

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 JESSE L. STEINFELD, M.D.

AFFIDAVIT OF JESSE L. STEINFELD, M.D.

Jesse L. Steinfeld, M.D., being first duly sworn, deposes, and says:

1. I am a physician licensed to practice in the States of California, Ohio, Maryland, Minnesota, Virginia, and the District of Columbia.

2. I received my M.D. degree from Western Reserve School of Medicine in Cleveland, Ohio, in 1949.

3. I am a Diplomate, certified by the American Board of Internal Medicine in 1958.

4. I was Assistant Director of the Blood Hospital, City of Hope in Duarte, California, from 1958-1959, where I was in charge of the cancer chemotherapy program.

5. From 1959-1968, I was Assistant, Associate, and then full Professor of Medicine at the University of Southern California, School of Medicine, and from approximately 1960-1968, I served as cancer coordinator and was in charge of the medical oncology program. During the latter half of my tenure at U.S.C., I was chairman of the Western Cooperative Cancer Chemotherapy Group.

6. I was the Deputy Director of the National Cancer Institute from 1968 to 1969.

7. I served as United States Surgeon General from 1969-1973. I was Deputy Assistant Secretary for Health and Scientific Affairs in the U.S. Department of Health, Education, and Welfare, from 1969 to 1973.

8. I was Chairman of the Department of Oncology and Director of the Comprehensive Cancer Center at the Mayo Clinic 1973-1974.

Affidavit of Jesse L. Steinfeld, M.D.

9. From 1974 to 1976, I was Professor of Medicine at the University of California at Irvine, California, during which time I was Chief of the Medical Service at the Long Beach Veterans Administration Hospital in Long Beach, California.

10. Since 1976, I have been Dean of the School of Medicine at the Medical College of Virginia in Richmond, Virginia.

11. I had an Atomic Energy Commission Fellowship in Medicine at the University of California, 1952-1953, to learn the use of radioactive isotopes in medical research. I served as a Clinical Investigator with the National Cancer Institute from 1954-1958. I served as a member of the Krebiozen Review Committee in 1963, a member of the Clinical Studies Panel (1964-1966), and a member of the Chemotherapy Advisory Committee in 1967, and currently am a consultant, all with the National Cancer Institute.

12. Because of my interest in cancer chemotherapy, I served as a member of the California State Cancer Advisory Committee from 1961-1968, and was Vice-Chairman in 1967.

13. Among my professional memberships are the Society of Nuclear Medicine, the American Association for Cancer Research, the American Society of Hematology. I am a Fellow in the American College of Physicians. I am a past President of the American Society of Clinical Oncology.

14. For over 20 years, I have been involved in cancer research, particularly with respect to the metabolic effects in cancer patients that occur as the cancer grows and metastasizes. My other major professional interest is in the evaluation of new cancer chemotherapeutic agents.

I have attached my curriculum vitae as Exhibit I and my Bibliography as Exhibit II.

Cancer is a term that is used to describe neoplasms that are characterized by unregulated, uncontrolled, and unrestrained growth and proliferation. There are many different forms of cancer and many different causes of the disease. Human cancer can be caused by certain natural and synthetic chemicals, radiation, and, in a number of animal species, by viruses acting alone or in combination. There are over 100 different forms of human cancer. No one therapy is effective in all forms of human cancer.

Cancers differ in rate of growth, time between onset and metastases, the nature or extent of metastases, and in the time between onset and serious impairment of bodily function. Some cancers grow very slowly and may be present for years before producing seriously adverse or lethal effects. Acute leukemia in childhood and choriocarcinoma in the female are examples of rapidly growing tumors, which can be controlled or even cured with the use of cancer chemotherapeutic agents. Without treatment these cancers are usually fatal within one year. However, breast cancer in the adult female is a variably progressive disease with patients surviving as long as 15 years without any treatment. Of course, adequate treatment results in the cure of as many as 85% of patients whose disease is localized when discovered. Sixty-five percent of all patients with breast

