THE CANCER LAW

1959-1964

REPORT TO THE GOVERNOR
ON THE ACTIVITIES AND ACTIONS OF THE
STATE OF CALIFORNIA, DEPARTMENT OF PUBLIC HEALTH
AND THE CANCER ADVISORY COUNCIL
JANUARY, 1965
Hon. Edmund C. Brown, Governor of California  
Sacramento  
Hon. Hugh M. Burns, President pro Tempore,  
State Senate, Sacramento  
Hon. Jesse M. Unruh, Speaker  
State Assembly, Sacramento

Gentlemen:

Pursuant to Chapter 789, Statutes of 1959, we are pleased to transmit herewith the report of the Cancer Advisory Council, the Cancer Diagnosis and Therapy Evaluation Unit of the State Department of Public Health and the State Board of Public Health. This report summarizes activities for the five year period since the original enactment of this legislation.

Respectfully submitted,

Malcolm H. Merrill, M.D.
Director of Public Health
THE CANCER LAW
1959-1964

Health and Safety Code

Division 2 Chapter 7 Sections 1700-1721

Report to the Governor on the
Activities and Actions of the
Cancer Advisory Council,
The Cancer Diagnosis and Therapy Evaluation Unit,
State of California, Department of Public Health,
and The State Board of Public Health

January, 1965
SUMMARY

of Report to the Governor of California on the Activities and Actions of the Cancer Advisory Council, Cancer Diagnosis and Therapy Evaluation Unit, California State Department of Public Health and the State Board of Public Health.

Quackery in medicine is as old as the art of healing itself. Efforts to contain quackery through legal means have been realized gradually in recent decades. However, legislation to control medical quackery has failed to keep pace with the influx of fraudulent techniques.

The impetus to limit cancer quackery, a costly and particularly sensitive type of medical fraudulence, was stimulated largely by physicians and laymen appalled at the consequences: use of quack cancer treatment may delay scientifically sound forms of treatment, producing disability and premature death. The concern of many citizens over this situation received legislative consideration first in 1957.

California, in 1959, became the first state to enact legislation to challenge cancer quackery by passing the Cancer Law (Health and Safety Code, Division 2, Chapter 7, Sections 1700-1721). The law stipulates that diagnostic and therapeutic means for cancer be scientifically sound, subject to scrutiny. To implement the Cancer Law, an investigatory activity, the Cancer Diagnosis and Therapy Evaluation Unit, was established in the State Department of Public Health, through which evidence could be assembled, testing and investigation conducted, and recommendations for legal action reported to the Cancer Advisory Council. The Council, a 15-man body of competent medical experts and educators and laymen, evaluates the data, submitting its recommendations to the State Director of Public Health. The adoption of regulations to
outlaw fraudulent agents is actually invested in the authority of the State Board of Public Health, acting in response to the Director's reports. Further, the Cancer Advisory Council may recommend to the Director the issuance of cease and desist orders to those practitioners known to have used or currently using agents banned by regulation.

The Cancer Law is liberally drafted, permitting a person found dispensing quack cancer agents considerable flexibility of action. Once a complaint or report is received and an investigation is approved, two legal alternatives occur: response by the practitioner in an accusatory hearing, or, conduct of an investigatory hearing which may result in an accusatory hearing and further action by the Council. Failure to supply an agent for analysis violates section 1707 of the Cancer Law, resulting in conclusive presumption that the agent is of no value.

The Council reviews extensive evidence before taking action. It may involve testimony of expert witnesses; testing procedures such as animal studies, chemical analyses, clinical tests; court actions; opinions of medical school Deans and other medical experts; and interviews with relatives of cancer victims treated by the agent in question. Testimony introduced in the Departmental hearings is also evaluated. Clinical evaluation, naturally, is important. While medical technology has made some remarkable advances, with few exceptions, surgery, radiation and certain forms of chemotherapy are the treatment methods for cancer most commonly accepted. They are advocated by qualified medical men and currently taught in Schools of Medicine. In the evaluation of an anti-cancer agent, successful therapy must include measurable reduction in tumor size demonstration by palpation, radiographic or visual observation, onset of calcification or favorable alteration in abnormal blood findings. Contrary to claims of cancer quacks such things as
feelings of "well being," gain in weight, increase in appetite do not reflect response of the cancer to a drug.

Since 1959, six agents have been ruled unlawful for "prescription, administration, sale or other distribution" in California through the actions of the Council. Two agents have been considered at public hearings on October 20, 22, 1964, and further action is pending. The six agents against which the Council and the State Board of Health have acted include: the Hoxsey agent; Laetriles; the Bolen Diagnostic test; the Koch Synthetic Antitoxins; the Lincoln Staphage Lysate; and Mucorhcin.

Ten practitioners have been investigated without subsequent action and more than one hundred and thirty are known to require investigation.

Public response in the enforcement of the Cancer Law has been vocal, although protests and complaints were expected. Most of them are made during the public hearings prior to adoption of prohibitory regulations but the constitutionality of the Law and the actions taken by the Department, which are questioned, can actually only be settled in the courts. To date, no court actions have been required. Clinical testing, while not considered mandatory by the Attorney General, may be recommended by the scientific members of the Council where feasible or justified. Considerable leniency has been displayed by the Council to permit proponents of the agents to have time to provide evidence substantiating their positions.

The Cancer Law, which has already displayed effectiveness in curbing some of the agents used in California, has also served as a prototype for legislation enacted since in several other states. As the first major attempt to render insult to medical chicancery, the Cancer
Law, to be even more effective, should be reenacted and strengthened. Only through its continuance can cancer quackery be seriously threatened in California, and the health of our citizens substantially protected.

Table 1

<table>
<thead>
<tr>
<th>Name of Agent</th>
<th>Cancer Advisory Council Report</th>
<th>Date Adopted State Board of Health</th>
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<td>Sept. 20, 1963</td>
<td>Nov. 3, 1963</td>
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Table 2

Practitioners against whom Cease and Desist orders have been issued:

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<td>Francis M. Altig, M.D. (D.O.) Rosamond, California</td>
<td>Hoxsey Remedy</td>
<td>July 23, 1963</td>
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<td>Willoughby W. Sherwood, M.D.</td>
<td>Hoxsey Remedy</td>
<td>Aug. 31, 1963</td>
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<td>Chinese Herbs</td>
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INTRODUCTION

Quackery in medicine is as old as the art of healing itself. It has been described as the second oldest profession, and since ancient times has figured all too prominently in the records of medical history. Only in the last century, as medical science has become increasingly refined, can the trappings of quackery be distinguished from the proven merits of medical knowledge. Only since the passage of the Federal Food and Drug Act in 1906, its amendment in 1912 and its complete replacement by the Federal Food, Drug and Cosmetic Act of 1938 have the advertised remedies -- tonics, serums, mechanical devices, innocuous pills and palliatives -- been subjected to a degree of scrutiny limiting the susceptibility of the public. Despite the protection afforded by this Act, medical chicanery in the United States continues to be a serious practice, more than a billion dollars being expended fruitlessly each year by individuals in pursuit of false cures and false hopes, often delaying the use of recognized diagnostic and therapeutic means.

For medical chicanery to survive, in spite of remarkable strides to improve the state of the public health, two factors must prevail: the rare salesmanship and resourcefulness of medical quacks -- both the deliberate frauds and the misguided -- and a deficiency in the social climate which prevents many persons from accepting the limits of medical science in avoiding disease, preserving life and easing pain. The medical quack thrives most successfully in a setting where people are anxious yet uninformed about health maintenance, although the victim may be the intelligent man, threatened by severe illness, who is taken in despite sophistication in matters of health. The very rapidity of
change has left great gaps in the ability of all Americans to be aware and understand the scope of medical care. Here, in a setting where improvements in conditions of life, remarkable advances in medical technology and application of preventive measures prolong life, the medical quack is able to operate because not all of the population benefits equally by these salutary changes. In this arena the art of the medical charlatan has become more devious and unprincipaled, and segments of the public more gullible. Combating quackery, therefore, has become a matter of concern not only to legitimate medical practitioners but also to government agencies and private citizens.

In seeking ways to curb the perniciousness of medical quackery, however, the legal process has met considerable opposition. Only in a few phases of medical quackery has lack of public acceptance or legislation been able to limit its course. Most recently, quackery involving cancer diagnosis and treatment has met serious rebuttal, chiefly due to the vigorous energies of citizens determined to rout fraudulence from management of this disease.

Perhaps because of the psychological and social setting of cancer, quackery involving this disease seems especially vicious. One factor which cannot be overlooked is that interference in a legitimate pattern of diagnosis and treatment can produce untold delays in obtaining life-preserving medical care. Unlike a number of less formidable -- or fatal -- diseases, cancer does not depend on time for healing. For too many persons, reliance on unproven quack methods has increased their risk of premature death from cancer and has convinced still others that they have the disease when in fact they may not.

Legislation to control the menace of medical quackery has failed to
keep pace with the influx of fraudulent techniques. Ingenuity and deviousness cannot be contained until victims of medical quackery in fact report their suspicions to the proper authorities, and even then, the legal procedures required to inhibit use of a quack agent are very involved. Federal authority to combat medical quackery is fairly limited: means are available through the Pure Food and Drug and Cosmetic Act, the Federal Trade Commission and the Post Office Department. Individual states, however, are in a far better position to legislate controls and enforce them.

In this tradition, laws governing medical quackery -- in particular cancer quackery -- have been enacted in California. Several factors influenced this pioneer legal approach: first, the apparent fertility of California as a site of medical quackery; second, the conscientiousness of professional and lay citizens to alter this reputation; and finally, the overall public health concern to bring reputable medical management to the disease which kills over 22,000 Californians each year. The attraction of medical quacks to California has a colorful, though unpleasantly long history. The recent population bulge of the past two decades, especially in the ranks of the elderly, has only increased the opportunity for medical quacks to flourish -- and remain concealed. News of medical quackery travels slowly: often it is the relative of a duped victim who becomes suspicious; other times it is the medical specialist to whom a patient ultimately turns, too late to receive proper diagnosis and medical care; and occasionally, a quack technique simply fails to attract attention and subsequently disappears. Responsible persons in public health and the branches of science which deal with cancer as a genuine health problem are particularly sensitive to the harm created by
cancer quackery. Because a number of sites of cancer are amenable to early detection and treatment which means the difference between death and survival, health-conscious citizens gravely resent the untold waste which quack management produces.

Prior to the enactment of laws to curb quackery in California, the State was host to a number of remarkable charlatans who bilked Californians of millions of dollars for fraudulent diagnosis and treatment. Ranked as "dean of all twentieth century charlatans," Dr. Albert Abrams amassed a fortune of over two million dollars during his lifetime chiefly through the application of "The Electronic Reactions of Dr. Abrams." Abrams began his career in medicine quite authentically, studying at Europe's leading medical centers before returning to his native San Francisco to practice. In 1910, his departure from traditional medicine was noted by publication of Spondylotherapy: Spinal Concussion, which attracted many devotees despite the condemnation of the California Medical Society. Abrams toured the country, giving clinical courses in Spondylotherapy -- at $200 per course. Successive publications indicated that Abrams had definitely slipped over the abyss into the realm of quackery. Disease, Abrams believed, is a disharmony of electronic oscillations; diagnosis must detect and measure the alteration; treatment originates in readjustment of vibrations.

By submitting a "drop of blood" or "an autograph" -- which Abrams claimed was just as suitable -- to his diagnostic machine, Abrams could determine not only the presence of illness but the age, sex and religious belief of the patient. The high-water mark of the E.R.A. cult, dominated by use of Abrams diagnostic and treatment machines, was probably 1923, when more than 3500 of these devices were in operation by Abrams and his
disciples. These machines, aptly known as the Dynamic Abramic Pole and the Oscillator, contained nothing more than a number of common electrical gadgets. They could be leased or purchased.

A Michigan doctor sent Abrams some blood from a rooster, only to be told that the "patient" suffered from malaria, cancer, diabetes, and a couple of venereal diseases. More precise determinations were made from the blood of a guinea-pig. An Abrams' disciple in Albuquerque found the "patient" ill with cancer, sinusitis (left-side) and a streptococcal infection of the Fallopian tube.

The wave of confidence in the Abrams' techniques did not immediately decline after his death in 1923. If anything, his success had encouraged other potential quacks to believe that people will fall for almost anything, and that in California they may fall harder.

One of his successors was Dr. Ruth Drown, a Los Angeles chiropractor, who also utilized blood diagnoses. Dr. Drown maintained blood files on her patients and was able to tune in on the lucky patient by broadcasting healing rays to him while he, in fact, remained at home. Dr. Drown sold her machines across the nation. Challenged by a group of Chicago scientists, her diagnostic ability was demonstrated to be deficient. She claimed that one patient with tuberculosis actually had cancer of the breast, blindness, and malfunction of sixteen other organs ranging from the right ovary to the ears. In 1951 Dr. Drown was prosecuted for violation of the Federal Food, Drug and Cosmetic Act and found guilty.

