obtained from cancer chemotherapy is the following:
Categories of Response

Category O: No Clinically Useful Effect on the Course of the Disease.

- 0-0 Disease progresses - no subjective benefit.
- 0*A Disease progresses - subjective benefit without favorable objective changes.
- 0 B* Favorable objective changes without subjective benefit.
- 0*C Subjective benefit and favorable objective changes in measurable criteria, but of less than one month's duration; then the disease progresses.

Category I: Clinical Benefit With Favorable Objective Changes in All Measurable Criteria of the Disease.

- I*A* Distinct subjective benefit with favorable objective changes in all measurable criteria for one month or more.
- I*B* Objective regression of all palpable or measurable neoplastic disease for one month or more in a relatively asymptomatic patient, who is able to carry on his usual activities without undue difficulty. The observed tumor regression should be unequivocal and it is suggested that all lesions be reduced at least 50 percent in bulk (or by the sum of the products of two diameters). This category applies as long as the regression persists and ends if any lesion, old or new, recurs.
- I*C* Complete relief of symptoms, if any, and regressions of all manifestations due to the active disease for one year or more. The relation to the frequency of therapy is not relevant, if the disease does not recur between courses of therapy.

*Categories apply as long as improvement from baseline persists. Superscript time in months of duration of response. Example: 0*A or I*B3.

Category II: Interruption or Slowing in the Progression of Disease Without Definite Evidence of Subjective or Objective Improvement.

No criteria are presently available to classify this type of response. Statistical evidence of prolongation of survival time in specific patterns of cancer may some day be applicable.

The adequacy of the course of therapy should be defined in the patients who complete the course of treatment. In most cases therapy is given to the point of toxicity in order to give the maximum opportunity
for an anti-cancer effect. This then would represent an adequate trial unless tumor regression and a satisfactory clinical response occur before any signs of toxicity appear. The levels of toxicity should be recorded on each patient visit along with an estimate of the category of response. The suggested estimated levels of toxicity are as follows:

**Levels of Toxicity**

1+ - Slight but measurable signs.
2+ - Moderate disturbances related to drug effect.
3+ - Toxicity severe enough to be life-threatening but patient recovers.
4+ - Toxicity either directly lethal or as proximate contributing cause of death.

In addition to the measurements of tumor one should evaluate the patients subjective status as well. In this regard, pain, appetite, weight measurements, and activity status should be recorded. A useful estimate of performance status is that developed by Dr. David Karnofsky of the Sloan-Kettering Institute in New York City which follows on the next page.

In the evaluation of an agent, reproducibility of response with the same agent in the same patient when relapse occurs; and the reproducibility of response from patient to patient within a single tumor diagnostic type or in patients with different types of cancers is important. Correlation of tumor response among different forms of cancer; the survival rate among patients treated as compared with patients not receiving this therapy; and the cure rate among patients treated with this agent as compared to those who do not receive this therapy are all important.

Finally, in the evaluation of any agent accurate observation and complete records of patient visits, patient complaints, patient
examinations including examination of pertinent physical findings on each visit, as well as accurate tumor measurements, patient's weight, drug doses prescribed and taken by the patient, as well as laboratory reports and X-ray films, etc. are indicative of the care with which any investigation has been performed.

**Criteria of Performance Status (PS)**

<table>
<thead>
<tr>
<th>%</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>Normal; no complaints, no evidence of disease.</td>
</tr>
<tr>
<td>90</td>
<td>Able to carry on normal activity; minor signs or symptoms of disease.</td>
</tr>
<tr>
<td>80</td>
<td>Normal activity with effort; some signs or symptoms of disease.</td>
</tr>
<tr>
<td>70</td>
<td>Cares for self; unable to carry on normal activity or to do active work.</td>
</tr>
<tr>
<td>60</td>
<td>Requires occasional assistance but is able to care for most of his needs.</td>
</tr>
<tr>
<td>50</td>
<td>Requires considerable assistance and frequent medical care.</td>
</tr>
<tr>
<td>40</td>
<td>Disabled; requires special medical care and assistance.</td>
</tr>
<tr>
<td>30</td>
<td>Severely disabled; hospitalization is indicated, although death not imminent.</td>
</tr>
<tr>
<td>20</td>
<td>Very sick; hospitalization necessary; active supportive care necessary.</td>
</tr>
<tr>
<td>10</td>
<td>Moribund; fatal processes progressing rapidly.</td>
</tr>
<tr>
<td>0</td>
<td>Dead</td>
</tr>
</tbody>
</table>
D. Criteria for Evaluating Chemotherapy in Acute Leukemia:

For patients with acute leukemia the criteria for evaluating chemotherapy are different. In this instance one evaluates separately the bone marrow, the peripheral blood findings, the physical findings, and the symptomatology. Each of these four areas have been listed as category. M for bone marrow; H for hemogram; P for physical findings and S for symptomatology. These are defined below along with the criteria for rating disease status and the terms for describing the response to therapy.

1.0 Criteria for rating categories

1.1 Bone Marrow (Category M)

1.11 Ratings for Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Blast Cells</th>
<th>Leukemic + Blast Cells*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parameter</td>
<td>Rating</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>0-5</td>
<td>0-5</td>
</tr>
<tr>
<td>2</td>
<td>6-25</td>
<td>6-39</td>
</tr>
<tr>
<td>3</td>
<td>25</td>
<td>39</td>
</tr>
</tbody>
</table>

1.12 Ratings for Category M

Rating of this category will be determined by the most abnormal parameter found. Bone marrows qualifying for M1 ratings must contain qualitative and quantitative normal erythropoiesis, granulopoiesis, and megakaryopoiesis.

1.2 Hemogram (Category H)

1.21 Ratings for Parameters

<table>
<thead>
<tr>
<th>Rating</th>
<th>Hemoglobin</th>
<th>Neutrophilic Granulocytes</th>
<th>BLASTS*</th>
<th>Platelets</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>M 12 F 10</td>
<td>1,500</td>
<td>0</td>
<td>100,000 (phase) or normal</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>500</td>
<td>&lt;5%</td>
<td>≤100,000 or decreased</td>
</tr>
<tr>
<td>3</td>
<td>&lt;7</td>
<td>&lt;500</td>
<td>25%</td>
<td>≤25,000 or 25% of normal</td>
</tr>
</tbody>
</table>

*This term includes blast cells as well as all cells which cannot be classified as either blast cells or more mature normal elements, and includes "leukemic cells," "pathologic lymphocytes," and stem cells.
1.22 Ratings for Category H
The rating for category H is determined by the sum of the ratings for all of the parameters (hemoglobin, neutrophilic granulocytes, blast* cells, and platelets). Rating indicating improvements in this category must not be ascribable to transfusion of any blood elements. Mononuclear cells must not exceed 7,000 cells/cumm (10,000 for < 2 years) for an HI rating. The appearance of 1-2% of blast cells on an isolated count will not preclude an HI rating.

<table>
<thead>
<tr>
<th>Rating</th>
<th>Sum of Parameter Ratings</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>3</td>
<td>&gt;8</td>
</tr>
</tbody>
</table>

1.3 Category P - Physical Findings

1.31 Ratings for Each Parameter
Each physical finding constitutes a measurable parameter. The degree of abnormality for each parameter will be rated as follows:

a. Liver
   1 = within normal limits of age
   2 = definite enlargements (to umbilicus)
   3 = enlargement below umbilicus

b. Spleen
   1 = within normal limits for age
   2 = definite enlargement (to umbilicus)
   3 = enlargement below umbilicus

c. Lymph Nodes
   1 = within normal limits
   2 = definite enlargement
   3 = massive enlargement (grossly visible)

d. Other Leukemic Organ Involvement
   (If present, note and score separately; skin, CNS, kidney, lungs, etc.)
   1 = none
   2 = definite
   3 = marked

1.32 Ratings for Category P
The final rating for Category P is based on the sum of the numerical values given to each Parameter.

* This term includes blast cells as well as all cells which cannot be classified as either blast cells or more mature normal elements, and includes "leukemic cells," "pathologic lymphocytes," and stem cells.
<table>
<thead>
<tr>
<th>Category P Rating</th>
<th>Sum of Parameter Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>= 4</td>
</tr>
<tr>
<td>2</td>
<td>= 5-8</td>
</tr>
<tr>
<td>3</td>
<td>&gt; 8</td>
</tr>
</tbody>
</table>

1.4 **Category S - Symptoms**

Rating for Category S is determined by the performance activity of the patient ratings listed below:

1 = Asymptomatic and normal activity
2 = Symptomatic with normal or limited activity but less than 50% of normal waking hours in bed.
3 = Symptomatic with more than 50% of time in bed.

II. **Criteria for rating disease status**

A. **No Evident Disease:** A rating of one in all categories (M1 H1 P1 S1)

B. **Moderate Disease:** A rating of 2 in one or more categories but no rating of 3 in any category.

C. **Extensive Disease:** A rating of 3 in one or two categories.

D. **Extreme Disease:** A rating of 3 in more than two categories.

III. **Terms for describing the response to therapy**

A. **Complete Remission (CR):** Improvement to disease status A.

B. **Good Partial Remission (GPR):** Improvement to disease status B.

C. **Poor Partial Remission (PR):** Improvement to disease status C.

D. **No Remission (NR):** No change in any status

E. **Progressive Disease (PD):** Deterioration from initial disease status or, if initially in status D, documented deterioration in any category.
CHAPTER 6

THE CANCER LAW -- WHY?

