

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

IN THE MATTER OF)
) Docket No.
A RULEMAKING PROCEEDING)
CONCERNING LAETRILE)

AFFIDAVIT OF JOHN T. P. CUDMORE, M.D.

County of San Diego)
State of California) ss

Before me personally appeared John T. P. Cudmore, M.D., who being first duly sworn, deposes and says:

1. I am a physician, licensed to practice in the State of California.
2. I received a Bachelor of Arts Degree from Rollins College, Winter Park, Florida in 1934 and a Doctor of Medicine Degree from Temple University School of Medicine, Philadelphia, Pennsylvania in 1939.
3. I was in the private practice of surgery in New York, New York from 1946-1956 and have been in private practice in oncology in San Diego, California from 1956 to date.
4. I was Board qualified by the American Board of Surgery in 1954 and was a Fellow in Surgery at the Memorial Center for Cancer, New York City, from 1952-1956.
5. I am a member of the American Cancer Society, American Association for Cancer Education, American Society of Clinical Oncology, and the Society of Surgical Oncology. I currently serve on a number of cancer committees of the American Cancer Society, California Division and the San Diego County Medical Society.

6. My Curriculum Vitae is attached hereto as Exhibit 1. It provides a summary of my education, training, and experience and a list of my hospital and teaching appointments, organizations, committees, and meetings attended.

7. I have been regularly engaged in the medical management of cancer since 1956. My work requires that I be, and I am, acquainted with the literature published in professional journals related to drugs used in the treatment of cancer. As indicated in my Curriculum Vitae, I attend meetings of experts in my field of medical specialization at which drugs used in the treatment of cancer are discussed and evaluated.

8. Amygdalin, commonly called Laetrile and also referred to as "Vitamin B-17", although there is no evidence that it is in any way a vitamin in the accepted sense, is an unproven remedy which is being promoted as a preventative and cure for cancer. The composition of amygdalin is such that I do not recognize it, nor is it generally recognized by experts qualified through scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use in the treatment or prevention of cancer.

9. Although there has been a considerable amount of publicity, chiefly in the news media and popular press, alleging that amygdalin or Laetrile is useful for treating cancer in humans, and that it is non-toxic, I know of no confirmed pre-clinical studies in laboratory animals which indicate that amygdalin has any activity as a potential chemotherapeutic agent for the treatment, prevention, or mitigation of cancer. Further, because amygdalin or Laetrile is ineffective in animals, I totally agree with other experts in cancer chemotherapy that it will also be ineffective in treating human cancers. As amygdalin is a cyanogenic glycoside which contains the cyanide group in its molecular structure, there is also doubt as to the safety of the drug when taken by mouth as cyanide poisoning and brain damage have been reported.

10. In my practice of oncology in San Diego since 1956, I have examined numerous patients after their treatments with amygdalin or Laetrile in nearby Tijuana, Mexico. I have never seen any evidence of cure or palliation with Laetrile. I can conclude from my personal experience that Laetrile or amygdalin is ineffective in the treatment and prevention of cancer.

11. I have seen a number of patients die after forsaking orthodox cancer therapies for Laetrile or amygdalin. The following case histories are perfect examples where the patient was denied a possible cure of cancer by the use of Laetrile or amygdalin:

CASE HISTORY NO. 1

This patient was a 71-year-old male with an ulcerative chest wall lesion and a diagnosis of rhabdomyosarcoma of 14 years duration. Had this man been diagnosed and treated early, he might have expected a 30 percent cure rate from treatment by surgery, radiation, and chemotherapy. He had received Laetrile and other unproven therapies in various Mexican clinics and when seen by us, it was his first exposure to orthodox American medicine. The patient rapidly died from metastatic disease. In this case, a possible cure was prevented by the use of Laetrile and other unorthodox methods.

CASE HISTORY NO. 2

This patient was a 65-year-old female with carcinoma of the breasts of three years duration. She was seen with ulcerative breast cancer and bilateral pleural effusion. She had received Laetrile, Hoxsey, and other unorthodox treatments in Mexico without benefit. As this patient was not seen early, her expected cure rate from treatment with surgery, radiation, and chemotherapy could not be predicted. In general, the cure rate for cancer when confined to the breast is about 85-90 percent and when the cancer has spread to the axilla, the cure rate is about 45 percent. This

patient was denied a possible cure of her cancer due to delaying her treatment by the use of Laetrile.

CASE HISTORY NO. 3

This patient was a 50-year-old female with disseminated carcinoma of the breast of five years duration. Because this patient was not seen early her precise chances of cure cannot be predicted; however, the cure rate for cancer of the breast is approximately 85-90 percent. This patient also received Laetrile in Mexico without apparent benefit. She subsequently died; another possible cure delayed by the use of Laetrile.