In the decades following Dr. Abrams' remarkable success, medical quacks emulated but seldom approached a duplication of his reputation or wealth although some were able to practice effectively under the
badge of a legitimate medical degree. Most of them did not confine their "technology" to one disease entity, such as cancer, but worked with equal persuasion on the entire spectrum of bodily ills.

Shortly before legislation was enacted in California, one of the most exotic forms of medical quackery was revealed, the "Film-O-Sonic" device by which both diagnosis and treatment of disease including cancer were claimed. Before being apprehended, the trio advocating "Film-O-Sonic" had netted $200,000. They were particularly compatible associates, and they had been able to command clientele throughout the State.

The cast of partners included three: Chiropractor Emerson B. Hartman, manufacturer Webster Billington, both of Southern California, and their Northern saleswoman, Mrs. Golda Franzen. The modus operandi for the promotion was usually this: the victim who either thought he had cancer or actually did would be referred to Mrs. Franzen through interested persons, perhaps previous "patients." Mrs. Franzen screened inquirers to determine their sincerity. The patient would then travel to an office in San Bernardino where, with the aid of a Gavitronic Life Ray Machine, Dr. Hartman would stroke his hands over the patient's anatomy. His customary diagnosis would be cancer or some "bacterial" disease. Criteria for diagnosis would vary from cold shivers in his finger nails to a twitch of the ring finger. In the case of cancer, the chiropractor's hands would become cold as they passed over the malignant lesion. He would then advise the patient to buy his book "Professional Secrets for Doctors and Laymen," a dazzling little hand-book alternately devoted to case histories of improbable cures and the theory of vibrations, Dr. Abrams' old saw. Hartman's "germ" theory of cancer, and its cure by use of diet and treatments with the Film-O-Sonic
Vibrator were also documented.

The patient would then return to Mrs. Franzen, purchase a machine (for as much as $500), or if the patient lived in southern California purchase the machine from either Hartman or Billington. The treatment was exciting and extremely modern: the strict diet consisted of "wonder water," a nectar of grape juice, orange juice and urine; the vibrating machine was in reality a tape play-back device without a speaker spilling forth the tune "Smoke Gets in Your Eyes." The patient would apply two pads wired to the device over the region of the body affected by cancer. The Lord's Prayer was a second selection invoked in certain types of cancer.

Many victims had been ensnared in the Film-O-Sonic trap before the trio was brought to justice, since the legal process to put them out of business was long. Publicity about the case offered a warning for a time to the naive, but did not necessarily prevent other quack practitioners from continuing their work.

In November 1957, the Bureau of Food and Drug Inspections responded to an inquiry of a private citizen, who subsequently died of cervical cancer, as to the efficacy of the machine and supporting diet. Subsequent investigation and simultaneous arrest of the three parties resulted in a complaint filed by the State Department of Public Health for violations of the California Pure Drugs Act. All three defendants were charged with selling a misbranded device and advertising a device purported to have an effect on cancer. In September, 1959, the three were found guilty after a lively eight-day trial. All were given suspended sentences, placed on probation and charged nominal fines. Their appeal was denied by the Appellate Court. Payment of fines resulted in a reduction in a
portion of the jail sentence in two of the individuals concerned but since the third refused to pay his fine all of his jail sentence was enforced.

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 quackery must be structured to compensate for human fallibility.

Statutory Development to Control Cancer Quackery in California

The impetus to control cancer quackery stemmed originally from physicians and laymen troubled over the extent of the problem in this State. Prior to statutory enactment in 1959, professional societies, agencies of the government, and voluntary health organizations tried independently to make a serious dent in the situation. Their efforts were designed to combat a situation only slightly improved from that of forty years before.

"...Some forty years ago it was estimated that there were four thousand promoters of cancer cures in the United States. There were even charlatan hospitals with complete staffs, large buildings, and every appearance of sound fiscal backing. There were concerns which manufactured and supplied cancer cures upon a mail-order basis...."(4)
In fact, as late as the early 1950's, the existence of cancer quackery might not have been as pervasive but surely it was more adroitly contrived and masked.

Most fervent in its pursuit of the cancer quack has been the Cancer Commission of the California Medical Association. Since 1952, this body which comprises 18 physicians having clinical experience with cancer or teaching experience has carefully analyzed the problem. The Commission invited proponents of any treatment for cancer to submit the method, with proper documentation, for adequate trial by responsible, impartial investigators -- with the understanding that the results of such tests, whether favorable or unfavorable, would become a matter of record.(5)

The Commission then studied a series of alleged cancer remedies, aided by the Bureau of Investigation of the American Medical Association, the Federal and State Food and Drug Administrations, and the Committee on Cancer Diagnosis and Therapy of the National Research Council. Facts concerning all alleged cancer remedies were then released to the scientific community and the public at large through reports in specialized and mass media.

Investigations of the Commission followed a sound scientific procedure which included determination of the precise nature of the treatment method; interview of proponent and review of his scientific background; examination of both experimental and clinical evidence offered by the proponent; examination of any autopsy data available; securing drug for analysis and trial on experimental basis; treatment of a small number of patients, persons beyond reasonable hope of control by surgical or radiotherapeutic means, with autopsy examination if available; and consultation with other investigating groups and research
The activities of the Cancer Commission exposed several bogus cancer cures. This was accomplished largely through public information after extensive trial procedures proved the cures worthless. The work of this Commission is necessarily painstaking and slow, but it still continues, and in fact supports the activities of the Cancer Advisory Council. More important, however, is the role which members of the Cancer Commission played in bringing their type of scientific investigation to the attention of the legislature. The Cancer Commission fully believed cancer quackery could be combatted more expeditiously through the legal process with definitive action promulgated against cancer quacks, and potentially a higher degree of public education. The ability of the Cancer Commission to actually punish a cancer quack -- to put him out of business and more, to penalize him through legal sanctions -- is naturally limited. Only through a complete legal system could this type of injustice -- which smacks of criminal mischief -- be strictly treated.

Members of the Cancer Commission of the California Medical Association stimulated legislative attention in 1957 to the cancer quack problem. The proposed Bill was to be introduced from both sides of the aisle -- in both the Assembly and Senate -- simultaneously, but this was not done. Following hearings in the Assembly, the Bill came out of committee almost unanimously and passed overwhelmingly on the floor. In part, this was due to a very small but dramatic piece of testimony presented by a woman who came voluntarily to testify in favor of the Bill because of the death of her sister from cancer. The Senate hearings were more restrained. The Bill was expected to gain majority support but it failed by one vote to be passed out of Committee.
Therefore, the Senate established an interim committee before which proponents and opponents could be heard. Dr. Andrew Ivy, one of the promoters of Krebiozen testified as did Dr. Paul Kirk, whose chemical analysis indicated that Krebiozen as marketed contained nothing but mineral oil. No serious obstacles were presented at this time, and the Senate Interim Committee brought in the Bill, slightly revised, which was passed in the 1959 session and signed into law on June 5, 1959.

The law adds Chapter 7, Sections 1700-1721 to the Health and Safety Code. (See Appendix III for full text of this law.) The law places the responsibility for enforcement upon the State Department of Public Health and to assist the Department specifically creates a Cancer Advisory Council and a legal mechanism to provide for investigation or testing by procedures by which alleged cancer cures may be evaluated.

The need for this specific law is clarified in Section 1700:

"...Vital statistics indicate that approximately 16 percent of the total deaths in the United States annually result from one form or another of cancer...Accurate and early diagnosis of many forms of cancer, followed by prompt application of methods of treatment which are scientifically proven, either materially reduces the likelihood of death from cancer or may materially prolong the useful life of individuals suffering therefrom." (Emphasis added)

Scientific proof of efficacy or lack thereof was the objective proposed by this section. The law was drafted with one further observation in mind: that despite intensive public education there remains a lack of adequate and accurate information for the layman to knowledgeably distinguish plausible, scientific activity from fraudulence. Misrepresentation of diagnostic or therapeutic skills was stated as
a fact. Human fallibility was implied. This law, therefore, was designed to protect the public from the specific misrepresentations of false "cancer cures."

To implement these statutory provisions, an investigatory body known as the Cancer Diagnosis and Therapy Evaluation Unit has been created within the framework of the State Department of Public Health to assemble evidence, arrange for testing or investigation for presentation to the Cancer Advisory Council for evaluation and ultimately for submission to the State Board of Public Health for regulatory action.

Functions and Policies of the Cancer Advisory Council

The Cancer Advisory Council advises the State Department of Public Health regarding policies and procedures which might best serve to evaluate questionable methods in cancer diagnosis and treatment. It is not invested with administrative or executive powers. The initial activities of the Council were to recommend procedures to be followed in the evaluation of the use of unorthodox methods in cancer diagnosis and treatment. This involved decisions on investigatory procedures and testing according to the language prescribed in Section 1711 of Chapter 7 entitled Cancer. The Council reviewed the means available by which authentic scientific trials could be made.

The composition of the Cancer Advisory Council was specified by law (Section 1701). Of the 15-man Council, six positions must be held by faculty members from the schools of medicine and surgery in California; two by representatives of the non-profit cancer research institutes in the State; three positions must be held by physicians in private medical or surgical practice; three unspecified positions have usually been filled by members of the health, education, or business professions; the final
position is filled by the Director of the State Department of Public Health who sits ex-officio. The direct liaison between the Council and the Department is further provided by the Executive Secretary of the Council, a physician and pathologist, who also heads the Departmental Unit undertaking the investigatory assignments needed for Council review and action. Legal counsel is provided by members of the staff of the California Attorney General. A chairman is elected each year by the members.

The Council is empowered to create committees for specific duties, to review committee reports, and, most actively, to participate in hearings called by the Department.

Members of the Council receive no compensation for their services, but are reimbursed for any necessary travelling expenses incurred in the discharge of their duties.

Governor Brown appointed the First Council in November 1959. (See Appendix I for complete list of members who have served on the Cancer Advisory Council). The Council is required to meet twice a year, and has held two or more meetings annually in the performance of its duties. Because of the ethical practices involved, the Council in its advisory capacity makes its recommendations to the State Director of Public Health for final action. On the basis of these recommendations the Department may in turn recommend to the State Board of Public Health the adoption of specific regulations banning the prescription, administration, sale or other distribution of those agents which have been shown to be of no value in the management of cancer. Further, the Cancer Advisory Council recommends to the State Director of Public Health that cease and desist orders be issued against those practitioners known to have used or who
are currently using an agent banned by regulation.

Since 1959, six agents have been ruled unlawful for use or sale in California for the treatment or diagnosis of cancer through the action of the Cancer Advisory Council. Moreover, cease and desist orders have been issued to a total of nine persons known to be employing these agents.

The Role of the Cancer Diagnosis and Therapy Evaluation Unit

In order to be able to bring the full measure of the law into play, the Cancer Advisory Council relies upon the investigative unit, the Cancer Diagnosis and Therapy Evaluation Unit. It is through the investigations of that unit that questionable cancer agents and practitioners are disclosed and the agents collected, submitted for precise testing or other evaluation, findings being referred to and acted upon by the Cancer Advisory Council.

In addition to fulfilling detailed investigative activities, the Unit provides full staff assistance to the Council: here are maintained the files of the Council and those of the Department pertaining to Council activities. The staff of this Unit implements the recommendations of the Council; prepares agenda material for its meetings; suggests scheduling or cancelling regular meetings of the Council and hearings of the Department. Hearings may be called at any point when the Department suspects an agent to be fraudulent.

Members of the staff, in addition to their concentration on discovering cancer quackery and bringing it to the attention of the responsible authority, devote some time to education of the public. Both by addressing public gatherings and through publication of reports, the Unit augments the information provided by mass media, voluntary health
agencies (e.g. American Cancer Society), and health education services. By public information, the Council may be able to expose and restrain more expeditiously, the worthless and wasteful use of quack agents. Just as public awareness has helped to hasten the greater control of environmental hazards, public awareness about cancer quackery may inhibit some of its strength and save many persons needless expense and suffering.

However, education alone cannot stem the resourcefulness and adroitness of quacks nor the skilled forensic talent they employ. A means to investigate and bring legal redress is also necessary. Primary emphasis on the daily workings of the Departmental Unit devolves, therefore, upon investigation and testing.

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. Chart 1 illustrates the two prime alternatives of action taken in a number of cases so far handled by the Cancer Advisory Council.
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 allures 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 Mucorhician 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 Cancer Advisory Council to find them guilty of abuse of Section 1707. Upon the recommendation of the Council, cease and desist orders were issued to both parties by the Director.

