A REPORT TO THE 1976 LEGISLATURE

ON

REGULATION AND CONTROL OF DIAGNOSIS AND TREATMENT OF CANCER PURSUANT TO

SECTION 1719, HEALTH AND SAFETY CODE

State of California

Health and Welfare Agency

Department of Health

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TABLE OF CONTENTS

		PAGE
I.	The Problem	1
II.	Regulatory Activities	3
	A. Regulations	3
	B. Legislation	3
	C. Investigations	3
	1. Major and/or Unusual Investigations	. 3
	D. Hearings	9
	E. Contracts with Individual (Scientific) Consultants	9
	F. Other Cases of Interest	9
	G. Meetings of the Cancer Advisory Council	10
III.	Educational Activities	10
	A. Health Education Presentations by the Department of Health	10
	B. Overall Changes	10
IV.	Research Studies	ıi
v.	Summary	11
	Appendix Members of the Cancer Advisory Council	12

I. THE PROBLEM

California has a major health problem involving cancer fraud. This has apparently spread to a nationwide network with shipments of fraudulent cancer drugs being sent from the Bay Area to many interstate points. Since most of these drugs are manufactured outside of the United States, the U.S. Customs Service has become involved and is a coordinating constituent of a joint task force which includes efforts from our own Food and Drug Section and U.S. Postal Inspection Service. The U.S. Attorney's Office in the San Diego area is the Federal agency litigating this matter. It is the objective of this task force to identify the conspirators and bring about control of an international market in which cancer victims are exploited of millions of dollars and thousands die prematurely. It is too early at this time to give any additional information.

Amygdalin is the name preferred now by the promoters of Laetrile. Its notoriety continues to be enhanced by newspapers and television stations who willingly utilize the presentations of the Laetrile advocates, calling it a controversial substance. It is regretable they fail to recognize that many people will lose their lives because of their promotion of this ineffective material.

Participants in this fraud go to great lengths to promote their beliefs and are reported to be soliciting patients who are midway in therapy at some of the radiation centers. Similar activities have interfered with appropriate surgery and chemotherapy. The anxieties of entering a program of extensive surgery or other therapy for cancer makes it easy for the promoters of this fraud to lure the less knowledgeable to their program falsely represented as "non-toxic" and "natural".

The principal pseudo-health organizations hold meetings in which Laetrile (also called Amygdalin and "Vitamin B17") is touted as an "effective non-toxic" agent for treatment of cancer and nutritional therapy. Under the current program of deception, lists of "nutrition oriented" doctors are provided the patient to visit with their cancer problems. In order to avoid prosecution, the practitioners disclaim any intent of treating cancer. Instead they pretend to offer nutritional therapy as a treatment for the "nutritional deficiency" or the "nitriloside deficiency disease" which they allege the patient has. Treatment consists of excessively large doses of the known vitamins as well as the intravenous administration of "Vitamin Bl7". The latter is never given alone so that its activity can be singled out. The relatively enormous intravenous doses of this substance are given daily over a period of two weeks, following which the patient is placed on an oral "maintenance program". This is all combined with a special dietary program. This fraudulent deception is currently being challenged in actions by both the Department of Health and the Department of Consumer Affairs in an attempt to expose and prosecute practitioners utilizing this dodge.

A nationwide ultraconservative organization appears to be the spearhead for a national distribution system utilized by the promoters and distributors (shippers) from the Bay Area. There is a reason to believe at one time organized crime figures in the country became interested in this now very lucrative fraud. The incurable and terminal cancer patient is very often the victim. His early demise renders prosecution difficult for lack of a complaining witness.

Because these victims are so incapable of defending themselves, the responsibility of the State to protect them is correspondingly greater.

II. REGULATORY ACTIVITIES

A. Regulations

No new regulations were promulgated.

B. Legislation

No new legislation has been promulgated.

The felony provisions under AB 3046 were charged in three cases this year involving Sections 1707.1, 1714 and 1715, California Health & Safety Code.

C. Investigations

In 1975, thirty-three new cancer fraud investigations were reported. Fifty-four cancer law cases were carried over from 1974 and all 87 were investigated. At the close of 1975, eight defendants were awaiting criminal trials and one physician license revocation hearing is pending.

1. Major and/or Unusual Investigations

a. A careful investigation by Food and Drug investigators and undercover agents revealed a cooperative arrangement for the import, sale, distribution and administration of Laetrile in the Southern part of the State last year.

Officers of U.S. Customs, U.S. Postal Service, Chula Vista
Police Department and our own Food and Drug investigators
participated in an investigation which resulted in the
purchase of a large quantity of Amygdalin. The purveyors
were arrested, their establishments searched under authority
of a search warrant and a large quantity of Amygdalin seized
in vials, tablets and bulk along with a tablet making machine
and extensive records. Additional arrests followed. Trial was
begun in San Diego County July 29, 1975.