CASE HISTORY NO. 4

This patient was a 43-year-old female with generalized lymphosarcoma of seven years duration. In addition to orthodox chemotherapy, the patient received Laetrile which failed to control her disease. Lymphosarcoma is incurable at the present time with any method of therapy. The patient died.

The physician who treats cancer is interested in the length of life and the quality of that life of the incurable cancer patient. There is no evidence that Laetrile provided any benefit in prolonging this patient's life or its quality.

CASE HISTORY NO. 5

This patient was a 65-year-old female with primary operable breast cancer. When first seen by me, she was certainly potentially curable (90 percent cure rate). In 1965, the patient refused surgery and thereafter received Laetrile intravenously, as well as directly into her tumor. The patient returned to my care three years later at which time the mass was ulcerated and needle biopsy of the breast was positive for breast cancer. All of this occurred after administration of Laetrile. The patient continued to refuse orthodox treatment and later developed cancer in the opposite breast and in both axillae. The patient's status is unknown; however, a potential cure was certainly delayed and perhaps made impossible by unacceptable treatment and the administration of Laetrile.

CASE HISTORY NO. 6

This patient was a 40-year-old female with disseminated carcinoma of the breasts. General cure rates for breast cancer have been previously stated. When first seen by me, this patient had little chance of recovery. The patient had previously taken Laetrile and she ultimately died.

CASE HISTORY NO. 7

This patient was a 47-year-old male with pleural mesothelioma. At present, this type of tumor is incurable. Despite Laetrile administration, a persistent tumor was demonstrated in autopsy. Here, again, in the case of the incurable cancer patient, there was concern about the length of the patient's life and the quality of that life, and no evidence was seen that Laetrile provided any benefit to either.

CASE HISTORY NO. 8

This patient was a 56-year-old female with carcinoma of the ovary. If seen early, she would have had a 50 percent chance of cure. When first seen by me, the patient's cancer was incurable. She had received Laetrile for two weeks without improvement. The patient died.

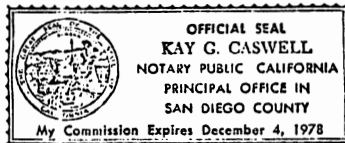
CASE HISTORY NO. 9

This patient was a 64-year-old male with carcinoma of the lung. The chance of cure with surgery, radiation, etc., is about ten percent; however, this patient was incurable when seen by me. He had received 54 grams of Laetrile intravenously without benefit. The patient died.

12. Many cancer patients can be helped with conventional cancer therapies. When patients get involved with Laetrile or other worthless remedies, they lose valuable time in obtaining known effective treatment. I see no reason whatsoever for the United States Food and Drug Administration to exempt Laetrile from the present laws requiring that a drug be proven both safe and effective for its intended uses before it may be allowed to be marketed in interstate commerce in this country.

John T. P. Cudmore, M.D.
JOHN T. P. CUDMORE, M.D.

Subscribed and sworn to before me by the said John T. P. Cudmore, M.D., this 21st day of March, 1977.



Kay G. Caswell
Notary Public KAY G. CASWELL
My Commission Expires: Dec. 4th, 1978

CURRICULUM VITAE

Name: John T. P. Cudmore, M. D.
 Address: 108 University Avenue, San Diego, California 92103
 Phone: 291-6270
 Birthdate: March 6, 1912

Education: A. B. degree, Rollins College, Winter Park, Florida, 1934. M. D. degree, Temple University School of Medicine, Philadelphia, Pennsylvania, 1939.

Internship: Bellevue Hospital, Second Surgical Division (Cornell). New York, 1939-1942. Intern and House Surgeon.

Fellowship: Fellow in Surgery. Memorial Center for Cancer, New York City, 1952-1956.

Board Certification: Board qualified, American Board of Surgery, 1954.

Service: Surgeon, United States Army, Medical Corps (Memorial Hospital Unit, 14th Evacuation Hospital, China, Burma, India); Combat Surgeon, Merrill's Marauders, Burma-1942-1946.

Experience: Private practice of surgery, New York, New York. 1946-1956.
 Private practice in oncology, San Diego, California, 1956 to date.

Hospital Staffs: Alvarado Community Hospital Hillside Hospital
 Centre City Hospital Mercy Hospital
 College Park Hospital Mission Bay Memorial
 Coronado Hospital Paradise Valley Hospital
 Cabrillo Medical Center and Scripps Memorial Hospital
 Doctors Hospital Donald N. Sharp Memorial
 Grossmont Hospital Community Hospital
 Heartland Community Hospital Villa View Community Hospital

Hospital Appointments: Past Chairman of Allocations, Damon Runyon Cancer Fund, Sharp Memorial Hospital
 Member, Transfusion Committee, Sharp Memorial Hospital 1968-1970. Chairman, Cancer Committee, Mercy Hospital, 1973. Member, Tumor Boards of Mercy, University, Grossmont, Doctors and Paradise Valley Hospitals.