cancer will survive at least five years with adequate treatment using surgery, radiotherapy, and/or chemotherapy. It is not uncommon for the extent of impairment to fluctuate from time to time over the course of the disease. Occasionally, patients experience complete remission of their cancer for causes that are unknown. However, early detection and swift effective treatment with surgery, radiotherapy, and chemotherapy are the only known methods for controlling cancer. Some forms of cancer can be cured and others controlled for many years through prompt use of effective therapy. Forty years ago one in five cancer victims survived five years. In 1977, one in three cancer victims will survive five years. Application of existing knowledge could increase this number to one in two cancer victims over the next few years.

The claim that any particular chemical substance would be capable of treating, preventing, or controlling all forms of cancer is simplistic, improbable, and unfounded. It is not supported by any known scientific evidence and should be regarded as false. Drugs useful in acute leukemia may or may not be effective in breast cancer, colon cancer, or neuroblastoma. Appropriate treatment with drugs requires knowledge of the natural history of the disease, the status of the patient's other bodily functions: cardiovascular, pulmonary, renal, immunologic and bone marrow among others. The dosage and timing of chemotherapy must be adjusted not only to the type of cancer, but to the particular patient. Much of the success

in cancer treatment relates to the necessary and extensive other medical care given the cancer patient to support his vital functions during the period of treatment. That this has been successful is shown by the increase in survival among cancer patients over the last 40 years.

My duties require that I be, and I am, familiar with those drugs that are generally recognized as safe and effective in the treatment and management of cancer. I keep informed about the status of current cancer patient management by reading the medical and scientific literature relating to cancer, conducting research, teaching, attending meetings where experts discuss drugs that are so recognized, and by conferring with colleagues who are experts on the control of cancer.

I am informed and understand that amygdalin is a cyanogenic glycoside. Cyanogenic glycosides are chemicals which contain in their molecular structure a sugar, a non-sugar, and the cyanide group, ( $-C\equiv N$ ). I know of no cyanogenic glycoside that is generally recognized as safe and effective for the treatment, prevention, or cure of cancer, for the relief of pain associated with cancer, or for any medical purpose. The composition of the cyanogenic glycosides, in general, and of amygdalin, in particular, is such that I do not recognize them, and they are not generally recognized among experts qualified through scientific training and experience to evaluate drugs, as safe and effective for the treatment of cancer, for prophylaxis against cancer, for relief of pain associated with cancer, or for any medical use.

Neither amygdalin nor any other cyanogenic glycoside is generally recognized as safe for any such uses as of March 23, 1977. None of these substances has ever been so recognized in cancer management. The scientific literature contains no reports of adequate, well-controlled, scientific studies, or other evidence upon which such recognition may be predicated. I know of no recognized medical text in which use of amygdalin or any cyanogenic glycoside is recommended for the treatment of cancer. I know of no medical school where use of these substances for such purposes is taught. I know of no expert in cancer chemotherapy who is of the view that there is evidence these substances have any useful effect in treating cancer. To repeat, I know of no report in the scientific literature describing an adequate, well-controlled study which demonstrates that amygdalin or any cyanogenic glycoside is safe and effective in the cure, mitigation, treatment, or prevention of cancer.

The proponent's theory is that cancer cells are high in B-glucuronidase, which splits cyanide from amygdalin, which cyanide then preferentially kills cancer cells. This presumably occurs because cancer cells as compared to normal cells are low in another enzyme, rhodanase which converts the cyanide to a non-toxic chemical, thus killing cancer cells and protecting normal cells. The above theory is faulty from a number of points of view:

- 1) Not all cancer cells are high in B- glucuronidase.
- 2) Even if they were high in B-glucuronidase, that enzyme would not split off cyanide since the bond is a glucoside not a glucuronide.

- 3) Cancer cells' rhodanase levels are not uniformly lower than that of many normal cells.