The defendants were Dr. James Privitera, Carroll Leslie,
Phyllis Disney, Winifred Davis and William Turner. All five
defendants were charged with conspiracy to violate the law
(Penal Code 182).

One charge of violating Section 1707.1, H&S Code, was withdrawn as the witness in this charge died of her cancer before she could testify. Two defendants were charged with violation of Section 1707.1, H&S Code.

Jury selection involved the largest number of jury panels in San Diego history.

A unique feature of the trial was the videotaped testimony of one cancer victim with court (but not jury) convened in her home. This videotape was played for the jury in the trial and is part of the court record.

Testimony was presented by many patients of the physicians and a wide variety of experts of all degrees of expertise.

The case went to the jury December 11, 1975. All defendants were found guilty on December 16, 1975.

effectively against an Orange County Chiropractor engaged in the treatment of leukemia with a vegetable juice regimen, vitamin therapy, spinal adjustment and a pressure form of acupuncture. Gary Couture, D.C., prescribed vitamins to a

patient for her hypoglycemia following an analysis of her "electromagnetic field". An associate of this practitioner told the cancer victim that her problem stemmed from numerous nerve impairments concentrated in her neck and pancreas and that electro-acupuncture would be the appropriate treatment. The leukemia victim was told that her condition was within the scope of chiropractic and that he could help her condition.

The practitioner determined which vitamins should be taken by having the patient hold various bottles in her outstretched, left arm. He determined that eight bottles of vitamins and food supplements should be dispensed for her leukemia according to her resistance of his pressure upon her arm. The victim was told to discontinue her current treatment with her oncologist. Two other cancer victims were given similar treatments.

This practitioner admitted that he grossed \$22,000 while treating eight-hundred patients monthly. The practitioner was charged with six felony counts under the newly amended Cancer Law statutes. After two months, Gary Couture was allowed to plead guilty to a misdemeanor as a result of a plea bargaining process. He was sentenced to two years summary probation on condition that he pay a \$500 fine and \$1,000 restitution to the State of California to defray the cost of the investigation, that he refrain from violating all laws including that he not treat or represent to treat leukemia. Publicity releases to warn other potential victims of the forementioned health hazards has had a definite preventative medical effect to protect the

California consumer in addition to the deterrent effect of the successful prosecution. This publicity with a public health warning connotation resulted in a 60% loss of business and a savings of \$160,000 over a year's time to the California consumer.

Other violations of the Cancer Law took on a bizarre but lucrative aura in a Riverside County case scheduled for a preliminary hearing on January 9, 1976. Three persons allegedly violated the Cancer Law when they offered to diagnose potential cancer victims by iris analysis (practitioner stated that each part of the eye corresponds to a part of the body; that visually he could tell how severely the body is affected by the shape and density of the obliteration of the iris). Treatment for such conditions include colonics (colon enema) and chirurgery (bloodless surgery in which the practitioner's hands are placed on various parts of the patients body followed by flicking his . hands in the air thus ridding the patient of waste material out of the patient's system and into the patient's lymph glands). Treatment also includes a special bottled water, herbs and diet. Iris analysis cost the patient \$50; the report of the analysis, case history and nutritional therapy \$50; herbal formulas \$20; colon therapy \$20/treatment; chiropractic and chirurgery treatments \$15; and the special water \$2 per bottle. The usual length of treatment per patient was six months.

This analysis report to a normal undercover agent concluded that she had a toxic condition of the blood and a heavy congestion in the cerebellum. Iris analysis was described as a sensitive system

of diagnosis and was better than physicals or tests in showing results. On another agent, the practitioner performed chirurgery on her breast, head and kidneys, stating that this would help the brain cells to balance themselves. Colonics were necessary to rid the patient of toxic substances. Cancer was described as an excess of toxins in the body. One undercover agent was told that she could counteract her cancer with proper diet, herbs, loosening of the spine and proper elimination with colonics; that once the body is detoxified, there will be nothing for the malignant cells to feed on; that she should not return to her doctor or go to the hospital.

This trio had a large clientele in the desert area. The prompt filing of charges for these violations of the Cancer Law provided greater public health protection to hundreds of potential cancer victims since the principal defendant went out of business and the secondaries volume was greatly reduced.

d. Clarence Runkle, an unlicensed person, was found to be treating cancer through the use of mysterious radiation emanating from metal rods that Mr. Runkle waved over the diseased area. Mr. Runkle has a prior conviction for practicing medicine without a license, but in this case he claimed to be practicing faith healing and so would be exempt from this statute. The use of the metal rods and the acceptance of payment for his services were sufficient to negate his claim of faith healing. Mr. Runkle was charged with five felonies under the Cancer Act and five misdemeanors.

- Mr. Runkle plead guilty to violation of the California Cancer

 Law and Business & Professions Code. Runkle was sentenced to

 45 days in the county jail and placed on 3 years formal probation.
- Food and Drug Fraud Unit personnel provided substantial evidence and testimony in the civil action of U.S. v General Research Laboratories, Institute of Nutritional Research et al in the U.S. District Court Central District of California which resulted in a permanent injunction on April 25, 1975. Defendants were enjoined from manufacturing and selling "(Bee) Seventeen" and "Aprikern" in interstate commerce.