The preceding text serves as the background against which the Cancer Law should be viewed. It is both because cancer is a difficult and unpleasant disease, and because fraud in its diagnosis and treatment can be so devastating, that legal means to curb this menace became so urgent. The combination of factors is one which encourages quacks: a disease which is on the increase, which can be fatal, which may involve costly treatment, personal sacrifice, and anxiety; a population which is not consistently well-informed, or even when informed willing to act; a legal setting hospitable to naturopaths, health fanatics, and other non-professional "practitioners" of medicine. California could offer cancer quacks a fertile market.

HISTORICAL DIGEST

Cancer quackery, in California and elsewhere, has been but one form of medical chicanery which plagues mankind. And only since the passage of the Federal Food and Drug Act in 1906, its amendment in 1912, complete revision as the Federal Food, Drug, and Cosmetic Act of 1938, and subsequent repeated amendments, have the advertised remedies -- tonics, serums, mechanical devices, innocuous pills and palliatives -- been subjected to a degree of scrutiny limiting the public's susceptibility to medical fraud. Despite the protection afforded by the Act, medical fraud has continued to be a serious practice, more than a billion dollars expended fruitlessly each year by individuals in pursuit of false cures and false hopes.

Part of the reason is that the Federal Food, Drug, and Cosmetic Act -- and its state counterpart, the California Pure Drugs Act -- are
limited in their application. The Federal law is concerned only with
interstate shipment of new or experimental drugs, with particular atten-
tion being directed to whether they bear appropriate warnings regarding
use. It is not concerned with devices, but does pertain to commercial
drug preparations; those used for prescriptions and those used experi-
mentally by investigators. Also, under the State law, it is illegal to
advertise that a drug or device has any effect in the management of some
48 diseases, including cancer. Quite naturally cancer quacks do not
invite regress by advertising their wares -- at least not as cancer cures.
Despite the complexities of the Food and Drug Laws, they cannot restrain
from use many of the drugs and devices used by cancer quacks; however, in
a case in which a drug is being touted as an "investigational new drug,"
interstate shipment can be halted by the Federal Food and Drug Adminis-
tration if an effective new investigational drug application has not
been filed with the Administration. It is neglect of this legality and
the failure to submit adequate samples for evaluation which may lead to
serious difficulty with FDA: Krebiozen is a case in point.

But until 1959, cancer quackery throughout this nation remained
virtually untouched by existing law. Thousands of Californians, seek-
ing relief from their anxieties, spent millions of dollars on useless
quack "cures." Many persons sought quacks after receiving recognized,
conventional therapy; many avoided such therapy; many persons were
advised unwisely that they had cancer when in fact they did not. On
whose conscience does such wasted effort and expense reside? Surely not
on the quack's.

But in 1959, the California Legislature passed Senate Bill 194,
providing a means for combating medical quackery in the diagnosis and
treatment of cancer. This pioneer legislation was signed into law, June 5, 1959, and became Chapter 7, Sections 1700-1721 of the Health and Safety Code. (Appendix I)

The enforcement of the Cancer Law became a responsibility of the State Department of Public Health, assisted by the Cancer Advisory Council, a 15-member group of physicians, scientists, and laymen. Members of the Cancer Advisory Council are appointed by the Governor. (Appendix III: Members of the Cancer Advisory Council, November 1965, and Previous Members).

The Cancer Law, as originally written and passed, was to expire December 31, 1965. In the current Regular Session of the Legislature, after full hearings, the Cancer Law, without revisions, was extended two years. (Appendix II)

Among the materials presented in hearings was the report, The Cancer Law 1959-1964. It elucidates the history of medical quackery, with particular emphasis on its prevalence in California. It also discusses the difficulties in developing appropriate legislation to reduce medical quackery. Detailed discussion of the six agents prohibited to date through operation of the Cancer Law indicate the colorful diversity found among fake cancer remedies, as well as describing the extensive investigatory and hearing procedures observed before definite action was taken.

This pioneer law is the prototype of similar legislation enacted in Nevada, Colorado and Pennsylvania, and the model for regulations to control cancer therapy in Kentucky, North Dakota and Maryland.

Beneath the factual framework about the Cancer Law, how it operates and what it has accomplished, are myriad case histories of individuals
duped by fake cancer remedies. These stories are perhaps more factual and vivid than any narration of legislative procedure. Such case histories need no embellishment to resemble the truth. And the number of admitted episodes of cancer quackery is but a small sample of those which exist in total. For many individuals become so ensnared by the trap of cancer quackery that they never report their misjudgment to authorities. It is entirely possible that those cases which come to the attention of the Cancer Diagnosis and Therapy Evaluation Unit are but the visible tenth of the giant iceberg beneath. The Cancer Law is the first legal means to assuage the grief of many individuals "taken in" by cancer quacks.

California has been host to charlatans of all dispositions throughout its history. It is not a fact of which to be proud. Prior to this decade, the State proved a happy hunting ground for memorable cancer quacks: Dr. Albert Abrams, Dr. Ruth Drown, and the "Film-Q-Sonic" trio, Webster Billington, Emerson Hartman, D.C., and Golda Franzen. Against their activities, and those of their companions in fraud, existing California law was only partially operative. Summing up the background of medical chicanery which flourished in California is this statement from the report, The Cancer Law 1959-1964:

"One observation may be made by citing these three episodes which took place in California: outrageous as they were, the legal process to thwart them was at best stunted or virtually incapable of preventing great harm to be performed on unsuspecting patients. The desperation of a victim of cancer is real; cancer quacks thrive upon this emotional guarantee. Desperation also prevents victims from reporting their doubts.
to the proper authorities. Beyond educating the public to be more sophisticated about legitimate, credible cures for cancer, the legal means of curbing cancer quackery must be structured to compensate for human fallibility."

Such was the setting when the Cancer Law was enacted. Responsible citizens, physicians, scientists could not but insist that some legal means be developed to contain this scourge. While activities of the California Cancer Commission of the California Medical Association are devoted to investigating all purported treatments for cancer, the Commission is not vested with any legal powers or restraint from use or distribution of agents they find ineffective in the treatment of cancer. Apart from exposing bogus cancer cures through public information channels, an admittedly slow process, the Cancer Commission has no power to "outlaw" or "ban" an agent or bring civil redress to its proponents.

But the Cancer Law, for which the Cancer Commission and others worked to realize, does provide a legal mechanism to investigate and evaluate diagnostic and treatment agents used in cancer management. It further provides that, after evaluation, the opinion of the Cancer Advisory Council, through its recommendation to the Director of Public Health, can result in adoption of a prohibitory regulation. Moreover, persons found violating the regulation may be subject to cease and desist orders.

A complete outline of the legal procedure under which the Cancer Law operates, and a discussion of alternative actions available to the proponent of a suspect agent are described below.

Methods of Operation in the Enforcement of the Cancer Law

The means by which an agent used in cancer management is scrutinized
under the Cancer Law do vary. The following illustrates the two alternatives of action taken in a number of cases so far handled by the Cancer Advisory Council.

COMPLAINT OR REPORT RECEIVED

Investigation Approved by Council

Departmental Investigatory Hearing

Accusatory Hearing
before a Hearing Officer

Accusatory Hearing
before Hearing Officer

Council study of Findings
and Proposed Decision

Council study of Findings
and Proposed Decision

Recommendation of Council
to Department as to whether
Cease and Desist Order
should be issued.

Recommendation of Council
to Department as to whether
Cease and Desist Order
should be issued.

The process is never brief. The rights of a person suspected of employing fraudulent cancer diagnostic or therapeutic means are fully guaranteed during the entire process. The course taken in each case depends not on the method of exposure but upon the decisions made by the proponent using questionable cancer agents.

In order to initiate any formal investigation and subsequent legal proceedings, a complaint or rumor must be reported to the Cancer Advisory Council. It may be expressed by an individual being treated, a friend or relative who is concerned, by a voluntary health agency, governmental agency or other source to which the complaint is originally filed. Further, it may come from a member of the medical profession who is consulted for legitimate analysis and care only after fraudulent techniques prove useless. A physician placed in this
uncomfortable posture is justly angered: his skill in possibly relieving pain or arresting the course of the disease is severely impaired. Ultimately he may receive the brunt of a family's sorrow in failing to save a life which in fact had been detoured from proper treatment by the allure of cancer quackery. A number of complaints, therefore, come first to the attention of the Cancer Commission of the California Medical Association and are, in turn, referred to the Cancer Advisory Council.

The Council appraises the merits of a complaint or rumor and then requests the Cancer Diagnosis and Therapy Evaluation Unit to conduct a detailed investigation. At this point one of the most complex phases of activity takes place: locating witnesses to attest to the effects of diagnosis and/or treatment in question. This process may take months, for cancer quacks are skilled in camouflaging their work and documentation of it. The suspected agent -- a mechanical device, pill, serum or other nostrum -- must be obtained. This, too, is not always easy. But far more difficult is bringing forth persons actually victimized by the practitioner using the agent in question. The Departmental Unit must rely only on investigatory techniques permitted by law, and they take time to produce suitable evidence.

Once sufficient evidence is collected, the Department issues a subpoena to the party suspected of practicing cancer quackery to appear at a confidential, investigatory hearing and to furnish samples and information regarding his agent. At this point, two alternatives are available: compliance with the subpoena in its entirety or an appearance without samples. In the cases reviewed to date by the Council, both alternatives have been exercised. In either case, an
accusatory hearing may follow. And again, the individual may choose either to defend against the accusation in person or not to do so.