If, however, an individual complies with the subpoenas 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, or 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 a 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, 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, two 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," and Chew Cohong Yuen, D.C., an herbalist.
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 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.

Criteria Accepted for Clinical Evaluation

While medical technology has made some remarkable advances in both diagnosis and treatment of cancer, with the few exceptions elucidated below, surgery and radiation (e.g., X-ray, radium, radioactive isotopes) are the methods of treatment most commonly accepted. They are advocated by qualified medical men and currently taught in Schools of Medicine in California and elsewhere. In teaching institutions, emphasis is placed on early diagnosis where chances of cure are best. These chances are largely nullified when a person with early cancer wastes time on worthless therapy before submitting to conventional treatment methods. The economic loss incident to the purchase of the fraudulent therapies is nothing when compared to the loss of life because of delayed treatment by acceptable methods.

For more than a decade, much basic research and clinical investigation has been conducted concerning the causes of cancer with improvement of treatment methods by surgery, radiation and appropriate chemicals. Chemotherapy is accepted as a first choice procedure only in a limited number of malignancies.
A large number of chemicals although useful in the palliation of some varieties of cancer are not indicated in localized cancer where eradication by surgery or radiation is the preferred treatment. Chemical agents may be classified according to the type of action they produce and include the alkylating agents, the antimetabolites, the steroid hormones and other miscellaneous ones.

In the evaluation of an anticancer agent, successful therapy includes measurable reduction in tumor size demonstrated by palpation, radiographic or visual reduction in size, onset of calcification or favorable alteration in abnormal blood findings. Contrary to the claims by cancer quacks, feelings of "well being," gain in weight, increase in appetite, reduction in pain and ambulation in a previously bedridden patient do not necessarily reflect any response of the cancer to the drug. These types of responses may be due to a beneficial psychological effect incident to exposure to a new medicine, new doctor, extravagant promises, or a change in environment.

Therefore, the agents which were brought to the attention of the Cancer Advisory Council had to comply with established scientific patterns of evaluation. In each case, evaluation included extensive evidence before any decision was formulated to prohibit the further application of the agent in question.
SPECIFIC AGENTS INVESTIGATED UNDER THE CANCER LAW

1. Hoxsey Agent

Harry M. Hoxsey, a naturopath, began the treatment of human cancer patients in Taylorville, Illinois in 1921, with a remedy containing potassium iodide, licorice, cascara, pepsin, and extracts of red clover blossoms, burdock, stillingia, berberis and poke roots, prickly ash and buckthorn barks. These ingredients, exclusive of potassium iodide, are essentially those contained in Fluidextract Trifolium Compound, which appeared for the last time in the National Formulary, 5th Edition, 1936.

Hoxsey subsequently dispensed his remedy in numerous Eastern and Midwestern locations. In 1936, Hoxsey opened a cancer clinic in Dallas which operated under his auspices or that of his associates until closed by court order in 1960, following legal action brought by the Federal Food and Drug Administration. During most of Hoxsey's active career he was in trouble with the authorities as well as local medical societies, even though he nearly always practiced in collaboration with a licensed physician.

The Cancer Advisory Council directed its attention first to the Hoxsey treatment which had been known to be in use since the late 1950's. The formula used in California was essentially the same as that used by Hoxsey himself.

In evaluating the Hoxsey treatment, the Council drew on a wealth of evidence and scientific data: it considered the testimony of expert witnesses, animal studies, chemical analyses, Federal court actions, opinions of Deans of California Schools of Medicine, interviews with relatives of cancer victims who had received the Hoxsey treatment, and
finally the testimony presented during investigatory hearings held on six California practitioners who were prescribing the treatment.

Two public hearings before a committee representing the State Board of Public Health were held on the proposed regulation. At the Los Angeles hearing, approximately 250 advocates of the agent appeared, about 50 of them testifying to its efficacy. The evidence presented here was largely testimonial, consisting of claims made by the witness himself, relatives, friends or even remote acquaintances who were benefitted by the medication.

During the investigatory hearings, the Cancer Advisory Council listened to a fantastic theory by proponents of the treatment regarding the effect of potassium and iodine ions on the electrical potential of the cancer cell leading to its ultimate destruction; to claims that the Hoxsey treatment was directed toward a deranged general metabolism rather than cancer itself although the proponents admitted that between a quarter and three-quarters of their clientele was comprised of patients who either had cancer or believed they did. They made a further claim that supportive medication given concurrently was requisite to the basic treatment. (Supportive therapy was admitted by the Council to have a place in conventional treatment for cancer or other diseases but not directed toward the basic disease. For example, if anemia, pain, constipation, etc. are coexistent with a major disease, they are treated independently of treatment of the basic disease.)

In evaluation the merits of the Hoxsey agent, the Council reviewed the recognized pharmacology, toxicology and therapeutic qualities of the ingredients contained in this remedy. The most potent is potassium iodide. Iodine is important in normal diet to prevent endemic goitre, and potassium iodide is used as an expectorant in asthma and other conditions.
where tenacious bronchial secretions are a problem. Prior to the use of penicillin, potassium iodide was widely used in the treatment of tertiary syphilis when manifested by gummas. However, these proven medicinal effects of potassium iodide are somewhat offset by the toxic reactions which may result from its ingestion. The symptoms of iodism as these reactions are called are numerous: upper respiratory symptoms simulating a common cold; skin reactions varying from a simple urticaria to an acneform eruption or progression to a lumpy disfigurement; fever; asthenia; mental depression; loss of sexual potency; iodide parotitis incident to irritation of the salivary glands; and more serious, the breakdown and reactivation of an arrested tuberculous lesion due to the histolytic action of the drug. Toxic reactions may be exhibited not only upon prolonged administration of therapeutic dosage, such as that encountered in use of the Hoxsey remedy in amounts varying from 65 to 1000 mg. per day, but because concentration of the drug is cumulative in the body after doses as small as 60 mg. per day.

The other components of the Hoxsey remedy -- root and bark extracts -- are used variously as flavorings or laxatives. In combination, the majority of these ingredients are pharmacologically inert, and even when mixed with potassium iodide unable to exert any ameliorative value -- either as "tonic" to a patient or destructive to the malignancy.

Experimental data were obtained by the Cancer Advisory Council to further substantiate the implausibility of the Hoxsey remedy favorably reducing cancer. Dr. Max Alexander Goldzieher, an experimental pathologist, conducted several experiments dealing with the effects of potassium and calcium ions on both animals and humans with cancer. Post-mortem studies of mice indicated that the tumors treated with
potassium salt grew faster and reached a larger size over specified time than those in mice treated with calcium salt. In an experiment on persons with far advanced, incurable cancers, 27 volunteers were placed on a diet highly deficient in potassium. While on this diet a marked shrinkage of their cancers took place but the experiments had to be stopped after three to six weeks since symptoms of potassium deficiency, such as cardiac weakness and general debility, appeared. Upon return to a normal diet, the tumors began to grow again. Contrary to the claims propounded by practitioners of the Hoxsey treatment, potassium iodide does not decrease malignant growth, but in fact speeds it up.

Clinical data were also reviewed by the Cancer Advisory Council, provided by testimony presented in court action against the Hoxsey Cancer Clinic in Dallas, Texas.

The opinions of the Deans of California Schools of Medicine were sought in this first investigation and in subsequent hearings. In no case was the Hoxsey method recognized as a reputable scheme for cancer management. One of the Deans emphasized in his statement the current thought among medical educators regarding judicious instruction about cancer.

"Surgery, radiotherapy, and chemotherapy are the principle modalities of cancer treatment employed at .... The decision as to choice of therapy is made after a diagnosis has been clearly established and often is arrived at by joint consultation with special interests and abilities in the field of oncology...The clinicians and investigators are constantly aware of the need for adequate controls in order to establish the effectiveness of any given method of treatment. The teaching of cancer therapy is, likewise, dependent on the fundamental precepts of the scientific
method as applied to experimental models, animals, and the human patient with cancer."(9)

Action of the Cancer Advisory Council

On May 31, 1962, the Cancer Advisory Council concluded its studies by finding that the Hoxsey Method in any combination was of no value in the diagnosis, treatment, alleviation or cure of cancer and recommended to the Director of the State Department of Public Health that appropriate action be taken to prohibit its prescription, administration, sale or other distribution. After appropriate public hearings, a regulation containing those features was adopted by the State Board of Public Health on September 21, 1962. This regulation appears as Section 10400.0, Chapter 5, Subchapter 2, Article 2 of the Administrative Code and became effective November 1, 1962.

Following hearings described previously, specifically for using the Hoxsey agent in violation of this regulation, cease and desist orders were issued to five practitioners in 1963 -- Francis M. Altig, M.D. (D.O.), Nelson E. Mathison, M.D. (D.O.), John H. Friend, M.D. (D.O.), Willoughby W. Sherwood, M.D. and Charles L. Hawk, M.D., all of Southern California.

2. Laetrile (Beta-Cyanogenetic Glucoside)

One type of palliative promoted during the post-war decades in this country was Laetrile, an agent which derives its name from the first and last syllables of the reported chemical name of this group of substances, laevo-rotatory-nitriles. As a beneficial form of treatment for cancer, laetriles were purportedly recommended on the theory that these chemicals produce a reaction with an enzyme supposedly present in excess in malignant tissue. As a result of this reaction, "nascent hydrogen cyanide is liberated," producing a selective cyto-
toxic effect on the cancer. Therapy of this nature was first applied
to human cancer by Ernst T. Krebs, Sr., M.D., shortly after 1920, when
"substantial clinical results" were reportedly obtained from the use
of a beta-cyanogenetic glucoside named amygdalin. Amygdalin is an
extract of apricot pits.

In 1952, Mr. Ernst T. Krebs, Jr., claimed he had synthesized a
new Laetrile, beta-cyanophoric-glucuronoside, which in the presence of
an enzyme beta-glucuronidase released quantities of nascent hydrogen
cyanide (HCN). Based on a claim that a significant number of cancers
developed greater amounts of beta-glucuronidase than most non-neoplastic
tissues, Mr. Krebs theorized that the "triggering" effect of the
glucuronidase on the Laetrile in cancer released HCN to a degree lethal
to the cancerous cell. A safety margin exists, however, due to several
chemical factors in the human system.

Stimulated by these findings, Mr. Krebs and his proponents developed
a number of synthetic substances known as "Laetriles." Beyond the
chemical theory, proponents identified a fundamental biologic rationale
for Laetrile therapy derived from the unitarian or trophoblastic theory
of cancer advanced by the Scottish anatomist, John Beard.

Laetrile and other drugs were produced and distributed by the John
Beard Memorial Foundation, San Francisco, an institution operated by Mr.
Krebs, Jr. in association with his father and B.A. Krebs, D.O. Before
becoming successful with Laetriles, the Krebses had produced and
promoted chymotrypsin, also a purported cancer remedy. Although chymo-
trypsin has been discredited as affecting cancer, it is still in
limited use in cancer treatment, to dissolve blood clots, and in the
treatment of infections.
The investigation of Laetrile began a number of years before the Cancer Advisory Council was created. The Cancer Commission of the California Medical Association studied the matter for several years, presenting its findings in an article in *California Medicine*, April 1953. The Commission reviewed experimental evidence offered by the proponents of Laetrile and that developed by independent investigators, autopsy data supplied by the proponents and further obtained by the Commission, clinical evidence developed by independent investigators, reports of consultants from the National Cancer Institute, Department of Biochemistry of the University of Southern California, and observations of the availability and costs of Laetrile. The sum of this evidence was clear: Laetriles in no way were capable of arresting or curing cancer. One of the consultants, Dr. Jesse P. Greenstein, Chief of the Laboratory of Biochemistry at the National Cancer Institute, explained the implication that a "tumor" beta-glucuronidase enzyme does exist.

"The fact is...that beta-glucuronidase is found in all tissues of the animal body and in particularly high concentration in spleen, liver and endocrine organs, as well as in plasma and in tumors arising from estrogen influenced tissues. Per gram of tissue, the spleen and liver have a higher concentration of beta-glucuronidase than do most tumors, and these normal organs together weigh more than most tumors. There is much more 'normal' beta-glucuronidase than 'tumor' beta-glucuronidase in any animal body."

Throughout the investigations by the Cancer Commission obstacles were numerous: information concerning the Krebbses and their foundations, the distribution of Laetrile, its use by a number of physicians were attended by a constant series of conflicting statements; claims were
made and denied; supplies of Laetrile were repeatedly promised for clinical and experimental use but eventually refused; and repeated implications were made that the Commission's intent was to discredit the proposed treatment rather than merely to evaluate it. Mr. Krebs himself oscillated from pronouncing vast claims due to Laetrile and then denying them. An evaluation of the efficacy of a cancer treatment outlined by and deemed acceptable to Mr. Krebs included criteria such as decrease in pain, increase in appetite or weight, sense of well being, or increase in life expectancy.