The court found that "Vitamin Bl7" was also commonly known as Amygdalin and Laetrile and was used in the treatment, prevention, cure and mitigation of cancer in man; that Aprikern was unfit for food due to its hydrogen cyanide content. The court concluded that both products were misbranded and adulterated. Reported as U.S. v General Research Laboratories 397 Federal Supplement 197, 1975.

f. A Bay Area chiropractor was charged with violations of the California Cancer Law and Business & Professions Code when he was found treating breast cancer by spinal manipulation, special diet and the application of a large magnet over the affected area. He strongly recommended to patients that they do not undergo a biopsy, claiming that surgery would cause the cancer to spread over the entire body.

A warrant was issued for Earl Conroy's arrest. He promptly fled the country to New Zealand. The warrant remains outstanding to welcome him should he decide to return.

D. Hearings

No hearings were held in matters involving compliance with the California Cancer Law.

E. Contracts with Individual (Scientific) Consultants

The prosecutions of physicians involve fundamental or scientific testimony by experts in various fields. The subject matter is frequently complicated and technical requiring careful and thorough trial preparation of the facts for presentation to the judge and jury. Contracts for individual consultants are drawn to cover various areas of expertise for such court presentations.

F. Other Cases of Interest

The Board of Medical Examiners recently conducted an accusation against the license of Stewart M. Jones, M.D., of Palo Alto. The Hearing Officer found him guilty of administering Laetrile to cancer patients in violation of Regulation 10400.1. His license was suspended for one year and probation was made for two years and the suspension was stayed.

Serious errors resulted from inadequate appreciation of the doctor's fraudulent practices and major applications of Food and Drug Law interpretation were omitted. The Department of Health, the Cancer Advisory Council and the Attorney General's Office all protested this decision during the period when a change in this decision could be effected. At the same time, Dr. Jones requested the striking of the period of probation and the dismissal of all charges. After considerable discussion in Executive Session, the Board of Medical Examiners denied both sets of petitions and allowed the Hearing Officer's recommended punishment to stand.

G. Meetings of the Cancer Advisory Council

There were two regular meetings of the Cancer Advisory Council this year. The first was held on May 14, 1975 and the second on October 8, 1975.

III. EDUCATIONAL ACTIVITIES

In June 1975, a liaison committee of the Department of Health, the Federal Food and Drug Administration, the American Cancer Society and the California Medical Association in joint cooperation but acting as independent agencies presented a program of training to volunteer physicians and other interested persons in the separate departments to facilitate their handling of speaking engagements particularly those involving a confrontation with persons promoting cancer fraud. It is felt that this type of activity is essential to assist the public in understanding the realistic values of cancer therapy and to mitigate in some measure the extensive publicity received by the various promoters of cancer frauds.

Participants of this training program are currently appearing on radio and television programs. They are making effective rebuttals of the claims by Laetrile advocates.

A. Health Education Presentations by the Department of Health

Members of the Food and Drug Section of the Department of Health made a number of health presentations to various organizations including colleges, high schools, medical staffs of hospitals, senior citizens' groups, etc., including a seminar at Stanford University.

B. Overall Changes

Promotion of cancer fraud has continued to be highly sophisticated. It is so financially remunerative it is believed there may be underworld participation. Financial rewards are believed second only to narcotics, according to U.S. Customs officers.

Cooperative study of certain practitioners of this fraud is underway involving the cooperation of the U.S. Treasury Department, U.S. Postal Inspection, the investigative unit of the State Food and Drug Section of the Department of Health, local and other Federal agencies.

The recent decision in Federal Court cited above clearly states the Federal point of view which confirms and supports those of this department.

IV. RESEARCH STUDIES

Extensive studies at the Southern Research Institute, the Arthur D. Little Research Corporation, have been published in cancer chemotherapy reports this Fall and will be supplemented by additional, extensive (and authentic) reports from the Catholic Medical Center of New York and the Sloan-Kettering Institute when their current work on this subject is completed.

Up to the present time, there has been an enormous amount of research done on all types of animal tumors to determine if there is any value in the use of Laetrile in cancer. No evidence of any significant effect has been found. Were it not for the long history of prior use and current artificially stimulated interest, it would have long since been dropped from consideration for use in cancer.

V. SUMMARY

Many types of cancer fraud have been perpetrated on the public. The current major fraud involves the use of Laetrile also known as Amygdalin or "Vitamin B17". Interstate commerce is involved. The shipments from the Bay Area consist of material imported from either Germany or Mexico. Thus both Customs and FDA Regulations are in violation. Three physicians have been involved with alleged violations of either the law or their licensing provisions and are, or have been, prosecuted or have been or are about to undergo hearings with respect to licensure. Additional investigations are underway.

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