If the individual does respond to the accusations but has not furnished samples, he presents as defense personal testimony and all other evidence he and counsel can provide to support his case. This procedure was the choice of practitioners, Wendell Hendricks, D.O., accused of administering the Lincoln, Koch and other agents, and Charlotte Steiner, D.C., accused of using Mucorhicin and the "Grape Cure." Under Section 1707 of the Cancer Law, failure to supply the State Department of Public Health with samples of agents being evaluated and named in the subpoena results in a conclusive presumption that the agent is without value in the diagnosis, treatment, alleviation or cure of cancer. This is precisely the course chosen by both Hendricks and Steiner. Their decisions not to submit agents for analysis led the hearing officers from the Office of Administrative Procedure to find them guilty of abuse of Section 1707 and to recommend the issuance of cease and desist orders. Upon approval by the Council, cease and desist orders were issued to both parties by the Director of Public Health.

If, however, an individual complies with the subpoena in its entirety, the conclusive presumption of ineffectiveness is not invoked and the Department must prove that the agent in question is ineffective or of no value.

The proof is a very involved process. If a party complies, the Cancer Advisory Council then recommends a thorough investigation of the agent in question. The Council's evaluation may involve testing procedures such as those of the laboratory, clinical analysis,
animal experiments, the records of court proceedings or other scientific study. Investigation may provide evidence that the agent in question has failed to ameliorate the condition of cancer patients to whom it has been administered. Evidence produced either by investigation or testing is then submitted to the Cancer Advisory Council for evaluation. The Council may conclude that the agent may have value, no value, or that the evidence is inconclusive. To date, none of the agents reviewed as above by the Council has been found of value as claimed by its proponent. Naturally, the Council has found valueless only those agents which it sincerely believes fail to effect positive changes in cancer management.

By far the largest number of persons who have complied with the Departmental subpoenas have fully exercised their rights to notice, opportunity to be heard and to rebut evidence and the like. In itself, this suggests that rights of the individual rank very high in the language of the Cancer Law. Once the Cancer Advisory Council finds an agent to be of no value, it may propose that a regulation be adopted prohibiting its use in California. Before any such regulation is adopted a public hearing must be held. It is these hearings, several of which have taken place since 1959 before a committee of the State Board of Public Health, that arouse public interest and serve as a sounding board for many opinions on cancer and its treatment. If no concrete evidence is received nullifying the report, findings and recommendations of the Cancer Advisory Council which are based on the documentation and investigation undertaken by the Cancer Diagnosis and Therapy Evaluation Unit and the studies of the Council, other evidence received at the public hearing and the proposed regulation
are presented at a regular meeting of the State Board of Public Health, which may adopt the proposed regulation. Here the several agencies involved in the evaluation of cancer quackery actually are brought to bear on a single problem. The very nature of a regulation, as adopted by the State Board of Public Health, is serious: therefore, the Council and Departmental Unit do not propose a regulation until they are fully convinced that it is justified and is the only means of containing a particular form of quackery abuse.

Once a regulation has been adopted by the State Board of Public Health, and incorporated into the State Administrative Code (Chapter 5, Subchapter 2, Article 2, Sections 10400. et seq.), the individual again has a choice to make: he can consent to the issuance of a cease and desist order, based on findings of fact by the Cancer Advisory Council, or he can submit to an accusatory hearing. Experience to date indicates that once the public hearing on a prohibitory regulation has resulted in its adoption by the State Board of Public Health, most parties implicated choose not to face an accusatory hearing. Four individuals, Willoughby W. Sherwood, M.D., Charles L. Hawk, M.D., Nelson E. Mathison, M.D. (D.O.) and John H. Friend, M.D. (D.O.), all accused of using the Hoxsey treatment, consented to cease and desist orders. Francis M. Altig, M.D. (D.O.), however, did offer defense. The Cancer Advisory Council reviewed the proposed findings of the hearing officer who found the charges to be true as alleged and a cease and desist order was duly issued after full hearing.

There is one other method of arriving at a cease and desist order. By stipulation the accused may agree to accept a cease and
desist order containing a clause which states that he does not admit the validity of the accusations against him. In this instance no testing or evaluation of his agent is necessary.

To date, three persons have stipulated to a cease and desist order without admitting the charges against them: Catherine E. Harmon, D.C., who was found to be using a device of her own improvisation called a "Harmonizer," Chew Cahoone Yuen, D.C., an herbalist, and Howard F. Parsons, M.D. (D.C.), who was using a variety of diagnostic and treatment agents.

It is a point of legal interest that, even in its short term of application, the Cancer Law has proved to be extremely flexible. The extent to which a person accused under the act may dispute the charges brought against him was ably tested in the Altig case. And the fact that several other practitioners also were willing to test the law nearly to its full extent reaffirms the fact that it was drafted liberally, to give utmost protection to persons who might be subject to its redress. In a matter as delicate as restraint of a possible salutary measure, prime emphasis on preserving the rights of the individual appears to strengthen the merits of the Cancer Law.

As shown in Chapter 8, investigation of new methods of diagnosing and treatment of cancer by appropriate research methods is conducted very extensively in California and is in no sense inhibited, interfered with or infringed upon by the cancer control law. The Council and the Department are free to conduct or have conducted testing if and when they deem it desirable. This is a question of professional judgment, and the Staff and Council are well qualified to make such judgment and to obtain clinical testing when indicated.
The California Attorney General was asked to summarize the legal rationale for regulating cancer diagnosis and treatment. The statements in this chapter define the constitutional rights of an individual -- both the unscrupulous quack and his victim -- and discuss the responsibility of government to protect innocent persons from deception.

The power of the State to regulate medical practice has long been recognized. There is no constitutional right to offer afflicted persons hope of relief by harmful or ineffective modes of treatment anymore than there is a right to offer them hopes of financial reward through fraudulent stock schemes. It was recently contended in preliminary litigation that the Food and Drug Administration's ban of Krebiozen from interstate commerce constituted an unconstitutional restriction on the practice of medicine. The Federal District Court dismissed this argument in the following words:

... The Plaintiff claims that he has a duty and a right to practice medicine as he sees fit (Pltf. br., 34). The comment may be made that the plaintiff does not have a constitutional right to practice medicine on his own terms. As the Supreme Court said in *Barsky v. Board of Regents*, 347 U.S. 422, at 451:

The practice of medicine in New York is lawfully prohibited by the State except upon the conditions it imposes. Such practice is a privilege granted by the State under its substantially plenary power to
Thus, it is clear that no constitutional rights are violated by laws which regulate the practice of medicine or the production and use of drugs.\(^{(17)}\)

The California Cancer Law, like the State and Federal Food and Drug Laws, prohibits the use of ineffective remedies as well as directly harmful ones. Reliance by the public upon an ineffective treatment, when effective treatment is available, may result in both physical and economic damage.

"The power of the State to provide for the general welfare of its people authorizes it to prescribe all such regulations as in its judgment will secure or tend to secure them against the consequences of ignorance and incapacity as well as deception and fraud." Dent v. West Virginia, 129 U.S. 114 (1889). In the Dent case, the Supreme Court of the United States upheld a system of medical licensing, and determined that no one has the right to prescribe an unproved remedy. A California Court held in People v. Ryan, 101 Cal. App. 2nd Supp. 927, 931-932 (1951) that the "unregulated trade in drugs without value" would result in "a large annual cost of life, health and money to suffering purchasers among the public, hopefully eager to buy."

In Drown v. U.S., 198 Fed. 999 (9th Cir. 1952), cert. denied 344 U.S. 920 (1953), the court upheld a conviction under the Federal Food and Drug Law for the use of ineffective devices and treatment of various diseases upon the ground that "While the instruments may be harmless in themselves, their danger lies in the possibility that ignorant or gullible persons are likely to rely upon them instead
of seeking professional advice for conditions they are represented to relieve or prevent."

The abuses arising from the resort by susceptible and sometimes desperate persons to unscrupulous or mistaken practitioners were recognized by the Senate Interim Committee on Public Health when it originally recommended the Cancer Law. The Committee's report states:

"For obvious reasons, the cancer patient and his family are peculiarly susceptible to the claims of 'secret' cures and 'unproven' remedies which are in fact neither secret nor unproven. In the opinion of the committee, this susceptibility, however well intentioned, not only leads the people over the hill to the poor house, but of even greater importance, it will only prevent the cancer patient from receiving proper care and treatment which could in many instances truly effect a cure or at least materially prolong the useful life of the patient." Second Progress Report, Medical Quackery, Senate Interim Committee on Public Health, page 10 (1959).

In the article, Comment, Quackery in California, 11 Stan. L. Rev. 275 (1959): "The existence of quackery in a community not only results in the economic victimizing of sufferers but deters timely utilization of recognized treatment which could otherwise save or prolong lives."

It has been argued upon political grounds that cancer patients, particularly terminal ones, should be allowed to receive any treatment they wish. This argument might have merit if we could be assured that no treatment of bona fide medical value could be furnished (i.e., that the patient was completely and irretrievably beyond hope of any cure by
any existing or foreseeably discoverable treatment) and that such treatment would be furnished by a practitioner well versed with all of the existing and reasonably foreseeable recognized treatments, and that such treatment would not be used on early cases, thereby depriving them of a chance for cure by conventional means. This ideal combination is invariably lacking in the cases with which the Cancer Advisory Council is concerned.

Further, the State has the obligation to see that the treatment of a completely hopeless case will not be a source for the enrichment of quacks. Experience has shown that patients seeking resort to unconventional remedies are all too often persons terrified by the prospect of surgical or irradiation treatment. The fears of such persons are played upon by the purveyors of various nostrums who hold out, expressly or impliedly, the hope of easier, cheaper relief.

