DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

IN THE MATTER OF	)	
	)	Docket No. 77N-0048
A RULEMAKING PROCEEDING	)	
CONCERNING LAETRILE	)	

AFFIDAVIT OF WALLACE I. SAMPSON, M.D.

County of Santa Clara)
State of California) ss

Before me personally appeared Wallace I. Sampson, 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 the Degree of Doctor of Medicine from the University of California in 1955.

3. I was an intern at Minneapolis General Hospital from 1955-56, a Captain in the United States Army Medical Corp from 1956-1958, a resident in pathology at the Los Angeles County Harbor General Hospital from 1958-1959, and a resident in internal medicine at Harbor General Hospital from 1959-1961.

4. I am a Diplomate certified by the American Board of Internal Medicine, a Fellow of the American College of Physicians, and a member of the American Society of Hematology and the American Medical Association.

5. I am regularly engaged in the practice of medicine and conduct a practice in Mountain View, California. I specialize in hematology and oncology.

6. In 1963, I was appointed Attending Physician at El Camino Hospital in Mountain View, California, and I am presently Senior Attending Physician in Hematology and Chief of the Hematology Clinic at the Santa Clara Valley Medical Center in San Jose, California.

7. My Curriculum Vitae is attached hereto as Exhibit 1. It provides a summary of my education, training, and experience.

8. "Unproven methods" is the term given by the American Cancer Society to methods and substances claimed to be of value in treating cancer but lacking scientific validity. Amygdalin or Laetrile, one of these "unproven substances", is of particular interest to me. I have studied, in addition to the science applicable to Laetrile, the various factors which have resulted in a demand for the substance among lay persons.

9. The Laetrile movement as a social phenomenon has surpassed all other "unproven methods" and has reached a magnitude unprecedented in modern history. Its success has resulted from a complex interaction of cultural factors and the personal needs of some patients with incurable illness. A key and probably the most important factor has been the failure of modern medicine and technological advances to cure or adequately control some cancers. These unfulfilled expectations lead patients to disappointments in standard medicine and to attempt a cure of their disease by pseudo-scientific methods.

10. The Laetrile movement has acquired several characteristics which distinguish it from other pseudo-scientific medical treatments of the past. The scientific and clinical rationale for Laetrile have been combined with a social network, political arguments, and literary support to create a belief system which has plausibility and social acceptability. Local and national organizations have been formed by laymen and patients to support Laetrile and other pseudo-scientific methods, thus lending a degree of social acceptability. A few scientists support Laetrile, thus lending a degree of scientitic legitimacy. A political organization has successfully established Laetrile as an issue of freedom from excessive governmental interference, thus adding a political legitimacy to the issue. In addition, physicians and nurses who actually administer the substance add a professional legitimacy.

Physicians who administer Laetrile also testify as to its efficacy without presenting reliable data. Although such physicians may have inadequate or no training in clinical cancer treatment, the public, being unable to evaluate clinical ability and judgment, often lends weight to their degree. Numerous newspaper articles and books have been written in support of Laetrile. In addition, The New York Times and two syndicated columnists have defended the taking of Laetrile.

Part of the rationalization of the Laetrile movement has been the "conspiracy theory". This states that the American Medical Association, the Food and Drug Administration, and the pharmaceutical industry have conspired to keep Laetrile illegal since it is a direct threat to their incomes and existence. The Laetrile participants have unified into a belief system set in an adversary relationship to a perceived mammoth and unyielding scientific and governmental health system. All of these factors serve to publicize and unify the Laetrile cause, help keep firm the belief in Laetrile's effectiveness, and dispel doubts as to its worthlessness. By looking at scientific theory as political and at the controversy as a political one, objective evaluation of the facts diminishes and becomes less important.

11. As part of my study of the structure of this Laetrile system, I interviewed twenty patients (or a close surviving relative in three cases), sixteen of whom had committed themselves to taking Laetrile enough to have completed at least one course of therapy. Four of the patients had discontinued treatment before completing one course of therapy.

Medical records were available for review in all but one case. In none of the cases was any alteration of the diseases attributable to Laetrile.

12. The interviews of these patients were conducted as standard medical histories and the patients' attitudes and perceptions toward taking Laetrile were studied via open discussions. These were not psychiatric evaluations, but discussions of the patients' perceptions of their illnesses and their involvement with the Laetrile system.

All of the patients stated that they took Laetrile because of their desire to try everything. This attitude is understandable without explanation. It probably applies to most cancer patients who are not aged or suffering from some other illness. Because Laetrile treatment was available and, though expensive, affordable, most patients felt they had little to lose.