This is a pseudo-theory unsubstantiated by biochemical or physiological data.

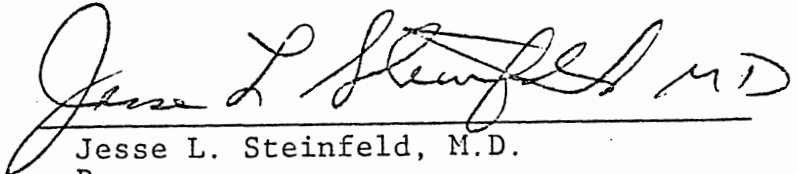
I have been asked to state my opinion concerning the public health significance of permitting cancer patients to receive and use amygdalin, in particular, and other unproven remedies, in general, when their use is proposed and promoted despite a lack of scientific evidence of safety and effectiveness. My opinion is that these materials and specifically, laetrile, are harmful because their use removes patients from accepted medical care and treatment, which could save their lives, that laetrile provides a false sense of security, that the purveyors of laetrile generally are not competent to provide adequate diagnosis and treatment of other complications of diseases associated with cancers and that their patients, therefore, suffer needless distress and may even die of unrelated disease, when they do not die of cancer.

I have been asked to render an opinion concerning the medical and scientific basis for, and the public health consequences of the availability of amygdalin, or other similar unproven cancer remedies, for clinical use in patients with "terminal" cancer. My opinion is: that there is no scientific evidence that laetrile is of value in human or experimental cancer. I have reviewed animal studies

performed by the National Cancer Institute, the Sloan Kettering Institute, and the Southern Research Institute on the use of laetrile for the treatment of a number of animal tumors. In no instance was laetrile effective in control of the disease, according to all accepted scientific and statistical criteria. I have reviewed the clinical records of a number of patients who received laetrile as treatment for cancer, while I was in California. In that review there was no evidence to support the view that laetrile was of value to cancer patients. I have reviewed the volumes of material submitted to the FDA in 1970, requesting an Investigational New Drug Application (IND) for laetrile. The application was not approved because of serious flaws or deficiencies in both the animal and human trials.

In summary, laetrile - after a quarter century, has been found to be of value only to those who sell it, since they make an enormous profit from their sales. The unfortunate cancer victims lose more than their money; they lose their lives.

City of Richmond )  
 State of Virginia ) ss

  
 Jesse L. Steinfeld, M.D.  
 Dean  
 School of Medicine

*Subscribed and sworn before me this  
 23rd day of March, 1977.  
 My commission expires January 8, 1980.  
 Richard H. Clark*

JESSE L. STEINFELD, M.D.

Dean, School of Medicine  
Professor of Medicine  
Medical College of Virginia  
Virginia Commonwealth University  
Richmond, Virginia 23298

A. Personal Information

1. Business Address: School of Medicine  
Box 636  
Medical College of Virginia  
Virginia Commonwealth University  
Richmond, Virginia 23298
2. Business Phone: Area Code (804) 770-6837, 6838
3. Home Address:
4. Home Phone:
5. Date of Birth: January 6, 1927
6. Place of Birth: West Aliquippa, Pennsylvania
7. Citizenship: United States
8. Sex: Male
9. Marital Status: Married
10. Wife's Maiden Name: Gen M. Stokes, married San Francisco,  
California, July 12, 1953
11. Children: Jacquelyn Mary Beth, July 30, 1954  
Jody Katherine, October 31, 1955  
Frances Susan, December 5, 1960

B. Education

1. High School: Aliquippa High School, Aliquippa,  
Pennsylvania. Graduated: January 1944
2. College: University of Pittsburgh, Pittsburgh,  
Pennsylvania: B.S., September, 1945
3. Medical School: Western Reserve, Cleveland, Ohio:  
M.D., June, 1949
4. Internship: Cedars of Lebanon Hospital, Los Angeles,  
California - Internship, 1949-50