Teaching Appointments: Assistant Clinical Professor in Surgery, University of California, San Diego, Medical School - 1968-1974.

Publications:

1. "Intracavitary Thiotepe for Malignant Effusions," American Surgeon, Vol. 28, pp. 90-95, 1962.
2. "Evaluation of 5-Fluorouracil (5-FU) in Surgical Practice." American Surgeon, Vol. 29 pp. 683-691, 1963.
3. "Comparison of High-Dosage and Low-Dosage Maintenance Therapy with 5-Fluorouracil in Solid Tumors," Cancer, Vol. 17, pp. 230-232, 1964.

Research:

Participatn in clinical evaluation of Thiotepe, 5-fluorouracil, Actinomycin-D, Alkeran, Hydroxy-urea and Vercyte, Depo-Provera.

Organizations: American College of Surgeons, Liaison Associate, Commission
American Cancer Society on Cancer
American Association for Cancer Education
American Medical Association
American Radium Society
American Society of Clinical Oncology
California Medical Association
Regional Medical Program
San Diego County Medical Society
Society of Head and Neck Surgeons
Society of Surgical Oncology
William S. MacComb Society

Committees: American Cancer Society
California Division
Board of Directors, 1972 to date
Executive Committee 1974 to date
Maconber Legacy Committee and Executive Committee
Nominating Committee, 1974 to date
Cancer Patient Needs Study, 1976
Professional Education Committee, 1972-1973
Chairman, 1975-1977
San Diego County Branch
Chairman, Nominating Committee, 1975-1976
Executive Committee, 1962 to date
First Vice-President, 1971-1973
Past Chairman of Scientific and Medical Education
President, 1973-1975
Vice-President for Personnel, 1969-1970
California Medical Association
Cancer Committee, 1972 to date; Chairman, 1973 to date
Ad Hoc Committee on Breast Cancer, 1977, Calif. Div.
Regional Medical Program
Chairman, Cancer Section 1971-1973
San Diego County Medical Society
Member, Cancer Care Committee, 1971-1972
Chairman, Cancer Care Committee, 1973
Member, Library Committee, 1970-1972
Chairman, Library Committee, 1973
Member, Program Committee, 1970-1974
Member, Ad Hoc Committee on Cancer Detection,
1970 to date
Smoking Research, San Diego, Medical Director, 1965-1973
State of California - Department Health, California Tumor
Registry Advisory Committee, 1977

- Committees: Past Chairman, Professional Health Commissions
- Civic Activities: Member of Vestry, St. Paul's Episocopal Church
Past President, Presidio Little League Baseball
- Meetings: California RVS Meeting (1969-1970 revisions), Palm Springs, California, February 1970
- Cancer Conference, U. S. Naval Hospital, April 1970
- American Radium Society Annual Meeting, March 1970, Coronado, California
- Symposium for Industrial Physicians, May 1970, San Diego, California
- Sixth Annual Cancer Conference, San Francisco, California, Zellerbach-Saroni Institute, October 1970
- National Conference on Smoking Health, San Diego, California, September 1970
- National Conference on Cancer of the Colon and Rectum, Coronado, California, January 1971
- American Radium Society Annual Meeting, Mexico City, March 1971
- Cancer Conference, U. S. Naval Hospital, San Diego, California, April 1971
- Current Concepts in Medical Oncology, Mount Zion Hospital, San Francisco, California, January 13-15, 1972
- Joint Meeting, American Radium Society, James Ewing Society and Society of Head and Neck Surgeons, Boca Raton, Florida, May 14-19, 1972
- Combined Health Agencies Drive Meeting, San Diego, California, June 28, 1972
- Seventh Annual Cancer Conference, Los Angeles, California, September 26-29, 1972
- Eighth Annual San Francisco Cancer Symposium, Mount Zion Hospital, February 1-2, 1973

Meetings:
(continued)

Symposium on Melanoma, sponsored by American Cancer Society and California Medical Association, Anaheim, California, March 10, 1973.

Joint Meeting of James Ewing Society (Society of Surgical Oncology) and the Society of Head and Neck Surgeons, New Orleans, Louisiana, March 25-29, 1975

18th Annual Cancer Conference, Naval Regional Medical Center, San Diego, California, April 8, 1975

American Society of Clinical Oncology Annual Meeting, San Diego, California, May 7-8, 1975

American Cancer Society, Annual Meeting, San Diego, California, September 17, 1975

American Cancer Society, San Diego Unit and San Diego Academy of Otolaryngology, Joint Meeting, San Diego California, October 18, 1975

Joint Meeting of the Society of Head and Neck Surgeons, Annual Meeting, San Diego, California, April 10-14, 1976

American Cancer Society, Annual Meeting, San Francisco, California, October 20-22, 1976