The Cancer Commission investigated the actual distribution and financial setting of Laetrile. Although Krebs had maintained that the development of the agent had been extremely costly commercial amygdalin was then available at about two cents per 100 mg. A witnessed statement from a patient treated for Hodgkin's disease certified that a week's therapeutic course included three injections of Laetrile at $50 each and three injections of so-called vitamin B_{15} at $10 each but cost to a physician being supplied with Laetrile was reported to be only $10 per ampule of Laetrile and $3 per ampule of vitamin B_{15}.

As a result of their investigations, the Cancer Commission indicated several defects in the claims made by the proponents, summarizing by stating that "No satisfactory evidence has been produced to indicate any significant cytotoxic effect of Laetrile on the cancer cell."(10) The Commission report cited independent studies, autopsy and histological studies, and the chemical and biochemical analyses which clearly indicated the inability of Laetrile to alter the course of cancer.

Without legal means, however, the Cancer Commission was unable to prohibit the continued sale and use of Laetrile. The Beard Memorial Foundation and Laetrile flourished.
Action of the Cancer Advisory Council

Laetrile was one of the agents which the Council began to investigate shortly after its appointment in 1959. At that time, the State Department of Public Health learned that two varieties of Laetrile, prunasin and laevo-mandelonitrile glucuronoside for experimental use had been produced synthetically. Krebs advised the Department that the product distributed to the medical profession was essentially the same as that used in the early 1950's but that an iodine compound, iodamine (diisopropyl ammonium iodide), had been added to some of the Laetrile used locally by Drs. Krebs. Production costs of the synthetic varieties of Laetrile were such that they were no longer deemed practical, even though they had not been in current use other than experimentally. The Krebses later specified that these experiments were solely on animals. Other information presented to Dr. L. Henry Garland and Dr. Kenneth Ernst in 1961 indicated that better cancer results were obtained by using ten times the dose recommended in earlier years (100 mg.). In animal experiments conducted by the Cancer Commission and the Cancer Advisory Council, doses up to 170 times that former amount did not present evidence of tumor control.

The Cancer Advisory Council requested current opinions regarding the validity of study methods used to evaluate Laetrile in 1952-53. Pathologists and former commission members were asked to restate their findings on autopsy material and to express their opinions as to the current validity of the study methods used in 1952-53. Confirmatory responses from both Commission members and pathologists were received. The National Cancer Institute was consulted for a current opinion on the enzyme beta-glucuronidase; no further evidence to modify Dr. Greenstein's
earlier opinion could be cited.

Extensive testing of Laetrile (both the earlier and later versions) was made by Dr. Paul L. Kirk, University of California, Berkeley, and also the Food and Drug Laboratories of the State Department of Public Health. The samples, identically labeled when obtained from the Hale Laboratories, in fact contained differing amounts of only one component, inorganic iodide. Otherwise, the contents were identical to the commercial product, amygdalin. Experimental studies were conducted at the University of California, Berkeley, on tumors in mice. No recognizable effect on tumor growth could be detected. Toxicity studies were also performed by Leberco Laboratories, Roselle Park, N.J.

Clinical evidence was presented at the hearings by Dr. William Beare, a San Francisco internist, who related in detail the history of a case of metastatic breast cancer treated with Laetrile, following radical mastectomy and X-ray therapy. The patient also received X-ray sterilization and injections of testosterone and steroids prior to death, as well as Laetrile. Therefore, the Council felt that reliable evidence of Laetrile's direct influence could not be determined due to the widespread concurrent use of other conventional treatment methods.

Case histories were supplied by Mr. Andrew R.L. McNaughton of Montreal and Dr. John A. Morrone, Jersey City, N.J. Many of the cases had received orthodox treatment; objective evidence of benefit was absent or insufficient; some contained no pathologic proof of malignancy; many were 1961 cases without followup; records were incomplete. On review, no evidence of palliation or alleviation from cancer as a result of treatment with Laetrile was found. Roughly 16 pounds of documentary material were submitted by proponents of Laetrile, including
case histories from physicians located in Mexico, Italy and the Philippines. Tenuous documentation again did not lend support to the case of Laetriles' advocates.

A member of the Cancer Advisory Council, while in Montreal, visited several medical installations where Laetrile was in use as a cancer treatment. Information given was scanty, largely testimonial, and some credence was placed on the Beard Anthrone Test, which also is discussed in this report.

Medical opinions on the efficacy of Laetrile in cancer treatment, and whether this method is included in medical curricula, were obtained from the Deans of California Schools of Medicine, and from two physicians on the staff of the University of California School of Medicine, Nicholas L. Petrakis, M.D. and Frederick H. Meyers, M.D. In no case did any of these physicians find that Laetriles offered valid, scientific evidence recommendable in cancer management.

After public hearings and pending final action by the State Board of Public Health, communications were received supporting Laetrile. All were given careful consideration by the State Department of Public Health and the Cancer Advisory Council. Three cases particularly were considered of sufficient clinical value to warrant further study before a final decision was made. One involved an adult, who as a boy 15 years previously had a tumor removed from one leg. The diagnosis at that time was neurofibrosarcoma and the recommended course of treatment to save the boy's life was amputation. This procedure was refused, and Laetrile used instead. The boy survived, and his parents credit the chemical. The Department obtained tissue from the original tumor which was submitted to two outstanding tumor pathologists, one in California,
one in New York. Both gave the same opinion and diagnosis: that the original diagnosis had been incorrect, the TUMOR WAS A BENIGN NEUROLEMOM.

In a second case there was evidence that a tumor although malignant had been totally removed by surgery before Laetrile was administered. And in the third case, a patient presumably receiving great benefit from Laetrile was, in fact, receiving conventional therapy at the same time.

In a San Francisco Federal Court in May 1962, E.T. Krebs, Jr., was found guilty of introducing drugs into interstate commerce which were misbranded and lacked proper application as a "new drug." Fines were imposed, and Krebs was placed on three years probation from a suspended jail sentence on condition that he cease the manufacture, production, sale, delivery or gift of any "new drugs", specifically including Laetrile, until State and Federal provisions had been fulfilled. The judgment was later altered to permit shipments to the McNaughton Foundation, Montreal, and to qualified experts, under specified conditions, who had cancer patients under treatment with Laetrile as of June 15, 1962. A new drug application had to be filed, but the Foundation failed to submit proper materials and thus did not succeed in obtaining approval by the Federal Food and Drug Administration. As the safety and efficacy of the products could not be ascertained, Laetrile could no longer legally be shipped interstate.

On May 20, 1963, the Cancer Advisory Council concluded its studies by finding that the Laetriles were of no value in the diagnosis, treatment, alleviation or cure of cancer and recommended to the Director of the State Department of Public Health that appropriate action be taken to prohibit their prescription, administration, sale or other distribution.
After appropriate public hearings a regulation containing those features was adopted by the State Board of Public Health on September 20, 1963. This regulation appears as Section 10400.1, Chapter 5, Subchapter 2, Article 2 of the Administrative Code and became effective November 3, 1963.

3. Bolen Diagnostic Test

In 1939, E. Goldberger published a rapid "bedside" method for determination of the erythrocyte sedimentation rate. In the test, three drops of blood are touched to the under surface of a glass slide, the slide righted and the blood allowed to clot and dry spontaneously. The slide is then interpreted by observing the pattern of the clot. On the basis of the fineness or coarseness of general detail, the character of the meshwork if present, and the presence or absence of central agglutination or peripheral rings of cells, a classification from normal to moderately rapid, to rapid to very rapid may be made.

H. Leonard Bolen, M.D., impressed with the simplicity of this test, began applying it to cancer diagnosis. His papers on using this procedure were published from 1942 to 1952. He reported that the clotting pattern among cancer patients is quite distinctive from that observed in patients with ulcer and inflammatory disease. In the latter, no meshwork or break-up of fibrin may be observed, the compact blood clot showing a central dark agglutination. In cancer patients, the pattern resembles a "dotted curtain" with no peripheral rings or central agglutinated mass. Microscopic examination reveals numerous three-cornered, tri-asteroid spicules observable in no other medical condition. The author did note false positives in 19 cases as varied as acute rheumatic fever, pregnancy and active tuberculosis. Clinical findings, he believed, differentiated these diseases from cancer,
and positive reactions gradually reverted to normal under appropriate treatment. This reversal was also noted in cancer patients on "eradication" of malignancy by either irradiation or surgery.

Bolen first reported 91.4% positive results in a series of 140 proved carcinoma cases. In his second paper, Bolen elaborated on the appearance of the blood clot: normal blood produces well-defined meshwork with red cells showing rouleau formation and tight packing; early carcinoma reveals less defined fibrin, and small areas of plasma devoid of red cells; in advanced cancer, no fibrin meshwork is visible, large plasma and red cell masses being distinguishable. Bolen later wrote of a study on 535 patients, 337 being benign and revealing a negative blood pattern, and 198 diagnosed as malignant with only 7 false negatives.

A close correlation with increased blood sedimentation rate was noted in cancer patients. This observation is not exclusive with Dr. Bolen nor inconsistent with his previous observation concerning nonspecific erythrocyte sedimentation rate.

**Action of the Cancer Advisory Council**

The Cancer Advisory Council learned that the Bolen diagnostic test was being used in both the Los Angeles and San Francisco areas, and that its reliability was being emphasized in statements to patients.

Investigation of the merits of the Bolen diagnostic test was not as elaborate as that involving devices, chemical products and other nostrums advocated in fraudulent treatment. This was partly because of the nature of the test itself and the fact that its very simplicity -- and its nonmarketability -- lent itself to extensive documentation in the literature. It was in the literature, therefore, that ample evidence could be found, substantiated by the opinions of medical educators.
regarding the wisdom of teaching the Bolen technique to medical students.

The literature review produced over 20 reports of evaluation studies in which investigators varied in opinion: a few thought the test to be of some value, others felt that it was unreliable; still others acknowledged that it had no value. Of those admitting some value, a few recommended that when positive, further intensive diagnostic studies are indicated especially in the absence of clear clinical confirmation.

The principle drawback to the Bolen test is the lack of its reliability. To be classified as a scientifically acceptable test for cancer, a test must yield positive results in 90 percent of cancer cases and false positive results in no more than 5 percent of young, healthy subjects. In the reports reviewed, including tests performed by Dr. Bolen as part of an evaluation study analyzed by the National Cancer Institute, false negatives ranged between 24 and 56 percent and false positives between 4 and 95 percent. Pregnancy was noted as being particularly likely to produce a false positive reaction.

The opinions of the Deans of the California Schools of Medicine and two other medical experts, Ralph W. Weilerstein, M.D., and William A. Atchley, M.D., reinforced the evidence suggested in the literature, that the Bolen test is not really scientifically reliable, especially in connection with a disease potentially as fatal as cancer. The medical educators stressed rather the importance of established, proven diagnostic tests which might suggest types of cancer, such as the Papanicolaou smear, roentgenographic studies, hematologic examinations, sigmoidoscopy. Screening by these recognized tests is regarded as reliable, although not always considered valid proof of cancer independent of a total examination.

On April 17, 1963, the Cancer Advisory Council concluded its studies
by finding that the Bolen Test was of no value in the diagnosis of cancer and recommended to the Director of the State Department of Public Health that appropriate action be taken to prohibit the administration of said test or one substantially similar thereto. After appropriate public hearings, a regulation banning such administration was adopted by the State Board of Public Health on September 20, 1963. This regulation appears as Section 10400.2, Chapter 5, Subchapter 2, Article 2 of the Administrative Code and became effective November 3, 1963.

4. Koch Synthetic Antitoxins

The products known as "Malonide," "Glyoxylide" and "Parabenzoquinone," as used in the treatment of cancer, are the agents concocted by William F. Koch, M.D. Koch earned his medical degree at the Detroit College of Medicine, Wayne University, in 1918, and within a year announced he had "developed a real specific cure for cancer." His thesis advanced the theory that cancer is caused by a microorganism resembling the spirochete of syphilis, which could be destroyed by a differential poison of his invention, "Koch's Synthetic Antitoxin." Organizations to develop and manufacture this nostrum such as the Koch Laboratories, the Koch Cancer Foundation, the Christian Medical Research League of Detroit and Raymer Pharmacal Company in Philadelphia, were in existence at different times.