C. Professional Background

1. Academic Appointments:

- a. Instructor in Medicine, University of California, San Francisco, California, 1952-1954
- b. Instructor in Medicine, George Washington University School of Medicine, 1954-1958
- c. Assistant Professor of Medicine, University of Southern California School of Medicine, 1959-1963
- d. Associate Professor of Medicine, University of Southern California School of Medicine, 1963-1967
  - 1) Senior Attending Physician, Los Angeles County General Hospital, 1964-1968
- e. Professor of Medicine, University of Southern California School of Medicine, 1967-1968
- f. Associate Director for Program, National Cancer Institute, 1968-1969
- g. Deputy Director, National Cancer Institute, 1969
- h. Deputy Assistant Secretary for Health  
Department of Health, Education and Welfare, 1969-73
- i. Surgeon General, United States Public Health Service, Department of Health, Education and Welfare, 1969-1973
- j. Professor of Medicine and Oncology, Mayo Medical School, Rochester, Minnesota, 1973-1974
- k. Professor of Medicine, University of California, Irvine 1974-76

2. Administrative Responsibilities:

- a. Member of the Radioisotope Committee, D. C. General Hospital, Washington, D.C., 1954-1958
- b. Associate Editor, Journal of the National Cancer Institute, 1956-1958, National Cancer Institute, Bethesda, Maryland
- c. Director, Radioisotope Laboratory, National Cancer Institute, 1954-1958
- d. Director, Hospital for Blood Diseases, City of Hope Medical Center, 1959
- e. Director, Cancer Chemotherapy Program, University of Southern California School of Medicine, 1960-1968
- f. Director, Clinical Cancer Traineeship Program, University of Southern California School of Medicine, 1960-1968

- g. Chairman, Radioisotope Committee, University of Southern California School of Medicine, 1960-1966
- h. Director, Radioisotope Unit, University of Southern California School of Medicine, 1960-1966
- i. Chairman, Interdepartmental Cancer Research Committee, University of Southern California, 1960-1968
- j. Member, Laboratory Safety Committee, University of Southern California School of Medicine, 1961-1964
- k. Coordinator, Phase I Activities of National Program in Cancer Chemotherapy for West Coast University Hospitals, 1963-1968
- l. Chairman, Western Cooperative Cancer Chemotherapy Group, 1963-1968
- m. Member, Editorial Board, CANCER RESEARCH, 1965- present
- n. Member, Search Committee for Physiology Department Chairman, USC, 1966
- o. President, Attending Staff Association, John Wesley County Hospital, Los Angeles, California, 1964-1966
- p. Member, University of Southern California Academic Senate, 1965-1966
- q. Project Director for Cancer Hospital and Cancer Research Institute, University of Southern California Medical School, 1966-1968
- r. President, 21st Pan American Sanitary Conference, 1971
- s. Chief, U.S. Delegation to 23rd, 24th, and 25th World Health Assemblies, 1970, 1971, 1972
- t. Chief, U.S. Delegation to 19th, 20th, and 21st Pan American Health Organization Directing Council, 1970, 1971, 1972
- u. Smoking and Health Annual Reports, United States Public Health Service, 1971, 1972, 1973
- v. Surgeon General's Report on Television and Violence, United States Public Health Service, 1973
- w. Chairman, United States Government Task Force on Health Problems in Micronesia, 1973
- x. Chairman, Department of Oncology, Director, Comprehensive Cancer Center - Mayo Clinic, Rochester, Minnesota, 1973, 1974

3. Government Service:

- a. U. S. Public Health Service, 1951-1958
- b. Inactive Reserve, U. S. Public Health Service, 1958-1969
- c. Surgeon General, United States Public Health Service, Department of Health, Education and Welfare, 1969-1973

D. Society Memberships

1. Local:

- a. Los Angeles County Medical Society, 1958-1968
- b. President, Los Angeles Chapter, American Federation for Clinical Research, 1964-1965
- c. Executive Committee, USC Chapter, American Association of University Professors, 1964-1966
- d. Phi Delta Epsilon, 1945 to present