The legitimate, experimental use of a drug or treatment is permitted under the Cancer Law, which exempts nonprofit use by bona fide qualified investigators. (Health and Safety Code section 1708) The Federal Food and Drug Laws also provide for experimental use of drugs or treatment designed to cure cancer under proper supervision and after necessary safeguards have been met. The inability or refusal to comply with these requirements by the exponents of some remedies investigated by the Cancer Advisory Council sheds serious doubt on their good faith. The following list of eight alleged cancer diagnostic or curative agents which have been evaluated, seven of which have been banned in California, speaks for itself:

**HOXSEY REMEDY:**

This oral remedy contains potassium iodide, cascara sagrada,
licorice, extracts of red clover blossoms, of burdock, stillingia, berberis and poke roots, and of prickly ash and buckthorn barks. Licorice has limited value as a flavoring agent and cascara as a laxative. Only potassium iodide has significant therapeutic properties, and these are NOT IN THE TREATMENT OF CANCER. The roots, barks and blossoms have no therapeutic properties; a formula containing them was dropped from the National Formulary in the 1930's.

LAETRILES: (Beta cyanogenetic glucosides)

There are several "glucosides," but the one promoted as a cancer remedy is extracted from apricot pits. Its generic name is known as the glucoside AMYGDALIN. According to its proponents, when injected into a vein, cyanide gas, lethal to cancer cells, is released by a particular enzyme at the site of the cancer which results in the death of the cancer cells. Unfortunately, this enzyme cited does not break down amygdalin. The theory is therefore invalid.

KOCH OXIDATION CATALYST: (Synthetic Antitoxins)

These agents, which are injected into the muscle, are supposedly marketed in dilutions as high as one part in a million and one part in a trillion parts of water. These preparations were examined chemically in the laboratory of the California State Bureau of Food and Drugs and elsewhere. Nothing but water could be detected.

LINCOLN STAPHAGE LYSATE:

It is claimed by the promoter, and confirmed in the California State Microbiologic Laboratory, that this preparation is a bacteriophage, a biologic which is useful in the laboratory identification of bacteria of the Staphylococcus group but not in the treatment of cancer. It is given by nasal inhalation or by injection.
MUCORHICIN:

This is an orally administered preparation developed by Philip L. Drosnes, a former tire salesman, and Lillian M. Lazenby, previously the manager of a hospital cafeteria. The remedy contains the drippings resulting from the culture of various fungus species on a particular culture medium and has been examined several times in the laboratories of the National Cancer Institute and the American Medical Association. During these examinations, remnants of fungus spores, mites, fecal masses of these mites, yeast cells and viable bacteria were found.

BOLEN TEST:

It is claimed that cancer may be detected by observing the pattern produced by a drop of blood which is allowed to clot on a glass slide. In a blindfold test, involving the author of the test, his findings were correct in only 55 percent of cancer patients and showed 17 percent false positives in cancer patients. This degree of error is unacceptable.

KREBIOZEN:

According to the proponents of this agent, Krebiozen is obtained from the blood serum of horses which have been injected with a killed culture of the fungus that causes lumpy jaw in cattle. Studies by the National Cancer Institute and the Federal Food and Drug Administration revealed that this agent is indistinguishable from creatine, a substance resulting from the metabolic breakdown of muscle protein. Krebiozen was found to have no value in the treatment of cancer. This finding was made by a committee of 24 scientists appointed by the Director, National Cancer Institute, upon examination of the clinical records of 504 cancer patients treated with Krebiozen. The proponents are now under Federal indictment and trial in Chicago charged with conspiracy, fraud and making false
statements. The Cancer Advisory Council found this agent without value and recommended that its use be banned in the State of California.

**ANTHRONE TEST:**

This is a chemical test for the detection of cancer performed on a portion of a 24-hour specimen of a patient's urine. In a contractual study between the California State Department of Public Health and one of the authors of the test, testing 101 urines of cancer patients and 94 urines of non-cancer patients, the results were compatible with the condition of cancer or non-cancer only about 50 percent of the time. Statistically equivalent results could be due to chance alone and might result from the flip of a coin.

The people of California have rejected and will continue to reject the concept that political freedom embraces the absence of regulations or restraints in the healing arts, which could result in fraud upon the public or dangers to the public health.
NEED FOR A SPECIAL CANCER LAW

It has been stated that there is no need for a special cancer law since there are existing laws sufficient to deal with the problem. However, these laws have not served to control cancer quackery. The following analysis demonstrates this fallacy.

a. The Cancer Law lends itself to the investigation of methods, techniques and devices in addition to drugs, chemicals or compounds. The requirement that information and samples of agents used in cancer diagnosis or treatment be furnished the Department on demand applies also to any individual, person, firm, association or other entity that renders health care or services to individuals who have or believe they have cancer or that by implication causes these individuals to believe they have cancer.

Unlike any other law, a proponent's refusal to supply or produce samples or the requested information concerning a purported remedy will result in a conclusive presumption that the agent is without value.

b. The Cancer Law makes available continuing review of all cancer diagnostic and treatment agents by a highly qualified panel of experts. This well-advised review is not available under any other law.
c. The effect of publicity and educational campaigns alone, without the ultimate weapon of legal proceedings, has proved to be insufficient. The Cancer Law, broad in scope as it is, corrects this defect.

d. A law such as we have dealing exclusively with cancer is justified because cancer quackery is the most serious form of medical fraud and constitutes the greatest hazard to life.
CHAPTER 8

FISCAL CONSIDERATIONS

One pragmatic consideration regarding the merits of the Cancer Law is that of expense.

How much does it cost to maintain the Cancer Law?

How does this cost compare to monies reaped by cancer quacks?

How does this cost compare to funds expended for cancer research, cancer control, public education and information about cancer?

How does this cost compare to funds expended by individuals who have cancer to obtain orthodox diagnosis, treatment, and hospitalization?

How does this cost compare to the loss of manpower due to cancer?

These questions are not rhetorical. It seems important to place the cost of maintaining the Cancer Law in perspective, to balance this sum against monies expended by individuals, the government, foundations and voluntary health agencies to try to control, prevent and find the cause of cancer, as well as to treat persons whom it touches.

The Cancer Law is administered by a small Fraud Unit in the Bureau of Food and Drug. The Cancer Advisory Council budget is less than $2,000 annually. The enforcement activities are part of the general activities against drugs and devices.

The Federal Food and Drug Administration (FDA) estimates that a billion dollars is spent annually by Americans on medical quackery, about half of it on nutritional quackery. Roughly 10 percent of this amount -- but possibly more -- is paid by Californians to quacks here, for quack remedies, devices and diets. Assuming that a fifth of that expense is for cancer quackery, the annual bill paid by Californians would be $20 billion. Since many individuals seek cancer quacks outside the state,
-- even outside the country -- this figure may be regarded as modest.

The FDA expends vast sums in investigation of quackery falling under their purview. The 33 man-years spent recently on Krebiozen investigations in preparation for the trial of the principals represent an investment exceeding a quarter of a million dollars.

The case of a single clinic, operating until 1961, amplifies the gross expenditures for cancer quackery. When proceedings forced this single clinic to close, records of 350 patients remaining in the premises indicated an annual income of about $105,000. This figure would be greater if records known to have been removed and hidden had been seen. So just since 1961, the citizens of California have been saved an estimated $420,000 which otherwise would have gone into the coffers of these particular charlatans had they continued in operation. Over the same period the cost of a program to control this activity and others has cost the citizens of California only about one-half of this amount.

The funds expended for cancer research alone are vast. The National Cancer Institute, American Cancer Society, and numerous foundations and individuals sponsor immense research ventures. In fiscal year 1964, the National Cancer Institute awarded 1,650 research grants totalling nearly $56 million for cancer research in this nation. This does not include grants for training, construction of facilities (such as the new California Cancer Field Research Facility in Berkeley), Health Service formula grants or projects. Nor does it include funds for "cancer control" or those expended by the Cancer Chemotherapy National Service Center. For example, in fiscal 1962, the California State Department of Public Health expended a total of $473,492 for cancer control activities: a Federal grant of $214,800 matched by State and local funds totalling $258,692. These funds support the conduct of special studies, professional education, and
the development of detection, diagnostic and treatment services related to cancer. The Cancer Chemotherapy National Service Center is estimated to have spent close to $100 million in the last 15 years testing chemotherapeutic materials in treating cancer.

In California, during fiscal year 1964, the National Cancer Institute awarded 126 research grants totalling $5,092,518. The American Cancer Society reported on September 1, 1965, that research grants totalling $1,867,307 were in effect in California at that time. Numerous foundations and individuals also support cancer research in California, although accurate figures are not available. But from these two major sources, we know that nearly $7 million is funded in a single year. In addition, the American Cancer Society spends considerable funds on public education and informational activities related to cancer -- its prevention, prompt diagnosis and treatment.

More difficult to determine are those funds expended by individuals to obtain conventional diagnosis, treatment and necessary hospitalization. Assuredly, these sums are huge. Medical care is costly; many forms of cancer require prolonged treatment and hospitalization; medications, diagnostic tests, irradiation, surgery, and nursing care are all factors of appreciable expense. Part of this burden is borne by public funds, especially for the medically indigent, but much of it is borne by families in which cancer strikes -- through health insurance and personal resources. Moreover, medical care costs have steadily risen in the past two decades.

Loss of life and disability exert a financial hardship, again not readily determined in dollars. But it is conceivable that tens of millions of dollars are expended in California on medical care related to cancer, and that manpower loss due to this condition is nearly as costly.
CHAPTER 9

ACTIVITIES OF THE CANCER DIAGNOSIS AND THERAPY EVALUATION UNIT, 1959-1965

The duties, and limitations of activity, of the Cancer Diagnosis and Therapy Evaluation Unit are specified in the Cancer Law, Section 1704. In particular, these activities take three forms: investigating violations of the Cancer Law; securing all requisite investigation and testing of agents being administered in cancer management (except those bona fide investigational agents being developed or applied in non-profit cancer research); and holding hearings related to compliance with the Cancer Law.