The Koch medications, known collectively as Koch's Synthetic Antitoxins or oxidation catalysts, were individually packaged in 2 ml ampules. Malonide and glyoxylide are claimed to be present in a concentration of one part in a trillion parts of water, and parabenzoquinone one part in a million parts of water. Malonide was not found to be present in the medication administered in California.
Glyoxylic acid, of which glyoxylide is the anhydride (the resulting element after water is removed), is a normal constituent of the human body. About two grams are formed daily -- at any given time there are about five milligrams in the human body, whether healthy or diseased. It would take a trillion 2 ml ampules of Koch's glyoxylide to equal the amount produced daily by the body, and two and one half billion ampules to equal the amount present in the body at any one time.

The use of Koch's Synthetic Antitoxins was brought to the attention of the Cancer Advisory Council following chemical analyses conducted by the laboratories of the State Bureau of Food and Drug Inspections, which revealed that the ampules contained nothing but water. The Cancer Advisory Council then sought other types of evidence to demonstrate the capabilities of Koch Synthetic Antitoxins as a "cure" for cancer. This evidence included autopsy reports, clinical studies, several chemical analyses, court actions, and the opinions of medical experts and Deans of California Schools of Medicine.

Autopsy data included the report of Mrs. Ruth Fallon, who died in 1961, from widespread cancer, primary in the uterine cervix. She had received numerous injections of the Koch medications in San Francisco, Los Angeles and Merced, but no effect attributable to the remedy could be found at autopsy or subsequent microscopic study. Her daughter had been able to purchase parabenzoquinone, by mail, within California as recently as February 1963.

Because of the original claims of Koch, the Wayne County (Detroit) Medical Society began investigating the treatment in 1919. Twelve beds in a local hospital were set aside for use by the Society's investigatory committee, of which five were occupied by persons with confirmed diagnoses of cancer. The management and treatment of these patients were delegated
to Dr. Koch but because of his negligence the patients gradually left the hospital and the committee subsequently discontinued the investigation. During several subsequent years records and patients totalling nearly 100 were examined by the committee which found no instance of decided benefit in any cancer patient which could be credited to Koch's treatment. The Canada Cancer Commission conducted a clinical investigation of the use of glyoxylide by Dr. David H. Arnott, but conclusively found the agent in no way beneficial in the treatment of cancer.

In addition to the chemical analyses conducted by the State Department of Public Health, the American Medical Association Laboratories found the Koch material indistinguishable from distilled water.

Among the most provocative forms of evidence examined by the Cancer Advisory Council were the transcripts of two court proceedings. The validity of the Koch remedies was considered by the U.S. Court of Appeals, 6th Circuit, in 1953, when the Court reviewed a cease and desist order of the Federal Trade Commission against the principles of Koch Laboratories, Inc., William F. and Louis G. Koch. The Court found that "representations in the advertising were misleading and false...that the products involved had no therapeutic value..." The Court upheld the earlier decision against the Koch Laboratories. In a second suit, a Tampa, Florida jury awarded $65,000 damages in a malpractice suit against a Tampa physician in 1953. The physician was charged with administering the Koch treatment for a sore on the lip which, in nine months, became a large, foul, fungating tumor. The patient was discharged by the physician at this time but upon treatment at a qualified cancer center he required extensive surgery to remove his lower jaw.

The opinions of the six Deans of the California Schools of Medicine and that of Ralph W. Weilerstein, M.D., and William A. Atchley, M.D.,
were sought. They uniformly concurred that no value could be ascribed to the Koch treatment and that medical teaching did not recognize any of the agents as acceptable to cancer management.

**Action of the Cancer Advisory Council**

On April 17, 1963, the Cancer Advisory Council concluded its studies finding that the Koch agents were of no value in the diagnosis, treatment, alleviation or cure of cancer and recommended to the Director of the State Department of Public Health that appropriate action be taken to prohibit their prescription, administration, sale or other distribution. After appropriate public hearings, a regulation containing those features was adopted by the State Board of Public Health on September 20, 1963. This regulation appears as Section 10400.3, Chapter 5, Sub­chapter 2, Article 2 of the Administrative Code and became effective November 3, 1963.

5. **Lincoln Staphage Lysate**

Robert E. Lincoln graduated from the Boston University School of Medicine in 1926. He was licensed to practice medicine in Massachusetts and in 1928 he joined the Massachusetts Medical Society. After an adverse report on his purported cancer remedy was made by the Society in 1952, his membership was abrogated when he failed to resign. Dr. Lincoln died in January 1954, but the Lincoln Foundation, Medford, Massachusetts, which he had founded, continued under the management of Dr. A. Ernest Mills.

The medical world first became aware of Dr. Lincoln and his bacteriophage therapy in 1948, when he submitted to the *New England Journal of Medicine* a paper entitled "Infectious Diarrhea and Infectious Hepatitis", which dealt with the treatment of those diseases with bacteriophage.
Since it was felt that insufficient evidence was demonstrated, the paper was rejected. Dr. Lincoln then presented his theory before a committee of the Massachusetts Medical Society, publisher of the New England Journal, and consented to have his claims studied by a scientific panel which he could assist in selecting. Dr. Lincoln failed to supply the Society with names, and the scientific evaluation was not conducted. Nor had Dr. Lincoln ever submitted his preparations for laboratory and clinical testing to recognized analysts such as the American Trudeau Society, the Surgeons General of the Armed Forces, the Veterans' Administration, the National Research Council, the American Medical Association or the Federal Food and Drug Administration. Instead, Dr. Lincoln elected to apply for patents on his material through the creation of the Lincoln Foundation Trust. The Trust was an association of his brother, himself and Charles W. Tobey, Jr., an attorney, who with his father, Senator Tobey, waged a noisy quarrel on the Senate floor to have the Lincoln treatment acknowledged as a cancer cure worthy of Federal support.

It was perhaps the sweeping praise heaped on Lincoln and his treatment by Senator Tobey which aroused the Massachusetts Medical Society to conduct a thorough investigation of the agent. Prior to its study in 1951, the Society had been beleaguered with requests from physicians, patients, and their relatives to share the information the Society had declined to publish on the grounds that it did not meet established scientific standards. The early requests concerned patients with sinusitis or multiple sclerosis, diseases also mentioned in the rejected paper, but later requests patterned after Dr. Lincoln's expanded claims included cancer and tuberculosis and "all the diseases the cause of which is unknown."
The agent in question, claimed by Dr. Lincoln to treat effectively a variety of diseases including cancer, is a bacteriophage and staphylococcal antigen derived from certain strains of staphlococci. The agent is identified as such in articles published by Dr. Mills, successor to Dr. Lincoln, and is confirmed by laboratory testing. The product identified as recently as 1963, purchased from the manufacturer, Delmont Laboratories, Inc., Swarthmore, Pa., is described thusly:

"Staphage Lysate is prepared by lysing cultures of serologic Types I and III staphlococcus aureus by the addition of bacteriophages antagonistic to them. After the lytic action is complete, the mixture containing heat labile and heat stable antigenic fractions of staphlococcus aureus, with its extracellular and intracellular enzymes and the culture media ingredients and living bacteriophage is then tested for safety and sterility according to U.S. Public Health requirements for biologic products and is standardized to contain 2,000 million lysed staphlococcus aureus and 10,000 million active staphlococcus bacteriophage particles per milliliter."

Bacteriophages are used in conventional laboratory practice to identify bacterial strains. A search of the literature indicates many articles dealing with this use, but only a rare reference to clinical use, chiefly dealing with usage in the upper respiratory tract or local infections. Dr. A. Ernest Mills is the author most cited in these instances. A wide search of the literature failed to reveal any references to the use of bacteriophage in cancer treatment.

The study conducted by the Massachusetts Medical Society in 1951-52...
was initiated to clarify the Society's position, and to correct a number of impressions easily accepted by the general public as a result of the interest accorded the Lincoln treatment by the U.S. Senate. Senator Tobey's support of the Lincoln agent was, at the time it came to light in The Congressional Record, considered noble, just praise for a technique which saved the Senator's son from premature death due to cancer. Senator Tobey died not long after the furor over the Lincoln agent subsided.

While the furor raged, however, it captivated the aspirations of the public that a cure for cancer had at last been found. The initial public announcement of a new system of medicine and a new mode of therapy in The Congressional Record seemed unusual to scientists, but the public knew no better. In consideration of the immense obligation to present an evaluation of the Lincoln agent through recognized scientific channels, the Massachusetts Medical Society advanced a remarkably determined study. Appointed to a review committee were a specialist in tuberculosis, a neurologist, a surgeon, a bacteriologist and a pathologist. The committee worked for eight months before issuing its report, handicapped in large part by Dr. Lincoln's reluctance to give them samples of his bacteriophages for proper laboratory studies. The committee did visit Dr. Lincoln, observing the actual use of the material, evaluating his diagnostic criteria, examinations of patients, laboratory data and records. In all cases, the committee found superficiality, rather than precision and thoroughness, evinced. Laboratory data were scant, no records of objective progress reports were available, no physicians of competence were known to be utilizing his materials, cases were not fully presented or documented, and no record of any
lasting benefit derived by his patients could be ascertained. The committee could find only that Dr. Lincoln had apparently proposed an "entire new system of medicine," with absolutely no valid scientific proof to support his claims.

The committee summarized its opinion by stating that no proof had been presented nor was obtainable to demonstrate that beneficial organic changes occurred in cancer or in other disease processes treated by Dr. Lincoln's therapy which were due to that therapy alone. The case of Charles Tobey, Jr., was a case in point: at the time Senator Tobey first roused the public by reading into The Congressional Record a "Dear Dad" letter praising the Lincoln treatment for relieving and in fact curing Tobey, Jr., of reticulum cell lymphosarcoma, it was known scientifically that conventional therapy, such as the surgery and radiation given before the use of the Lincoln agent, were capable of controlling this form of cancer. As a consequence of the study there was harassment and vilification of the Society by members of Congress, who implied threats of grant cuts if clinical trials of the Lincoln agent were resisted by the Society.

If the Lincoln agent were only to have been denounced as a result of this highly charged quarrel between vocal constituents, it probably would not have been severely harmed. But further evidence, particularly on evaluation by the National Research Council, did not help the Lincoln agent to be accepted. Dr. Lincoln again became uncooperative in complying with established scientific procedures; the 24 case histories he did present failed to support his premise that bacteriophages effectively arrested the course of disease alone. If they did anything, it was only temporary palliation. Death followed.
Action of the Cancer Advisory Council

At the time the Cancer Advisory Council first convened, the Lincoln agent was found to be in use in California. The Council obtained samples of the material currently being prescribed and used in California for analysis in the microbiological laboratory of the State Department of Public Health. The claims of content advanced by Lincoln, Mills and the literature accompanying the material, were found to be correct; however, no reason for assuming the agent was of therapeutic benefit in cancer treatment could be determined from this analysis, nor any evidence previously collected on its application.

The Council also requested the Deans of the California Schools of Medicine to discuss current teaching about cancer diagnosis and treatment, and requested again the opinions of Ralph W. Weilerstein, M.D., and William A. Atchley, M.D., on the merits of the Lincoln agent. The uniform response that the Lincoln method was of no value in the treatment of cancer compounded with the extensive evidence compiled by laboratory testing, and review of the study conducted by the Massachusetts Medical Society and the report of the National Research Council, permitted the Cancer Advisory Council to recommend that the Lincoln agent be outlawed in California.

On April 17, 1963, the Cancer Advisory Council concluded its studies by finding that Lincoln Staphage Lysate was of no value in the diagnosis, treatment, alleviation or cure of cancer and recommended to the Director of the State Department of Public Health that appropriate action be taken to prohibit its prescription, administration, sale or other distribution. After appropriate public hearings, a regulation containing those features was adopted by September 20, 1963. This regulation appears as Section 10400.4, Chapter 5, Subchapter 2,

Wendell G. Hendricks, D.O., was ordered to cease and desist from dispensing or using the Lincoln agent for failing to comply with Section 1707 of the Cancer Law requiring that samples be provided to the State Department of Public Health upon request.

6. Mucorhincin

Mucorhincin was developed by Philip L. Drosnes and Lillian M. Lazenby sometime between 1943 and 1948. Prior to assuming directorship of the Drosnes-Lazenby Cancer Clinic in Pittsburgh, Pennsylvania, Mr. Drosnes was reported to be a tire salesman and his associate, Mrs. Lazenby, was reported to have been in charge of a hospital cafeteria. During the fall of 1948, Mr. Drosnes and Mrs. Lazenby were convicted of practicing medicine without a license; the Clinic, which occupied the basement of a church was closed. The sentence was appealed and the case was dismissed for lack of evidence. Later in 1948, the Clinic was reopened under the direction of Paul A. Murray, M.D. In 1949, Joseph W. Wilson, M.D., joined Dr. Murray, assuming the position of medical director upon the death of Dr. Murray in 1954.