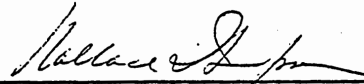
However, over 50% of the patients interviewed delayed, refused, or stopped standard therapies in lieu of Laetrile. This is a principal social danger in Laetrile's being available as an "unproven substance".

Part of the reason for avoidance of standard therapy is the orientation of the Laetrile system as one of opposition to standard, scientific medicine. The displacement of faith from the standard physician who offers no hope to the patient to the Laetrile practitioner who offers false hope enables the patient to render an exclusive commitment to the Laetrile system.

13. Three quarters of the patients interviewed tried other pseudo-scientific or unproven methods of treatment, such as megavitamin therapy, metabolic therapy, numerous dietary treatments, and immunotherapy by unapproved methods by unqualified persons. The reasons for Laetrile patients' high incidence of use of multiple unapproved remedies is twofold: first, there is a considerable amount of literature about such methods through the Laetrile organizations, as well as cross referrals from one method or therapist to another, and, second, evidence from these interviews indicates that there may be a certain constant percentage of the population that seeks non-rational, magical solutions to the conflict of dread and often uncurable illness.

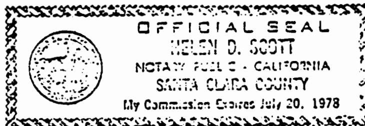
In contrast, in a separate series of fifteen consecutive patients who were on chemotherapy for cancer, only two admitted taking other remedies on their own.

14. Some of the other reasons these patients gave for trying Laetrile included family pressures, belief in the conspiracy theory previously discussed, belief that the testimonials of others who claimed benefit from Laetrile were true, dissatisfaction with the way the physician had informed them of their diagnosis and prognosis, and a significant belief that Laetrile would help them. There was a significant lack of attempts to obtain information from the American Cancer Society or governmental agencies as though the patients purposely tried to avoid the complications of having to evaluate disconfirmatory evidence.



WALLACE I. SAMPSON, M.D.

Subscribed and sworn to by the said Wallace I. Sampson, M.D., before me this 14th day of April, 1977.



Notary Public
My Commission Expires:

CURRICULUM VITAE

WALLACE I. SAMPSON, M.D.

[illegible]	M.D. University of California San Francisco, School of Medicine.
[illegible]-73	Internship, Minneapolis General Hospital, Minneapolis, Minnesota.
[illegible]-57	U.S. Army, Europe. General Medical Officer.
[illegible]	Resident in Pathology, Los Angeles County Harbor General Hospital; Instructor in Pathology, UCLA School of Medicine.
[illegible]	Resident in Medicine, Los Angeles County Harbor General Hospital, Torrance, California.
19[illegible]-62	Fellow in Hematology, Children's Hospital, San Francisco and University of California School of Medicine.
[illegible]-72	Private practice of Hematology and Oncology, Sunnyvale and San Jose, California.
[illegible]	Attending Physician, (Internal Medicine, Hematology) Santa Clara Valley Medical Center, San Jose, California.
[illegible]	Senior Attending Physician, Santa Clara Valley Medical Center and Chief, Hematology Clinic.
1967-[illegible]	Acting Chief Division of Hematology, Santa Clara Valley Medical Center.
[illegible]	Clinical Assistant Professor, Stanford University School of Medicine.
[illegible]	Acting Chief, Division of Oncology, Santa Clara Valley Medical Center.

PUBLICATIONS

1. Sampson, Saifi, and Wallerstein: Toxic Effects of Chloramphenicol in bone marrow - Proc. IX International Conference of Hematology, 1962.

2. [illegible] and Sampson: [illegible] of [illegible] Proc. [illegible] Int. Conference [illegible], Chicago, Illinois, 1963.

Publications - con't.

3. Schneiderman, Sampson, Schoene, and Haydon: Genetic Studies of a Family with Two Unusual Autosomal Dominant Conditions: Muscular Dystrophy and Pelger-Huet Anomaly. American Journal of Medicine 46:380, March 1969.

4. Sampson, W.I.: Megakaryocyte Abnormalities in Myeloproliferative Disorders; Clinical Research: XIX, 135, January, 1971.

5. Sampson, W.I.: Multiple Gene Derepressions in erythrocytes of DiGuglielmo's Syndrome, in preparation.

6. Lewis and Sampson, W.I.: PTC Deficiency with phalangeal and interphalangeal arthritic changes. Calif. Med.: 116; 81, March , 1972.

License - California

Organizations - American Society of Hematology
Fellow, American College of Physicians

ADDENDUM

1974 - 7 Clinical Associate Professor of Medicine, Stanford University School of Medicine.