In the first five years of the Cancer Law’s operation, the Cancer Diagnosis and Therapy Evaluation Unit has received complaints and other information in over 150 instances of suspect practitioners. Complete reports have been made on eight remedies: in seven, following hearings, the State Board of Public Health adopted regulations outlawing use; action is pending on Krebiozen. Cease and desist orders involving 21 different agents were issued against 14 users. Issuance of orders regarding such agents as Siccacell, the Harmonizer, and Grape Cure were based on failure to comply with Section 1707 of the Cancer Law, requiring materials for examination; orders regarding Laetrile, Hoxsey, Koch, Lincoln, Mucorhicin remedies and the Bolen test were based on tests and/or prohibitory regulations.

At the present time, more than a dozen persons are under investigation, selected as probably the most significant from the 150 complaints that have been received.

This chapter presents four aspects of the Cancer Law in operation: an analysis of typical authentic complaints of unorthodox medical practice; a summary of data assembled by the Cancer Diagnosis and Therapy Evaluation Unit for
evaluation by the Cancer Advisory Council prior to recommending action; a
count of digested, authentic case histories; and a history of actions taken
under the Cancer Law to date. All this information has been selected from
the files of the Cancer Diagnosis and Therapy Evaluation Unit. It is but a
small particle of the material collected and reviewed since the Cancer Law
became operative.

If progress against cancer quacks is to be measured, it should be
realized that to bring just one bogus practitioner to hearing, or for the
State Board of Public Health to adopt a prohibitory regulation, requires
meticulous and exhaustive investigative techniques and testing procedures.
A hearing is conducted only after very involved, painstaking efforts have
been made to document fully the enforcement requirements of the Cancer Law,
and to extend ample time for the accused to provide rebuttal materials. All
these measures involve funds -- considerably less funds than that reaped by
the quacks in promoting these false cures.

An idea of the time-consuming activities preparatory to formal action
may be gained from these facts. Since enactment of the law in 1959, CDTEU
staff have accompanied operatives to practitioners on 127 occasions; 79
visits were made to practitioners subsequently subject to cease and desist
orders; 48 visits did not produce evidence sufficient to justify accusatory
procedures. In the investigation of complaints and instruction of opera-
tives for their work, 111 interviews have been conducted. Many interviews
took several days. More than 60 interviews resulted in the 13 cease and
desist orders.

After preliminary investigation, 7 cases were referred for action under
the Medical Practice Act to the State Bureau of Food and Drug Inspections or
to the Federal Food and Drug Administration. In each of these cases which
came to trial, CDTEU staff spent from one to four days in anticipating and

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providing testimony.

Under the Government Code or the Administrative Procedure Act related to the Cancer Law, investigatory and accusatory hearings take from two to six man days each of professional staff time.

In addition to the more formal activities mentioned above, which result in definitive legal action, considerable staff time is devoted to educational and recruitment activities (e.g., speeches, demonstrations, exhibit preparations, etc.).

Before every scheduled hearing on a proposed prohibitory regulation, a deluge of correspondence comes to the CDTEU. It is the policy of the Department to acknowledge each letter; those letters directed to the Governor or the Director of Public Health are addressed personally and treated individually. Before the hearings on Krebiozen, between 800 and 1000 letters were received -- and answered.

The legal process of investigation and hearing is no less time-consuming for the Federal government. The Federal Food and Drug Administration estimates that 33 man-years were spent from January 1-October 15, 1963, preparing for the 1965 hearings on Krebiozen. During the trial, which has been in progress for over 28 weeks (as of November 15, 1965), the FDA has contributed substantial time through FDA witnesses and the activities of many other FDA employees.

Several other FDA investigations, on agents ultimately banned in California under the Cancer Law, were also excessively time-consuming. The FDA estimates that their staff engaged in 10 years of almost continuous litigation on the Hoxsey agent. Equally important and extensive were FDA activities on the Koch agent. The work of this Federal agency enables the California Cancer Law to be exercised with considerable efficiency, since much of the essential
investigation and court proceedings under FDA authority reinforced investigatory materials on these suspect cancer treatment agents.

The value of such prodigious activity, and need for constant observation of banned agents, is stated by FDA staff: "Such investigations may involve extensive medical and legal deliberation and consultation during the investigation and in the preparation and presentation of evidence...A lack of capability to proceed promptly against such practices (because of a shortage of personnel, facilities or funds...) may lead to great difficulty later. This is because the organization sponsoring the treatment in question will be allowed more time to publicize and promote (its) product and may increase its financial and organizational ability to defend (itself) against legal action. It is also of utmost importance that organizations, whether Federal, State or local, who have responsibilities in this field, have adequate personnel, funds, and facilities to follow up in situations where a correction has apparently been achieved. This is necessary since it has been our experience that other operations will seek to revive a treatment that has been publicized and that appears to be remunerative."
COMPLAINTS REGARDING UNORTHODOX MEDICAL PRACTICES

The files of the Cancer Diagnosis and Therapy Evaluation Unit contain records of many complaints registered against practitioners by laymen, physicians, and state agencies for a variety of reasons. The following few cases selected from many illustrate the scope of the complaints. There are complaints that the charges are excessive (case 1); that the values of the remedies are open to question (cases 1, 2, 5); that early cancer cases are treated with worthless remedies to the detriment of the patient and possible loss of life that might otherwise have been saved by adequate conventional treatment (case 7); that there is treatment of nonexistent cancer (case 11); that patients are handled inhumanely (case 15); and that the premises and practices are unsanitary (case 16).

<table>
<thead>
<tr>
<th>Complainant</th>
<th>Complaint</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Patient and M.D.</td>
<td>$1,000 charge proposed for food supplements and Laetrile administration. Diagnosis of cancer based on the now discredited Anthrone test.</td>
</tr>
<tr>
<td>2. Daughter of victim</td>
<td>Influenced patient not to seek conventional therapy; diagnosis made by Bolen test; treatment with Koch injection for hopeless, widespread cancer of cervix with recto-vaginal fistula.</td>
</tr>
<tr>
<td>3. Widow of patient</td>
<td>Treated cancer of lung with Krebiozen and recommended a diet of sunflower seeds, molasses, honey and herb teas.</td>
</tr>
<tr>
<td>4. Patient</td>
<td>Treated cancer of breast with an autogenous vaccine prepared from patient's urine.</td>
</tr>
<tr>
<td>5. Sons of patient</td>
<td>Prescribed autogenous vaccine as above for gastro-intestinal cancer and the discredited Bolen test for diagnosis.</td>
</tr>
<tr>
<td>Complainant</td>
<td>Complaint</td>
</tr>
<tr>
<td>-------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>7. Victim's widow</td>
<td>Cancer of lung suspected on X-ray examination by family doctor. The accused, however, used a diagnostic device, reporting no malignancy. Patient treated with an electronic device, April - July 1962. Patient then was inoperable and he died of lung cancer.</td>
</tr>
<tr>
<td>8. M.D.</td>
<td>A patient of the M.D. with cancer of the cervix was lured away with pellets of wheat grass, herb tea and honey.</td>
</tr>
<tr>
<td>10. Husband of deceased</td>
<td>His wife treated for cancer of intestine with Koch injections. Fee $1,600.</td>
</tr>
<tr>
<td>11. Victim</td>
<td>Charged $450 for Hoxsey remedy to treat nonexistent cancer.</td>
</tr>
<tr>
<td>13. Victim</td>
<td>Patient with urinary bladder symptoms treated for unconfirmed cancer with pills, a liquid and a rubbing lotion.</td>
</tr>
<tr>
<td>14. M.D.</td>
<td>Elderly couple treated for cancer (1 proved, 1 unproved) with pills, liquid, enzymes and vitamins. Fee $400.30.</td>
</tr>
<tr>
<td>15. M.D.</td>
<td>Cancer of breast, metastatic to liver, treated with injections. The accused refused to hospitalize the patient even though she was in great pain and had a marked ascites.</td>
</tr>
<tr>
<td>16. Patient, an R.N.</td>
<td>Premises dirty and unsanitary; rough pelvic examination without glove.</td>
</tr>
<tr>
<td>20. M.D.</td>
<td>A cancer patient of the M.D., undergoing conventional treatment with a chemotherapeutic agent, with good results, defected to a chiropractor who placed her on an initial diet consisting exclusively of grapes. After eight weeks, patient's condition had deteriorated greatly. She later died.</td>
</tr>
</tbody>
</table>
Complaints concerning fake cancer treatment number 10 out of 43 recorded during survey interviews in 1964 held with officials of Welfare units, Local Health Officers, Visiting Nurse Associations, American Cancer Societies, County Medical Associations, etc.
DATA CONSIDERED BY THE CANCER ADVISORY COUNCIL DURING EVALUATION STUDIES

One of the claims made by opponents of the Cancer Law is that all studies by the Cancer Advisory Council are inadequate since they do not include human clinical tests. Clearly this is a false claim. Prior to adoption of prohibitory regulations, clinical studies and other data were requested and examined during exhaustive studies of suspect fake agents. A detailed summary of data evaluated by the Cancer Advisory Council is given below.

Koch Synthetic Antitoxins

1. Action by Tampa, Florida jury: $65,000. judgment awarded for malpractice to patient (1953).


3. Chemical Analyses:
   a. Glyoxylide
      (1) This is the anhydride of glyoxylic acid, a normal constituent of the human body which does not exist in free form. On exposure to water, Glyoxylide is rapidly transformed into the acid. It would take a trillion 2 ml. ampules of Koch's glyoxylide in a 1 to a trillion dilution as claimed to equal the amount produced daily by the human body. Federal Trade Commission 1953: Commissioner of Food and Drugs 1946.
      