The agent itself, Mucorhincin, was described by Dr. Wilson as an enzymatic product of biologically processed whole wheat grain, and therefore could not be classified as a drug subject to administration by the Federal Food and Drug Commission. Mucorhincin was available to practitioners for general practice at the price of $6.75 per bottle -- equivalent to a week's supply -- administered orally only in conjunction with a diet.

The name Mucorhincin does reflect its contents, Mucor and Rhizopus, two fungi reportedly found in the agent. The substance was claimed by its dispensers to be a substrate produced by cultivation of a mold on a nutrient
medium composed of yeast, salt, whole wheat and sterile water. The secretion of the mold is the product used in the treatment of cancer.

Instructions supplied with Mucorhicin indicated the dosage, possible side reactions, and a supplementary diet list. The Drosnes-Lazenby Diet allowed considerable latitude among fruits and vegetables which may be cooked or uncooked, but must be fresh and unpeeled. Eggs must be soft-boiled or poached. Bran, oatmeal or whole wheat cereal preparations with raw milk, dark brown sugar, molasses or pure honey were permitted, as well as buttermilk, weak coffee or tea, raw certified milk and gingerale. No fried meats or fresh pork were allowed. To be avoided were highly seasoned or fried foods, pastries and starchy foods.

Mucorhicin was tested several times in the laboratories of the National Cancer Institute and the American Medical Association. Results of microbiologic examinations conducted in 1948, 1949 and 1956, were supplied to Dr. Walter E. Batchelder of the Cancer Commission, California Medical Association, by Oliver Field, Director, Bureau of Investigation, American Medical Association.

The first specimen examined in 1948 by the National Cancer Institute indicated that Mucorhicin is "very crude...a mixture of several fungus and animal species." Direct examination revealed the presence of Cladosporium, Penicillium, spp., Alternaria, Geotrichum and yeasts. In addition there are two types of mites...typical of the species frequently found in contaminated cultures of fungi upon which they feed. The most conspicuous elements of the material upon microscopic examination are the fecal masses of these mites containing partially digested fungus spores."(16) A reexamination of the material in March 1949 added nothing new to the analysis. A report from the Association Laboratory described in a
letter of 1958 states that: "Under high-dry magnification there were large numbers of formed and unformed yellowish debris. Numerous 'yeast' cells (some budding forms), many large cellular structures resembling granules...and numerous motile and nonmotile bacteria. Under gram stain the specimens showed a moderate amount of unformed gram-negative debris and a few short gram-positive rods."(16)

Mucorhicin was also examined in California at the request of the California Medical Association. Dr. Paul L. Kirk, prominent chemist and microbiologist at the University of California, Berkeley, examined the material in 1958 and again in 1962, at the request of the State Department of Public Health. His microscopic, cultural, antibiotic and chemical tests indicated that the material was a yeast culture, contaminated by two kinds of bacteria, lacking antibiotic activity as was being claimed. The 1962 report found no fundamental change in the material except possible "cleaning up" of extraneous contaminants rather than introduction of any therapeutic components.

Action of the Cancer Advisory Council

In 1959, when the Cancer Law was enacted, Mucorhicin may not have been used in California. However, by 1962, evidence presented before an Accusatory Hearing under Section 1704(d) of the Health and Safety Code indicated that it had been obtained and was being administered by practitioners in California. The hearing was called against Charlotte M. Steiner, D.C., October 29, 1962. Harold A. Delp testified under oath that Dr. Steiner had sold Mucorhicin to his wife for treatment of metastatic breast cancer in 1960 and 1961. Mrs. Delp had died on February 10, 1961 of metastatic carcinoma to brain and lungs from a primary source in breast (California death certificate #61-011343) after having used considerable
amounts of Mucorhicin to treat her malignancy. At the same hearing, Mrs. Bessie L. Tomlinson testified under oath that Mucorhicin had been prescribed by Dr. Steiner for a malignancy. Proof of her purchase was verified by two cancelled checks, $10.00 each, payment for direct purchases from the Pittsburgh Clinic. Dr. Steiner failed to supply a sample of Mucorhicin to the State Department of Public Health and thereby was advised to cease and desist dispensing the agent, under Section 1707 of the Health and Safety Code.

The Cancer Advisory Council continued to investigate the use and value of Mucorhicin. Documentation included: certified copies of death certificates of patients from widely separated states (Pennsylvania, Florida, Ohio, California, West Virginia) treated with Mucorhicin, all of which noted cancer as prime cause of death; laboratory findings of the National Cancer Institute, American Medical Association and Dr. Kirk; opinions of the Deans of California Schools of Medicine. Literature received by California physicians, claiming the therapeutic value of Mucorhicin, was also evaluated. No articles were ever published in recognized medical journals concerning Mucorhicin; testimonials and feature articles appearing in Pittsburgh media described its capabilities.

On April 17, 1963, the Cancer Advisory Council concluded its studies by finding that Mucorhicin was of no value in the diagnosis, treatment, alleviation or cure of cancer and recommended to the Director of the State Department of Public Health that appropriate action be taken to prohibit its prescription, administration, sale or other distribution. This action was scheduled for consideration by the State Board of Public Health on July 19, 1963 but prior to this meeting Dr. Wilson, the producer of Mucorhicin, offered to furnish clinical records which he
implied would show the agent to be of benefit in the treatment of cancer. This reasonable request was honored, but Dr. Wilson failed to present additional material supporting his claims. A regulation containing the features recommended by the Council was adopted by the State Board of Public Health on September 20, 1963. This regulation appears as Section 10400.5, Chapter 5, Subchapter 2, Article 2 of the Administrative Code and became effective November 3, 1963.

7. The Anthrone Test

Soon after its appointment in 1959, the Cancer Advisory Council learned that a biochemical test for the diagnosis of cancer was in use in California. Because the test had apparently not gained wide acceptance since it was initially reported in the literature (1955), and since the Council members were aware of the search for a reliable diagnostic tool for early diagnosis of cancer, it was decided to engage in a study to determine the merits of the test. A study was proposed in which H.H. Beard, Ph.D., one of the authors of the test, would perform tests on 200 specimens; simultaneous tests on the same specimens would be performed in the laboratories of the State Department of Public Health for comparison.

The test as reported by Beard and his associate, T.C. Terrell, M.D., both of Fort Worth, consists of the use of quantitative determinations of chorionic gonadotropin which they claim is produced in all cases of malignancy and excreted in the urine, as diagnostic and prognostic aids in cases of malignancy. The technique of the test is as follows: an acetone precipitate of an aliquot of a 24-hour specimen of urine is redissolved in a phosphate buffer; to one measured amount of the buffer-precipitate solution, anthrone-sulphuric acid reagent is added directly and the intensity of the resulting color due to the presence
of chorionic gonadotropin, anterior pituitary gonadotropins and polysaccharides, is measured in a colorimeter. To eliminate one of the elements contributing to color density, chymotrypsin is added to a second portion incubated overnight and then treated as above. The two colorimetric readings are converted to milligrams and the difference between them determined. The difference represents the chorionic gonadotropin fraction which has been responsible for the greater color intensity of the undigested specimen and which has been destroyed during the incubation period. From this figure, the amount excreted in 24 hours is calculated.

The critical difficulty with a test of this nature is the introduction of exceptions -- false positives -- which in this case included pregnancy and a variety of clinical conditions. Beard denoted the conditions which might generate false positives and these were excluded when selecting patients for study, but in no phase of the comparative studies did the results satisfy the standards adopted by the National Research Council: that false positive tests in apparently normal individuals under age 30 should not exceed 5%, nor that fewer than 90% positive tests be recorded in individuals with cancer. These values for specificity and sensitivity are observed throughout the nation, but the studies performed by Beard failed to meet these standards.

Dr. Beard agreed to the objective criteria and methodology recommended by the Department; specimens were furnished by the Cancer Research Institute of the University of California School of Medicine. Dr. Beard cooperated fully with the study design, but during its course introduced some deviation in the basic technique.

After approximately one-half of the specimens had been tested, an examination of findings in the Department Laboratory revealed that the
digested specimens on cancer patients consistently showed a greater color concentration (less transmission) than the undigested specimen -- precisely the opposite reaction expected with the test. In only 2 of the 23 cancer patients did both samples of a split specimen demonstrate the expected trend. Because the results in the Department were so inconsistent and unpredictable, this phase of the study was suspended.

Although the actual tests on patients performed by the Department Laboratory were worthless, several desirable objectives were realized: chiefly that the color reaction in the authors' standard must be due primarily, if not exclusively, to lactose and not to chorionic gonadotropin. Most significant, however, was the fact that the Anthrone test was completely unreliable.

Dr. Beard's results did not satisfy the rigorous scientific standards recommended by the National Research Council. On a single specimen of a patient's urine sent the same day as received, positive tests were obtained in 59% of cancer patients and 47% of controls, and on specimens sent a day apart, the percentages shifted to 52% of cancer patients and 49% of controls. When results on paired specimens were examined without regard for time of submission, there was disagreement in 38% of specimens from cancer cases and in 48% of the controls. The inconsistencies established in Beard's own laboratory served to reduce any credence given to this diagnostic technique.

Action of the Cancer Advisory Council

In addition to evaluating the results of these studies, the Council requested the opinions of the Deans of California Schools of Medicine and of medical experts, Ralph W. Weilerstein, M.D., and William A. Atchley, M.D. The Anthrone test is not regarded by any of these individuals as valid or
suitable for instruction. The failure of the test to meet criteria for sensitivity or specificity implies that the Anthrone test is completely unreliable and unacceptable as a diagnostic or prognostic test for cancer.

On August 17, 1964, the Cancer Advisory Council concluded its studies by finding that the Anthrone Test was of no value in the diagnosis of cancer and recommended to the Director of the State Department of Public Health that appropriate action be taken to prohibit the administration of said test or one substantially similar thereto.

8. Krebiozen

Possibly no other unproven treatment for cancer has received so much public attention or approbation as Krebiozen. This agent has been the subject of intense scrutiny by scientists and government officials, and loudly discussed by the press and by the general public. The events surrounding the introduction of Krebiozen as a potential cancer cure and the subsequent trials to test its capabilities produced an air of notoriety seldom seen in the medical world. Conviction in the power of Krebiozen cost one man, Dr. Andrew C. Ivy, a loss in his professional reputation.

Ivy launched Krebiozen to the public in March 1951 at a press conference. He was then Vice-President-in-Charge of the Chicago Professional Colleges, Distinguished Professor of Physiology and Head of the Department of Clinical Science, University of Illinois. Ivy's claim regarding Krebiozen's anti-cancer ability was based on preliminary clinical trials on 22 cancer patients to whom the agent had been administered. The agent itself was developed by Steven Durovic, a Yugoslav physician who migrated to Argentina where, with the support
of his brother Marko, he applied a theory he had considered for some
time. Durovic believed that each cell is composed of two antithetical
substances, one to stimulate growth and division, the other to restrain.
Normalcy of cell and tissue depends on the balance between these
substances. Further, he theorized, some of the body defenses against
disease, including cancer, are situated in the cellular activity of the
reticulo-endothelial system (RES); by stimulating these cells, an anti-
carcinogenic substance inhibitory to a malignant type of cell prolifera-
tion would gain prominence. Durovic believed such a substance would
be produced by exposing the RES to a causative organism known to
stimulate its proliferation. He tested the theory by injecting sterile
extracts of the fungus actinomyces bovis into the blood stream of
cattle and horses, bleeding them and extracting the plasma to recover
about 1 mg. of a whitish powder per horse. This extract from cattle
was initially called Kositerin by Durovic, who felt it had promise in
the treatment of hypertension.

Durovic came to Northwestern University in 1949 where the powder
was found ineffective in treating hypertension. Ivy became interested
in the same or a different product which appears to be that presently
known as Krebiozen, and began experimental and clinical trials. He
reported that it was non-toxic to animals and humans, was effective
against spontaneous animal tumors and that a "standardization" procedure
on patients with recurrent or untreated adenocarcinoma of the breast
produced a decrease of induration and size of the primary tumor or
recurrent nodule. Further clinical trials were undertaken by other
practitioners.

Krebiozen has a molecular weight of 923.93, is resistant to
temperatures up to 235°C, is soluble in water, certain oils and fat
solvents and purportedly is dissolved in mineral oil and marketed in ampules containing 0.01 mg. of the agent, the prescribed dosage for treatment. Dr. Paul L. Kirk reported to a California State Senate Interim Committee on Public Health (1958) that he had been unable to detect anything but mineral oil in the ampules.

From the first unprecedented announcement concerning Krebiozen, in a manner departing from traditional scientific reporting, the agent and its proponents have been central in a stormy controversy. The American Medical Association, responding to letters of inquiry from the public, undertook an investigation but the Krebiozen Research Foundation failed to reveal any details on the product for fear the patent rights might be stolen. Abstracts of 100 clinical records were evaluated by a Committee of the AMA and 98 failed to show material alteration in the course or progression of tumor growth or histopathologic changes in involved tissue.

Dr. Stoddard, President of the University of Illinois, appointed a Committee to evaluate a report by Ivy on 500 Krebiozen-treated cancer patients, which conclusively failed to produce favorable evidence. Human experimentation with Krebiozen was prohibited at the University of Illinois.

At the heart of the Krebiozen controversy was the need for clinical testing, preferably by the National Cancer Institute (NCI). Ordinarily preliminary testing -- either chemical, animal or both -- to determine the nature, toxicity and dosage levels is conducted under contract by disinterested scientists in non-governmental laboratories. To accomplish this and to provide for future clinical testing, if indicated, adequate supplies of the drug must be provided, it must be completely identified.
and must not previously have been evaluated by the National Cancer Institute. The data and quantity of Krebiozen submitted sporadically by its sponsors were considered inadequate to justify an evaluation study, and secondarily, Dr. Ivy repeatedly insisted that he personally participate in testing by administering the treatment and analyzing its effects and in the nomination of a team involved in testing. The National Cancer Institute and Dr. Ivy could not reach concurrence; the stalemate was repeated several times over a decade, aroused by Congressional interest, and in 1961, in connection with the trial of a libel suit filed by Dr. Ivy against Dr. Stoddard. The Judge hearing the case realized that the suit could not be decided unless the claims of the Krebiozen sponsors were validated. Secretary Ribicoff was asked to conduct an evaluation study, but he indicated that Ivy and Durovic had failed to comply with the requirements for testing.

In 1954, the sponsors of Krebiozen filed a new drug application which proved inadequate to satisfy legal requirements, again because its safety and effectiveness had not been ascertained by reputable scientific investigation.

Early in 1963, the Department of Health, Education and Welfare notified the Krebiozen Research Foundation, which had been flourishing despite its failure to achieve proper sanction by the Food and Drug Administration, that various Federal agencies would investigate records and patients. This investigation was expected to determine whether Krebiozen should be licensed for sale or approved for investigational use, and whether clinical trial by the National Cancer Institute was justified. Several months later, Krebiozen became subject to strengthened Federal legislation regarding "investigational" drugs. Interstate shipment would be prohibited if adequate filing of data confirming
claims was not made by June 7, 1963. Since no effective new drug application was on record for Krebiozen, the prohibition would be applied. Pickets protested at the White House June 5th and 6th. Durovic did submit an application June 6th but withdrew it June 12th; he was advised that interstate shipment of Krebiozen must cease and that users could not come to Illinois to remove the product for use outside the state.

An analysis by the Food and Drug Administration identified the agent as creatine hydrate, an amino acid derivative available from meat and a normal constituent in the human body where it is produced daily in amounts up to 100 thousand times that presumably contained in one ampule of Krebiozen. These findings were challenged by Dr. Durovic, and the controversy waged afresh. Further, clinical records on 504 patients treated with Krebiozen were obtained by the National Cancer Institute for review by 22 cancer specialists. Clinical testing was considered completely unnecessary after review of both the chemical analysis and clinical review, for the agent was found to be ineffective as an anti-cancer drug. Legal action transpired between Dr. Durovic and the Federal government, but the decision to no longer appraise Krebiozen was held firmly by the Federal government.

Action of the Cancer Advisory Council

At a time when chemotherapy has been gaining acceptance as a third, reliable form of treatment for some types of cancer, the Krebiozen episode posed a delicate problem. Its advocates were many and they were vocal; the press had been partner to the sensationalism which accompanied its introduction and the battles which ensued to have Krebiozen recognized as a legitimate treatment for cancer.
Yet, no acceptable evidence had ever been offered to validate the claims of Ivy and Durovic, and their constant resistance to traditional clinical testing further incriminated the agent as being of dubious value. In reaching a decision regarding the use of Krebiozen in California, therefore, the Cancer Advisory Council reviewed fully the information concerning its history and application, taking careful note of materials received from the National Cancer Institute. The opinions of medical experts and the Deans of California Schools of Medicine were sought, which confirmed the knowledge that Krebiozen was ineffective in cancer management.

On May 27, 1964, the Cancer Advisory Council concluded its studies by finding that Krebiozen was of no value in the diagnosis, treatment, alleviation or cure of cancer and recommended to the Director of the State Department of Public Health that appropriate action be taken to prohibit its prescription, administration, sale or other distribution.
DISCUSSION

The above case histories and analysis of the legal process by which the Cancer Advisory Council is able to reduce gradually the immense waste produced by cancer quackery do not alone suggest the reaction of the public whom the Cancer Law tries to protect. Although one hearing would have met the requirements of the law as prerequisite to the adoption of a regulation, two were held on each agent -- one in Los Angeles and one in San Francisco or Berkeley. Notices of these hearings were published 30 days in advance, as required by law, and those persons known to have an interest were notified individually of scheduled hearings. Notices of hearings were accompanied by a statement that "copies of the proposed regulations and reports of the Cancer Advisory Council were available for public inspection" at six convenient locations in the State. In addition to official notices, the Department issued news releases and date slips to daily newspapers, wire services and some television stations a few days prior to the hearings, announcing the purpose and place of the hearings.

Public response was not unexpected. Protests, arguments, complaints, objections and accusations regarding the action of the State Department of Public Health and its two affiliates, the State Board of Public Health and the Cancer Advisory Council, were registered orally in the public hearings on regulations, in hearings on individual practitioners, and further by letters, resolutions and questionnaires submitted to various members of State government. Not exempt were the Governor, the Attorney General, members of the Senate and Assembly, the Director of Public Health, his staff, and the Chairman and members of the State Board of Public Health. One open letter was addressed to "the President of the
United States and others."

These challenges showed many variations: it was stated in some that there was inadequate publicity about the hearings; that banning the remedies under consideration and others in the future would destroy the last hope of cancer victims; and that since these agents were non-toxic and palliative they should remain available. Most objectors stated that the proposed regulations violated their constitutional right of freedom of choice, that, in fact, the Cancer Advisory Council and the Department were exceeding their authority and jurisdiction, and/or that the whole law was unconstitutional.

Moreover, there were representations that the Council had acted too hastily, that its findings were based on inadequate evidence, and that controlled clinical testing was required under the law. The qualifications of the Council were questioned; there were charges that economic rather than scientific reasons influenced Council decisions; and, in protest to members of the State legislature after adoption of the individual regulations, it was stated that all cancer remedies except irradiation and surgery had been banned by the Council.

In response to these representations, many facts should be reasserted. The only agents banned at the present time are those discussed earlier. The constitutionality of the law and Departmental action under it can only be settled in the courts. Clinical testing under Section 1704(c) of the Cancer Law is not a mandatory requirement in the opinion of the Attorney General but may be recommended to the Department by the Cancer Advisory Council when so indicated and justified. Section 1711 provides for the utilization in evaluation studies of a wide variety of scientific disciplines and agencies, and solicitation
of their findings, opinions or conclusions in matters before the Council and the State Department of Public Health. Finally, mandatory clinical testing would demand personnel and budgetary resources unavailable to the Department.

Hearings are heard by a committee of the State Board of Public Health with the full intention of receiving any scientific evidence regarding the effectiveness of an agent as a cure or aid in diagnosis of cancer. The public is permitted full opportunity to express its interest and opinion before these hearings, to question the committee, and, in fact, to challenge. Reasonable privileges are accorded the proponents of the agents in question to present as much scientific evidence as is available; this leniency was clearly demonstrated by the postponement of final action in the summer of 1963 on four agents, Mucorhcin, Laetrile, the Bolen test and the Koch agent. Careful consideration was given by the State Board of Public Health to the material submitted during this extended period, including appraisal of three clinical records involving Laetrile, but no evidence was actually submitted during this interval to indicate scientific validity regarding the cancer-curing properties of these agents. Refutation of earlier findings could not be made, and hence the State Board of Public Health adopted regulations affecting these agents.

Medical fraudulence is a costly and serious business. It takes untold losses in human life, in both material and emotional resources. The California Cancer Law is the first major attempt by a state to control medical chicanery systematically; since its enactment, similar laws have been enacted in Nevada, Colorado and Pennsylvania and others aimed also at the control of cancer therapy in Kentucky, North Dakota.
and Maryland. But the problem of medical quackery is far more concentrated in California, affecting our citizens and their productivity. Therefore, it is of prime importance to continue the effectiveness of this pioneer legislation which attacks an important form of medical quackery.

To look upon the actions of the Cancer Advisory Council without due regard for the public resistance would not be realistic. Human emotion, especially agitated in a matter of life and death, cannot but exert a credible, often inhibiting, force in actually altering an unfavorable situation. The Cancer Law, as it has been applied in its first five years of existence, has been demonstrated to be nominally effective in reducing the means by which fraudulent diagnosis and treatment of cancer are allowed to deter sick persons from seeking medically-sound forms of care. If the Cancer Law is to control the serious menace of cancer quackery it needs to be strengthened and reenacted, so that the work which it is designed to do can be intensified.
REFERENCES


3. Ibid., p.30.


5. Ibid.

6. Ibid.


8. Ibid. David Karnofsky, M.D. pp. 75-114.


APPENDICES

Appendix I  
Members of the Cancer Advisory Council, October 1964, and Previous Members.

Appendix II  
Staff, Cancer Diagnosis and Therapy Evaluation Unit, State Department of Public Health, 1959-1964.

Appendix III  
Laws and Regulations Relating to the Diagnosis and Treatment of Cancer (individual copies of the booklet may be placed at the end of report)
APPENDIX I
Members of the Cancer Advisory Council
October 1964

Faculty Members of California Schools of Medicine

Thomas S. Nelsen, M.D.  Assistant Professor of Surgery, Stanford University School of Medicine, Palo Alto.

David A. Wood, M.D.  Director of the Cancer Research Institute and Professor of Pathology, University of California School of Medicine, San Francisco.

Jesse L. Steinfeld, M.D.  Associate Professor of Medicine, University of Southern California School of Medicine, Los Angeles.

Maurice H. Simmers, M.D.  Professor and Coordinator of Cancer Training, California College of Medicine, Los Angeles.

Joseph F. Ross, M.D.  Professor of Medicine, Professor of Biophysics and Nuclear Medicine, Director Laboratory of Nuclear Medicine and Radiation Biology and Chairman Department of Biophysics and Nuclear Medicine, University of California School of Medicine, Los Angeles.

Orlyn B. Pratt, M.D.  Professor and Head of the Department of Pathology, Loma Linda University School of Medicine, Los Angeles.

Non-Physicians and Surgeons

Mrs. Robert L. Brown  Immediate Past President, Los Angeles County Branch of A.C.S., Chairman, Division Education Comm. of A.C.S. for the State of Calif., Member National Committee on New & Unproved Methods of Treatment of A.C.S.

Edith R. Lindly, Ed.D.  Professor of Health Education, Fresno State College, Fresno.

Sol Silverman, Jr., D.D.S.  Associate Professor of Oral Biology and Chairman of Division, University of California School of Dentistry, San Francisco
APPENDIX I (Continued)

Representatives of Nonprofit Cancer Research Institutes

Renato Dulbecco, M.D.  Professor, Salk Institute for Biological Studies, San Diego.

Mr. Seymour Graff*  President, City of Hope Medical Center, Los Angeles

Physicians in Private Practice

John W. Cline, M.D.  Associate Clinical Professor of Surgery at Stanford University School of Medicine, Palo Alto.