      (2) Contents are indistinguishable from water. American Medical Association (1961) and State Department of Public Health Laboratories (5/4/60), State of California.
   
   b. Parabenzoxionone
      Revealed nothing but water. State Department of Public Health Laboratories (1/24/63), State of California.

4. Clinical Trials
   a. Wayne County Medical Society, Detroit. Dr. Koch deserted patients (12/22/19).
      56 cases (1/5/20).
      41 cases, 6 with no diagnosis (6/30/24).
   
   b. 8 cases, Canada. (2/7/42).
   

Laetrile (Beta-Cyanogenetic Glucoside)


2. Chemical Analyses and Studies:
   b. Dr. John W. Mehl (1953).
   c. Dr. Paul L. Kirk, University of California, Berkeley (1962).
   d. State Department of Public Health Food and Drug Laboratory (1961 and 1963).

3. Animal Studies:
   a. Dr. N. B. Friedman, Cedars of Lebanon Hospital, Los Angeles (12/2/52).
   b. Dr. C. Griffin, Stanford University, Palo Alto (1/23/53).
   c. Dr. K. B. DeOme, University of California, Berkeley (4/28/61).
   d. Diablo Laboratories, Berkeley (10/15/62).

4. Patients' Records: (Clinical Studies)
   a. California Cancer Commission 44
   b. Dr. W. K. Beare 1
   c. McNaughton Foundation 84
   d. Dr. R. Evers 5
   e. Dr. J. A. Restifo 6
   f. Dr. M. T. Dott 21
   g. Dr. R. Navarro 17
   Total 178

5. Autopsy Findings on 9 patients by the California Cancer Commission, 1952-53.


Lincoln Staphage Lysate

1. Identification as phage:
   a. Paper and letter by Dr. A. E. Mills, Manager of Lincoln
   b. State Department of Public Health Microbiologic
      Laboratory (2/1/63), State of California.

2. Clinical Studies:
   a. Committee of Massachusetts Medical Society, 193 cases (1951-52).

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3. In a "blindfold test" conducted by Dr. Lincoln, he reported that an unknown preparation of sterile broth was just as effective as his phage (1948).


Bolen Test

1. 21 reports from medical literature showed false positives ranging between 4 and 95 percent and false negatives between 24 and 56 percent.

2. A "blind" evaluation study (1942-52) conducted by Dr. Bolen on 315 individuals yielded the following results:
   - 83 percent True Negative (17 percent false positive)
   - 55 percent True Positive (45 percent false negative)


Mucorhizin

1. Documentary Evidence:
   a. Publication of American Cancer Society
   b. Literature from Drosnes-Lazenby Clinic

2. Public Hearings.

3. Laboratory Tests:


Hoxsey Remedy


2. Interviews with survivors of cancer victims.

3. Investigations of 3 California clinics (1960-61).

5. Court Records:
e. U.S. District Court, Dallas, Texas, Supplementary
   Injunctions (1960).
f. L.A. County Superior Court (1962).


Anthrone Test

1. Documentary Evidence:
c. A "New Approach to the Conquest of Cancer, Rheumatism and
d. Ibid, revised (1962).
e. Written directions for performance of test by H. H. Beard.
   (9/6/62, 3/26/63).

2. Laboratory Findings: (Clinical Studies)
a. State Department of Public Health Food and Drug Laboratory.
   (1962, 1963), State of California.
b. Results Obtained by Dr. Beard on 200 specimens from 100

3. Opinions of Deans of California Schools of Medicine.

4. Opinion of Dr. Paul L. Kirk, Chemist, Microbiologist, University
   of California, Berkeley. (2/25/64).

5. Statistical analysis of Dr. Beard's results. (8/17/64).


Krebiozen

1. Documentary Evidence:
a. Publications of American Cancer Society (2) - (Sept., 1962
b. Publications of American Medical Association (5)
c. Insertions into Congressional Record by Senator Paul H.
e. Insertions into Congressional Record by Senator William
   Langer, North Dakota. (5/20/59).

2. Exchange of Letters between Krebiozen proponents and U.S.
CASE HISTORY OF PATIENTS TREATED WITH UNPROVED REMEDIES

The case histories digested on the following pages have been stripped of any subjective or suggestive inference. If they evoke some degree of compassion, it is because even the hard facts, reported in simple chronological order, cannot help but suggest the personal stress experienced by victims of cancer quackery and their families. Such histories also indicate the extent of funds expended fruitlessly by persons who could well not afford such expense. And they imply that there is no single formula of the quack -- his business is tailormade to each victim.

When case histories of persons who become victims of cancer quackery are reviewed, they tend to fall into four categories: falsely diagnosed cancer; quack treatment ineffective when used primarily or exclusively on proved cancer cases; when supplementing conventional therapy; erroneous reports of "cure." In the latter case, evidence substantiates that "cure" did not occur; the patient either died of his disease, had also been given conventional treatment, or had no pathological diagnosis of malignancy.

The following case abstracts illustrate these various categories. None of the persons acting as undercover operatives for the State are included in these lists. All are bona fide patients.
Case #1: Mrs. B. P.

2/29/60 -- patient visits FCC complaining of stomach trouble. X-rays, laboratory work and physical examination performed.

Diagnosis: cancer of both lungs.

Treatment consists of cancer liquid and pills, diet and a proposed colon therapy -- oxygen instillations into the large bowel. Total price to be $1,105.

Comment: after returning to her home, patient visits her family physician. Upon thorough clinical and X-ray examination, it is determined that no cancer of the lungs exists.

Source of Information: Interviews with patient and her family physician.

Case #2: Mrs. D. Z. P.

8/17/60 -- a mass in right breast is discovered by a San Mateo physician. Biopsy and surgery refused. 10/60, patient goes to FCC.

Diagnosis: "colopathology."

Treatment consists of pills, liquid diet and oxygen enemas. Total cost paid: $960.

1/31/61 -- patient dies. Autopsy reveals cancer of right breast with axillary metastases.

Source of Information: Interview with husband of patient.

Case #3: Mr. C. S. L.

6/60 -- patient visits FCC complaining of respiratory difficulty.

Diagnosis: "colon trouble," with the implication that it was caused by cancer.

Treatment consists of oral medication, injections and oxygen enemas. Total cost paid: $2,200.

Comment: subsequent surgery on patient's lung reveals no malignancy.

Source of Information: Interview with patient.

Case #4: Miss O. F. S.

1/60 -- patient visits FCC clinic for an unknown reason.

Diagnosis: cancer of lung.
Treatment recommended consists of pills and oxygen enemas. Pills are not taken but enemas are continued for two months. Patient charged $1,500.

Comment: Subsequent X-ray elsewhere reveals no cancer of the lungs.

Source of Information: Patient interview.

Case #5: Miss M. C. V.

4/57 -- patient visits FCC clinic for an unknown complaint.

Diagnosis: cancer of the lung.

Hoxsey medication prescribed. Total cost: $400.

Comment: Subsequent X-ray examination by a San Fernando physician reveals no cancer of lungs.

Source of Information: Patient interview.

II

Treatment Ineffective on Proved Cancer Primarily Treated with Unproved or Unorthodox Remedies

Case #1: Mr. T. P. M.


7/1/59 -- patient visits FCC, where a diagnosis of cancer of the large intestine is made.

Treatment prescribed is Hoxsey medicine and instillation of oxygen into the colon. Fee of $800-$1,000 is paid to clinic.

During succeeding months, patient grows weaker and has episode of gastrointestinal bleeding. After a delay of six months without definitive treatment, surgical intervention reveals a large, fungating, malignant mass of the cecum with spread to the psoas muscle, duodenum and right ureter. The right colon and part of the duodenum are removed but widespread metastases appear 90 days later. Patient dies 5/23/60.

Comment: The six months delay in definitive treatment probably dissipated his chance for survival.

Source of Information: Interview with wife.
Case #2: Mr. B. S.

2/18/58 -- patient visits M.D. because of growth on right ear. No biopsy is performed, but a clinical diagnosis of skin cancer is made. Caustic liquid, suspected by the patient of being an acid, and an ointment, are applied over 2 1/2 months, resulting in partial loss of ear lobe.

2/19/60 -- a lesion appears in left nostril. Same physician applies the caustic liquid at first and then switches to Laetrile and RCL-25, the latter presumably an animal cell suspension made by a Mexican physician. RCL-25 therapy begins 9/61 continues about two years. Total cost: $2,168.05.

Lesion extends to right nostril and conventional therapy is sought.


1/19/63 -- recurrence is subjected to radical, mutilating surgery.

5/24/63 -- spread extends to the mandible; X-ray therapy is administered.

6/7/64 -- patient dies.

Comment: There was a delay of more than two years before definitive, conventional therapy was sought.

Source of Information: Interviews with patient, his wife and a medical report from surgeon.

Case #3: Miss V. P.

10/23/59 -- patient discovers a lump in left breast. Visits office of W.G.H. where "a blood test showed malignancy." Koch and Sicca-cell injections started; after about six months, poultices are applied which eventually cause a loss of tissue from breast. After 18 months of this treatment, at a cost of $1,201, the patient has a biopsy and a radical mastectomy for proved malignancy. (3/61).

Since the patient was told that the poultice would draw the tumor out; since there had been a loss of breast tissue because of the poultice; and since she had been treated over a period of 18 months without benefit, a civil action was filed based on spending a substantial amount of money for services having no value.

Source of Information: Interview with patient.

Case #4: Miss S. J. M. - 2 1/2 years old.