L. Henry Garland, M.D.  Clinical Professor of Radiology at University of California School of Medicine, San Francisco

Sol R. Baker, M.D.  Associate Clinical Professor of Radiology at the University of California School of Medicine, Los Angeles

Ex-Officio Member

Malcolm H. Merrill, M.D.  Director of California State Department of Public Health

APPENDIX I-2

Previous Members of the Cancer Advisory Council

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
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<tbody>
<tr>
<td>Mr. Richard Haber</td>
<td>Insurance Consultant in Contra Costa County</td>
</tr>
<tr>
<td>Ray D. Owen, Ph.D.</td>
<td>Acting Chairman of the Division of the Biological Sciences at the California Institute of Technology.</td>
</tr>
<tr>
<td>2/27/61 - July 1962</td>
<td></td>
</tr>
<tr>
<td>Mr. Louis Tabak</td>
<td>President of City of Hope Hospital, Los Angeles</td>
</tr>
<tr>
<td>11/23/59 - 12/4/62</td>
<td></td>
</tr>
<tr>
<td>Bernard R. Baker, Ph.D.</td>
<td>Program Director, Cancer Chemotherapy, Stanford Research Institute, Menlo Park</td>
</tr>
<tr>
<td>11/29/59 - 12/5/60</td>
<td></td>
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<tr>
<td>Mr. Allan K. Jonas</td>
<td>President of Jonas Corporation, a commercial and industrial real estate development company and Chairman of Education for ACS - L.A. County.</td>
</tr>
<tr>
<td>11/23/59 - 1/24/61</td>
<td></td>
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<tr>
<td>Henry S. Kaplan, M.D.</td>
<td>Chairman of the Department of Radiology, Stanford University School of Medicine</td>
</tr>
<tr>
<td>11/23/59 - 8/29/61</td>
<td></td>
</tr>
<tr>
<td>Ian Macdonald, M.D.</td>
<td>Surgeon and radiologist, University of Southern California, School of Medicine</td>
</tr>
<tr>
<td>11/23/59 - 1/15/61</td>
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</table>

* Mr. Graff died September 28, 1964.
APPENDIX II

Staff of Cancer Diagnosis and Therapy Evaluation Unit

K. F. Ernst, M.D.  December 1, 1959
Grant Leake  January 1, 1960 - September 15, 1960
J. Richard Jackson  September 16, 1960
Alfred A. Di Dio  December 16, 1963
Margaret Lucas  February 8, 1960 - July 17, 1960
Frances Nazarek  September 6, 1960 - December 22, 1961
Lois Sloan  February 5, 1962
Dora Mae Ipsen  December 3, 1962
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Laws Relating to the

DIAGNOSIS AND TREATMENT
OF CANCER

Excerpts from the
California Business and Professions Code
and the
California Health and Safety Code

STATE OF CALIFORNIA
DEPARTMENT OF PUBLIC HEALTH
2151 Berkeley Way
BERKELEY 4, CALIFORNIA

APPENDIX III
An act to add Section 2378.5 to the Business and Professions Code, and Chapter 7 (commencing at Section 1700), Division 2, to the Health and Safety Code, relating to the creation of a Cancer Advisory Council, and the regulation and control of the diagnosis, treatment, and cure of cancer.

The people of the State of California do enact as follows:

SECTION 1. Section 2378.5 is added to the Business and Professions Code, to read:

2378.5. The violation of any provision of Chapter 7 (commencing at Section 1700) of Division 2 of the Health and Safety Code, or any violation of an injunction issued under Chapter 7 of Division 2 of the Health and Safety Code, constitutes unprofessional conduct within the meaning of this chapter.

SEC. 2. Chapter 7 (commencing with Section 1700) is added to Division 2 of the Health and Safety Code, to read:

CHAPTER 7. CANCER

1700. The effective diagnosis, care, treatment or cure of persons suffering from cancer is of paramount public importance. Vital statistics indicate that approximately 16 percent of the total deaths in the United States annually result from one or another of the forms of cancer. It is established that accurate and early diagnosis of many forms of cancer, followed by prompt application of methods of treatment which are scientifically proven, either materially reduces the likelihood of death from cancer or may materially prolong the useful life of individuals suffering therefrom.

Despite intensive campaigns of public education, there is a lack of adequate and accurate information among the public with respect to presently proven methods for the diagnosis, treatment, and cure of cancer. Various persons in this State have represented and continue to represent themselves as possessing medicines, methods, techniques, skills, or devices for the effective diagnosis, treatment, or cure of cancer, which representations are misleading to the public, with the result
that large numbers of the public, relying on such representa-
tions, needlessly die of cancer, and substantial amounts of the
savings of individuals and families relying on such representa-
tions are needlessly wasted.

It is, therefore, in the public interest that the public be
afforded full and accurate knowledge as to the facilities and
methods for the diagnosis, treatment, and cure of cancer avail-
able in this State and that to that end there be provided means
for testing and investigating the value or lack thereof of
alleged cancer remedies, devices, drugs, or compounds, and
informing the public of the facts found, and protecting the
public from misrepresentation in such matters.

The importance of continuing scientific research to deter-
mine the cause or cure of cancer is recognized, and the depart-
ment shall administer this chapter with due regard for the
importance of bona fide scientific research and the clinical
testing in hospitals, clinics, or similar institutions of new drugs
or compounds.

1701. There is in the State Department of Public Health a
Cancer Advisory Council composed of nine physicians and
surgeons licensed to practice medicine in, and residing in, this
State, three persons who are not physicians and surgeons, two
persons representing nonprofit cancer research institutes recog-
nized by the National Cancer Institute, and the director of
the department, who shall be an ex officio member. The mem-
bers of the council shall be appointed by the Governor to serve
for terms of four years. The Governor shall make the first ap-
pointments hereunder for terms expiring, respectively, on the
fifteenth day of January, as follows: three in the year 1960,
three in the year 1961, four in the year 1962, and four in the
year 1963. The Governor, in appointing the first members, shall
appoint at least one member from the faculty of each of the
schools teaching medicine and surgery and located in this State
that are approved by the State Board of Medical Examiners
and the State Board of Osteopathic Examiners, or either of
them. The Governor shall endeavor to maintain one member
from the faculty of each school in making subsequent ap-
pointments.

1702. The members of the council, other than the director
of the department, shall receive no compensation for their
services, but shall be allowed their actual necessary traveling
expenses incurred in the discharge of their duties.

1703. The council shall annually elect one of its members
to serve as chairman. The council shall meet at least twice
each year, and as often in addition as necessary, for the pur-
pose of carrying out its duties.

1704. The department shall:

(a) Prescribe reasonable rules and regulations with respect
to the administration of this chapter.
(b) Investigate violations of the provisions of this chapter, and report such violations to the appropriate enforcement authority.

(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 any such investigation and testing.

(d) Hold hearings in respect of those matters involving compliance with the provisions of this chapter and subpoena witnesses and documents. Any or all such hearings may be held before the Cancer Advisory Council. Any administrative action to be taken by the department as a result of such hearings shall be taken only after receipt of the recommendations of the council. Prior to issuance of a cease and desist order under Section 1711, a hearing shall be held. The person furnishing a sample under Section 1707 shall be given due notice of such hearing and an opportunity to be heard.

(e) Contract with independent scientific consultants for specialized services and advice.

In the exercise of the powers granted by this section, the department shall consult with the Cancer Advisory Council.

1705. For the purposes of this chapter "cancer" means all malignant neoplasms regardless of the tissue of origin, including malignant lymphoma and leukemia.

1706. No person may undertake to treat or alleviate cancer by use of drugs, surgery, or radiation unless such person holds a license issued under a law of this State expressly authorizing the diagnosis and treatment of disease by use of drugs, surgery, or radiation.

1707. On written request by the department, delivered personally or by mail, any individual, person, firm, association, or other entity engaged, or representing himself, or itself, as engaged, in the diagnosis, treatment, alleviation, or cure of cancer shall furnish the department with such sample as the department may deem necessary for adequate testing of any drug, medicine, compound, or device used or prescribed by such individual, person, firm, association, or other entity in the diagnosis, treatment, alleviation, or cure of cancer, and shall specify the formula of any drug or compound and name all ingredients by their common or usual names, and shall, upon like request by the department, furnish such further necessary information as it may request as to the composition and method of preparation of and the use to which any such drug, compound, or device is being put by such individual, person,
firm, association, or other entity. This section shall apply to any individual, person, firm, association, or other entity that renders health care or services to individuals who have or believe they have cancer. This section also applies to any individual, person, firm, association, or other entity that by implication causes individuals to believe they have cancer.

The failure to either provide the sample, disclose the formula, or name the ingredients as required by this section shall be conclusively presumed that the drug, medicine, compound or device which is the subject of the department’s request has no value in the diagnosis, treatment, alleviation, or cure of cancer.

1708. This chapter shall not apply to the 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 to investigate the safety and therapeutic value thereof unless the department shall find that such drug, medicine, compound, or device is being used in diagnosis or treatment for compensation and profit.

1709. The failure of any individual, person, firm, association, or other entity representing himself, or itself, as engaged in the diagnosis, treatment, alleviation, or cure of cancer to comply with any of the provisions of this chapter, or with any order of the department validly issued under this chapter, is a misdemeanor.

The provisions of this chapter shall not apply to any person who depends exclusively upon prayer for healing in accordance with the teachings of a bona fide religious sect, denomination, or organization, nor practitioner thereof.

1710. The investigation or testing of any product shall not be deemed to imply or indicate any endorsement of the qualifications or value of any such product. No person shall make any representation that investigation or testing hereunder constitutes any approval or endorsement of his, or its, activities by the Cancer Advisory Council or the department. The investigation or testing of any product shall not be deemed to imply or indicate that such product is useless or harmful and during testing no person shall make any representation, except to the department or Cancer Advisory Council, that the product under test is discredited or that it has been found useless or harmful.

1711. Following an investigation or testing of the content or composition of any drug, medicine, compound, or device used by any individual, person, firm, association, or other entity in the diagnosis, treatment, alleviation, or cure of cancer, and after hearing as provided in Section 1704, the department, upon recommendation of the Cancer Advisory Council, may direct that any such individual, person, firm, association, or other entity shall cease and desist any further
prescribing, recommending, or use of any such drug, medicine, compound, or device, or any substantially similar drug, medicine, compound, or device, in the diagnosis or treatment of cancer.

In the investigation or testing required by this chapter to determine the value or lack thereof of any drug, medicine, compound or device in the diagnosis, treatment, or cure of cancer, the department shall, as it deems necessary or advisable, 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 this State or the facilities and findings of the Federal Government, including the National Cancer Institute. Upon a recommendation by the Cancer Advisory Council, the department shall arrange, by contract, for investigation by and submission to it of findings, conclusions, or opinions of trained scientists in the appropriate departments of universities, medical schools, clinics, hospitals, and nonprofit cancer research institutes recognized by the National Cancer Institute, and the submission to it of findings, conclusions, or opinions of other qualified scientists. Prior to the issuance of a cease and desist order under this section, the Cancer Advisory Council, by the affirmative vote of at least 11 of its members, at least one of whom shall not be a physician and surgeon, shall make a written finding of fact based on such investigation that the drug, medicine, compound, or device so investigated has been found to be either definitely harmful or of no value in the diagnosis, treatment, alleviation, or cure of cancer and the department must be satisfied beyond a reasonable doubt that the written findings of the fact are true.

1712. If an individual, person, firm, association, or other entity, after service upon him or it, of a cease and desist order issued by the department under Section 1711, persists in prescribing, recommending, or using the drug, medicine, compound, or device described in said cease and desist order, or a substantially similar drug, medicine, compound, or device, the superior court in any county, on application of the department, and when satisfied by a preponderance of the evidence that the written findings of fact required of the Cancer Advisory Council by Section 1711 are true, may issue an order to show cause why there should not be issued an injunction or other appropriate order restraining such individual, person, firm, association, or other entity from prescribing, recommending, or using such drug, medicine, compound, or device, or any substantially similar drug, medicine, compound, or device. After a hearing on such order to show cause, an injunction or other appropriate restraining order may be issued.

Proceedings under this section shall be governed by Chapter 3 (commencing at Section 525) of Title 7 of Part 2 of the
Code of Civil Procedure, excepting that no undertaking shall be required in any action commenced by the department under this section.

1713. Any person against whom an injunction has been issued, under Section 1712, may not undertake to use in the diagnosis, treatment, or cure of cancer any new, experimental, untested, or secret drug, medicine, compound, or device without first submitting it to the department for investigation and testing.

1714. It is a misdemeanor for any person willfully and falsely to represent a device, substance or treatment as effective to arrest or cure cancer. Nothing in this section shall abridge the existent rights of the press.

1715. A third violation, and subsequent violations, of this chapter is a felony.

1716. The director shall investigate possible violations of this chapter and report violations to the appropriate enforcement authority.

1717. County health officers, district attorneys and the Attorney General shall co-operate with the director in the enforcement of this chapter.

1718. The department, upon recommendation of the Cancer Advisory Council, may from time to time publish reports based on its investigation or testing of any drug, medicine, compound, or device prescribed, recommended, or used by any individual, person, firm, association, or other entity, and when, in the opinion of a majority of the members of the Cancer Advisory Council, the use of any drug, medicine, compound, or device in the diagnosis, treatment or cure of cancer constitutes an imminent danger to health or a gross deception of the public, the department may take appropriate steps to publicize the same.

1719. The department shall submit to the Governor, for submission to the Legislature in January of each year, a report of its activities under this chapter during the preceding 12 months.

1720. All hearings authorized by this chapter shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1, Division 3, Title 2 of the Government Code.

1721. The provisions of this chapter shall expire on December 31, 1965.