3/60 -- a biopsy of the right lower leg at the University of California Hospital, San Francisco, results in a diagnosis of a highly undifferentiated malignant tumor originating in connective tissue or synovia. Amputation is recommended but refused.
4/9/60 -- patient is taken to FCC where Krebiozen is prescribed, at a cost of $475.00. After one week at the clinic, the patient returns home where treatment with Krebiozen is continued for a total of 12 doses with no improvement. The clinic is notified, and a variety of medicines identified by the clinic as the Hoxsey remedy is prescribed but the pills are too large for a small child to swallow.


Source of Information: Interview with patient's parents, report of family physician and U. C. Hospital records.

Case #5: Mrs. V. R.


10/63 -- patient visits a doctor where a lump in the breast is diagnosed clinically as cancer and where she receives Laetrile treatments for cancer twice a week until 3/13/64.

3/18/64 -- patient admitted to Napa State Hospital.

3/25/64 -- Tumor Board, Napa State Hospital, reports a 4 cm hard lump, left breast. Mammography typical of a malignant lesion. Clinical diagnosis of cancer.

5/18/64 -- patient discharged from Napa State Hospital. Laetrile treatments resumed.

9/30/64 -- patient readmitted to Napa State Hospital. She is bedridden and requires narcotics for relief of pain in lower thoracic and lumbar vertebrae. Mass in the breast is ulcerating.

10/13/64 -- X-ray reveals lungs to be studded with soft tissue densities.

11/23/64 -- 1200r administered to vertebrae for pain.

11/25/64 -- Tumor Board, Napa State Hospital, reports osteolytic involvement of 11th thoracic vertebra. There is further metastatic spread in the lungs and the left arm is edematous.

12/3/64 -- patient bedridden at home, drinking copious amounts of carrot juice for her cancer.

6/23/65 -- patient dies at Letterman General Hospital. Autopsy shows cause of death to be cancer of left breast with widespread metastases. Specific findings are as follows:
Lungs: metastatic carcinoma, severe bilateral.
Pleura: metastatic carcinoma visceral pleura.
Lymph nodes: metastatic carcinoma to left axillary, supraclavicular, mediastinum, hilar and periaortic.
Bone marrow: metastatic carcinoma to left femur, thoracic and lumbar vertebrae and sternum.

Comment: Except for 1200r of X-ray to the vertebral given late in her disease for relief of pain, this patient had no treatment for cancer other then laetrile and, terminally, carrot juice.

Source of Information: Interview with patient, S. F. General Hospital, Napa State Hospital, Letterman General Hospital records.

III

Treatment with Unorthodox or Unproved Methods Ineffective on Proved Cancer Primarily Treated With Conventional Therapy

Case #1: Mrs. E. P.

7/60 -- Mrs. P goes to offices of T. A., after several operations for the removal of malignant melanoma from the orbit and shoulder. Krebiozen prescribed for first three months, then Hoxsey remedy. Patient dies 2/15/61. Total costs: $594.


Case #2: Mr. J. M.


Source of Information: Widow of patient.

Case #3: Miss Kathy Allison

8/54 -- it is reported that Kathy is soon to die of cancer. She is given the Hoxsey treatment.

2/55 -- State Senator Haluski of Pennsylvania introduces a bill to have 10 state legislators investigate the clinic in Dallas. (The report of this lay committee is not included in this digest.) Later the Senator presents Kathy to the Pennsylvania State Legislature as a case in which a malignancy has been cured with the Hoxsey medication. A leaflet is distributed stating that she has three attacks of pneumonia requiring hospitalization between 6 and 9/55.

10/3/55 -- patient dies.
The facts: Fall 1953, patient injures a rib. Early 1954, X-ray reveals tumor. At surgery, the rib and some of the tumor mass is removed. Prognosis: poor.

4/54 -- there is indication of recurrence but the symptoms clear under X-ray therapy. Hoxsey medication is then started.

1/55 -- X-ray shows further recurrence.

2/55 -- patient presented to Legislature as cured.


7/55 -- X-ray study shows tumor present but no "pneumonia."

9/55 -- her condition worsens but still no evidence of "pneumonia."


Case #4: Mr. R. S.

Both the mother and son appeared at a public hearing and testified that the latter had been cured of his malignancy with the Hoxsey remedy.

9/7/62 -- letter to State Board of Public Health from mother and father protesting proposed regulation. "Two years ago (1960) - Ewing's sarcoma - 6 months to live. Confirmed by City of Hope."

9/10/62 -- letter Dr. K. F. Ernst to parents requesting medical release.

9/14/62 -- parent's letter to Dr. K. F. Ernst - further protest and no release.


Mother: "Spring 1960 - swollen painful knee...fall 1960 diagnosis Ewing's - six months to live...weight loss to 139 lbs."

Son: "Cancer left knee, spread to liver -- my head -- my left eye started to bulge -- arms and hand swollen to twice their size -- could only walk room to room. "At first I had X-ray at Kaiser Hospital. "Was unable to produce blood because of X-ray to long bones. "I am now 21 years of age, able to vote, find our freedom jeopardized."
Objected to wording of 4th paragraph which stated that no person shall recommend the Hoxsey treatment. This is later changed to apply to a practitioner only.

9/29/62 -- facts brought out that in 12/60 patient discontinued radiation therapy against advice and sought Dr. T. A. for Hoxsey treatment. Through August 1961, he received several courses of X-ray therapy for metastatic lesions in skull, orbit, liver. 1/62 chest film at Kaiser Hospital negative.

10/17/62 -- during 1962 patient has hematuria and a large mass involving left kidney is found.

2/28/63 -- City of Hope Tumor Board on November 7, 1962, considers the diagnosis either an Ewing's or reticulum cell sarcoma and since there are multiple areas of involvement, liver, kidney, and multiple bony areas, use of an alkylating agent such as HN₂ or cytoxan is recommended. If the kidney fails to respond, radiation is recommended. Patient referred to private physician.

3/22/63 -- report of metastasis to left kidney with gross hematuria. Patient treated with X-ray. He has dramatic response as he has with other areas similarly treated.

9/24/63 -- patient dies. Cause of death: renal failure due to reticulum cell sarcoma, 4 years duration. Autopsy: Lymphoma or Ewing's sarcoma, bone, with renal metastases.

Summary:

1960 - Spring Onset of painful swollen knee.
1960 - Fall Diagnosis of Ewing's sarcoma (or reticulum cell sarcoma) of bone. X-ray therapy.

12/60 -- Discontinued X-ray against medical advice and started Hoxsey.

1961 -- Several courses of X-ray therapy to metastatic lesions.
10/17/62 -- Kidney metastasis with hematuria.
9/63 -- Kidney lesion treated with X-ray; dramatic response.
12/24/63 -- Patient dies.

Source of Information: Testimony in public hearings and patient's medical records.
Prognosis in Ewing's Sarcoma

<table>
<thead>
<tr>
<th>Source</th>
<th># Cases</th>
<th>5-Year Survival Percent</th>
<th># Cases</th>
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<tbody>
<tr>
<td>Bone Tumor Registry*</td>
<td>55</td>
<td>15</td>
<td></td>
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<tr>
<td>Mayo Clinic*</td>
<td>114</td>
<td>21</td>
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<tr>
<td>Geschicter*</td>
<td>135</td>
<td>6 (8)</td>
<td></td>
</tr>
<tr>
<td>Bethge**</td>
<td>435</td>
<td>8.5 (37)</td>
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</tr>
<tr>
<td>Coley*</td>
<td>73</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>McCormack*</td>
<td>63</td>
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Prognosis in Reticulum Cell Sarcoma of Bone

<table>
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</tr>
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<tr>
<td>Francis et al**</td>
<td>-</td>
<td>48</td>
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<tr>
<td>Wilson &amp; Pugh**</td>
<td>33</td>
<td>42</td>
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<tr>
<td>Bethge**</td>
<td>-</td>
<td>32.9</td>
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<tr>
<td>Coley*</td>
<td>20</td>
<td>50</td>
</tr>
<tr>
<td>Ivins*</td>
<td>39</td>
<td>74.3</td>
</tr>
</tbody>
</table>

Age Distribution and Incidence**

- Ewing's Sarcoma: Incidence Under 10 Years Majorit 20-40 Years
- Reticulum Sarcoma of Bone: Incidence Relatively rare 4.2% of malignant bone tumors Rare Majority (66%)

* Ackerman and Regan: Cancer, 1947 and 3rd Ed. 1962.  
** Fascicle 4, Atlas, Armed Forces Institute of Pathology.

Case #5: Mrs. M. K. D.

2/17/65 -- a letter of inquiry is sent to Dr. K. F. Ernst and Governor Brown by husband regarding the "lie" in the Cancer Advisory Council Report of 1963, in which the price of amygdalin (Laetrile) was quoted as 20¢ a gram.

3/2/65 -- a copy of a page from the 1950 catalog of Arthur H. Thomas Company, Philadelphia, shows amygdalin to be available for $17.50 per 100 gram bottle. This is the source of the information which led to the reference in the CMA report of 1953 regarding the price of amygdalin.

Spring 1965 -- this story is told by husband in Santa Ana Register and in testimony May 28, 1965, before the State of California Assembly Committee on Public Health.

Wife had surgery on two occasions for cancer of the uterine cervix. Following these procedures, it was stated that she was a hopeless case and that no more surgery was possible.

1/64 -- wife begins treatment with Laetrile in Tijuana, Mexico; after four months' treatment she has only minor symptoms of cancer.
9/64 -- she is hospitalized in San Francisco for "pneumonia" and during three weeks hospitalization she does not receive Laetrile.

10/17/64 -- patient dies. Husband believes the fatal outcome due to the interruption of treatment with Laetrile which is highly improbable since the death certificate lists cause of death as generalized carcinomatosis due to adenocarcinoma of cervix in a person purported to be practically recovered from her cancer three weeks earlier.


Case #6: Mr. R. S.

3/3/63 -- diagnosis of adenocarcinoma of prostate with metastases is made. At surgery, a large mass extending from the sacrum to the right kidney and laterally for 10 cm is noted. There is a similar mass on the left but smaller. Patient is discharged from the hospital on 5 ml of Stilbestrol per day.

5/27/63 -- patient enters North End Medical Center Hospital in Montreal, Canada, for treatment with Laetrile. On entry his hemoglobin is 13.8 grams, acid phosphatase 22 KAU.

6/13/63 -- hemoglobin, 13 grams, acid phosphatase, 18 KAU

7/26/63 -- during his hospital treatment, patient receives 10 grams of Laetrile. Intervals between doses not stated; Estraduril 80 mg. is injected intramuscularly every two weeks. Acid phosphatase: 30 KAU.

Comment: It is assumed that patient was on conventional therapy such as Stilbestrol and Estraduril during the period he was receiving Laetrile therapy. There was no change in hemoglobin, and when last recorded his acid phosphatase had increased.

Source of Information: Letter from parents: Canadian Hospital Abstract.

IV

Erroneous Report of Cure by Unorthodox Remedies

Case #1: Kathy Allison - See Case #3 (p.105)

Case #2: Mr. R. S. - See Case #4 (p.106)

Case #3: Robert E. Barker

A news story, 1944, indicates that "a Veterans Administration Hospital report definitely states that a cancer victim was cured by Harry M. Hoxsey. A large mass involving the cecum and ileum...was diagnosed as malignancy and five years later the patient had a normal colon."

The facts: A large mass involving ileum and cecum was encountered at surgery, and believed to be a malignancy, without the benefit of biopsy or other diagnostic procedures.
Comment: Barker was operated for acute appendicitis through a small McBurney incision. The surgeon felt a mass of some kind but a specimen was not taken. It is not uncommon to find nonmalignant growths or masses within the abdominal cavity, some of which disappear spontaneously.


Case #4: Mr. R. H.

4/44 -- patient is kicked in right leg at age 14.

4/45 -- pain recurs but disappears after 12 visits to a chiropractor.

4/11/46 -- a tender palpable tumor in the middle third of right thigh is noted.


6/63 -- patient is 31 years old and in good health.

8/26/63 -- specimens of the original tumor are obtained from St. Francis Hospital and reexamined. Dr. Arthur Purdy Stout of Columbia Hospital, New York City, diagnoses the tumor as a benign neurilemoma. He comments that the pain is probably due to scarring of nerve and not to recurrence; that the mass which appeared three years later may have been a hematoma because, if it had been a tumor, it would have affected the motor elements of the nerve as well as the sensory.

Specimens are also examined by Dr. Oscar N. Rambo, Jr., University of California, San Francisco, who confirms diagnosis of benign neurilemmoma. He comments that there is some nuclear pleomorphism which could be ascribed to degenerative changes attested to by deposits of hemosiderin and calcium in the tumor.

Comment: This is a case in which an erroneous diagnosis of malignancy was made initially and a cure attributed to treatment with Laetrile.

Source of Information: Parents of patient and pathologists' reports.

Case #5: Miss M. O. F.

12/58 -- patient develops seizure-like attacks, including loss of consciousness, staring, paralysis of right arm and loss of speech. There are no neurological findings.

4/61 -- bilateral carotid angiograms followed by a craniotomy are performed. Gross appearance at surgery is compatible with that of a glioma but the pathologic report states the tissue removed is not malignant.

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6/61 -- radiotherapy is directed to the tumor. This is followed by symptoms resembling those of December, 1958. Krebiozen therapy is begun in August 1961 and continued into 1963.

Comment: There is no pathologic diagnosis of malignancy and, even if one existed, the effect of radiation therapy can not be discounted. Consequently any Krebiozen effect cannot be evaluated.

Source of Information: Patient's testimony and medical records.
Table 1

<table>
<thead>
<tr>
<th>Name of Agent</th>
<th>Cancer Advisory Council Report</th>
<th>Date Adopted State Board of Health</th>
<th>Effective Date</th>
<th>Administrative Code Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lincoln Staphage Lysate</td>
<td>Apr. 17, 1963</td>
<td>Sept. 20, 1963</td>
<td>Nov. 3, 1963</td>
<td>10400.4</td>
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<td>Krebiozen</td>
<td>May 27, 1964</td>
<td>1967</td>
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Table 2

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<th>Name and Address:</th>
<th>Agent</th>
<th>Date of C &amp; D Order</th>
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<tr>
<td>Catherine E. Harmon, D.C.</td>
<td>&quot;Harmonizer&quot;</td>
<td>Dec. 26, 1961</td>
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<tr>
<td>El Monte, California</td>
<td></td>
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<tr>
<td>Moraga, California</td>
<td>Grape Cure</td>
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<td>Nelson E. Mathison, M.D. (D.O.)*</td>
<td>Hoxsey Remedy</td>
<td>Mar. 21, 1963</td>
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<tr>
<td>Long Beach, California</td>
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<tr>
<td>Costa Mesa, California</td>
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<tr>
<td>Los Angeles, California</td>
<td>4 cellular agents</td>
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*One of approximately 2,630 former osteopaths who were granted M.D. degrees by California College of Medicine in 1962.

-111-
<table>
<thead>
<tr>
<th>Name and Address:</th>
<th>Agent</th>
<th>Date of Case &amp; Death Order</th>
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<tr>
<td>Rosamond, California</td>
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<tr>
<td>West Los Angeles, California</td>
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<td>Charles L. Hawk, M.D.</td>
<td>Hoxsey Remedy</td>
<td>Aug. 30, 1963</td>
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<td>Chew Cahoone Yuen, D.C.</td>
<td>Chinese Herbs</td>
<td>Aug. 20, 1964</td>
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<td>Red Bluff, California</td>
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<td>Howard F. Parsons, M.D. (D.O.)</td>
<td>Bolen Test, Autogenous Vaccines, Koch Synthetic Antitoxins, Samuel's Short Wave Generator</td>
<td>Mar. 4, 1965</td>
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<td>Ernest T. Krebs, Sr., M.D.</td>
<td>Laetrile, Anthrone Test</td>
<td>Apr. 5, 1965</td>
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<td>San Francisco, Calif.</td>
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<td>Maurice H. Kowan, M.D. (D.O.)</td>
<td>Mucorhizin</td>
<td>May 21, 1965</td>
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<td>Los Angeles, California</td>
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<td>Santa Monica, California</td>
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<td>Klassen, David C., D.C.</td>
<td>Diet, Ultra-sonic Device</td>
<td>Mar. 21, 1966</td>
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<td>Burbank, California</td>
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<td>Miller, Palmer D., M.D.</td>
<td>Laetrile, Anthrone Test</td>
<td>June 13, 1966</td>
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<td>Drown, Leslie K., D.C.</td>
<td>Formula 4 Tablets, Rife Frequency Instrument, Raylax Device, Rocking Tables, Chiropractic Manipulations, Splenic Massage</td>
<td>Oct. 17, 1966</td>
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<td>Burlingame, California</td>
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<td>Fresno, California</td>
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<td>Name and Address:</td>
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<td>Date of Cease &amp; Desist Order</td>
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| Thomas W. Sherwood, D.C.  
   West Los Angeles, California | Hemotabs, Depolaray, G-K 400, Oscillowave-Bridge Machine, Diet, Liver Tablets | Dec. 3, 1966 |
| Louis Remy  
   Valley Center, California | Macrobiotics, Dietary Methods | Dec. 29, 1966 |
| Victor M. Margutti, M.D.  
   San Diego, California | Calbro Magnowave, Radi-onics Machine, 460 Vials, Eight Research Instruments | Sept. 25, 1967 |
| Leslie T. Kaa, D.C.  
   Oakland, California | Anthrone Test, Bolen Test | April 1, 1967 |
Public educational and informational campaigns require extensive planning and costly materials to be realized -- and effective. Part of such undertakings are the formulation and compilation of pertinent information, adapted to be useful to persons seeking information about reputable methods of diagnosis and therapy. Today, among the services which the American Cancer Society makes available are:

a. A year-round information and referral service.

b. Extensive literature and other educational materials (film strips, exhibits, etc.) on cancer, the disease, how to recognize symptoms and what to do about it.

c. A description of cancer research supported by the Society.

In addition, the American Cancer Society conducts both seasonal and continuing informational campaigns, trying to break down the barriers of fear and anxiety which can lead persons to neglect cancer -- possibly to seek quacks.

The following facts are samples of the information which is and should continue to be disseminated to the public about cancer:

a. Specific sites of cancer, if found early and treated promptly, would save the lives of one out of two cancer patients; the present rate is saving one out of three.

b. At first sign of one of the seven danger signals, see your physician.

c. Cancer consultation and treatment service, meeting standards set by the American College of Surgeons and the California Cancer Commission, is available in more than 70 hospitals throughout California.
d. Among this number, more than 20 are public hospitals, where care is available to the medically indigent.

e. The Tumor Tissue Registry, maintained by the California Cancer Commission, distributes sets of slides on rare or difficult tumors to 120 participating pathologists.

These facts, plus many more, constitute a body of information which, if disseminated -- and assimilated -- can help break down the "mystery" surrounding cancer, the mystery that causes some persons to avoid conventional care, risk premature death and great suffering, and causes some to seek the hollow solutions of the quack.