2. State:

- a. Member, Special Grants Committee, California Division, American Cancer Society, 1963-1968
- b. Chairman, Special Grants Committee, California Division, American Cancer Society, 1965-1968

3. National:

- a. American College of Physicians (Fellow)
- b. American Medical Association
- c. American Association for Cancer Research
- d. Society of Nuclear Medicine, 1955-present
- e. American Federation for Clinical Research
- f. American Society for Hematology
- g. American Association for the Advancement of Science
- h. Western Society for Clinical Research
- i. Western Pharmacology Society
- j. Sigma Xi
- k. International Society of Hematology
- l. American Society of Clinical Oncology
- m. American College of Clinical Pharmacology (Fellow)

E. Consultantships

1. Local:

- a. Consultant in Medicine, Long Beach Veterans Administration Hospital Long Beach, California, 1961-1968
- b. Member, Research and Education Committee, Long Beach Veterans Administration Hospital, Long Beach California, 1961-1966
- c. Consultant to Blood Hospital, City of Hope Medical Center, Duarte, California, 1962-1968
- d. Member, Tumor Board, Los Angeles County General Hospital, 1960-1968

2. State:

- a. California Cancer Advisory Council Member 1960-1968; Executive Committee 1965-1968; Vice President, 1966-1967

3. National:

- a. Brookhaven National Laboratory, Research Collaborator, 1961-1962
- b. Krebiozen Review Committee, National Cancer Institute, 1963
- c. National Cancer Institute: Task Force on Chronic Leukemia, 1963-1978
- d. Cancer Chemotherapy National Service Center: New Agents Committee, 1964-1968
- e. Clinical Studies Panel, National Cancer Institute, 1964-1965
- f. Member, Chemotherapy Advisory Committee, National Cancer Institute 1967-1978
- g. Numerous governmental committees with Deputy Director, National Cancer Institute, Surgeon General, U.S.
- h. Vice Chairman, Committee for National Health Insurance, 1974 -
- i. Advisory Group on Chemical Carcinogenesis, National Cancer Institute, 1973-1975
- j. Committee on Tobacco and Health, American Cancer Society, 1973-present
- k. Committee on Unproven Cancer Remedies, Minnesota Chapter, American Cancer Society, 1973
- l. Member, Cancer Center Review Committee, National Cancer Institute, 1974-
- m. Member, National Academy of Sciences Review group on Principles of Environmental Decision Making, 1974-
- n. Member, Executive Committee, Third World Conference on Smoking and Health, 1973-1975

- 5. Residencies in Medicine:
  - a. Veterans Administration Hospital  
Long Beach, California
  - b. University of California Hospital  
San Francisco, California  
"Laboratory of Experimental Oncology"
  
- 6. Fellowships:
  - a. Atomic Energy Commission: Post-doct  
Fellowship in the Medical Sciences,  
1951-1952
  
- 7. Awards and Honors:
  - a. B.S. with highest honors, University  
of Pittsburgh, 1945
  - b. President, American Society for  
Clinical Oncology, 1970
  - c. Governor, American College of Physicians  
1970-1973
  - d. The Golden Torch Award, City of Hope  
Los Angeles, California, 1971
  - e. Aliquippa Man of the Year, 1971
  - f. YMCA Focus on Fitness Award, as  
National Consultation Speaker, 1971
  - g. Honorary Fellow, Royal Society of  
Health, 1971
  - h. President elect, Association of  
Military Surgeons of the United States  
1971-1972
  - i. Honorary Doctor of Laws, Gannon College  
Erie, Pennsylvania, 1972
  - j. Special Award on Smoking and Health  
D. C. Medical Society, 1972
  - k. Distinguished Service Award, Los Angeles  
County Board of Supervisors, 1972
  - l. Special Award, Group Against Smoker  
Pollution (GASP), 1972
  - m. Honorary Award, Phi Delta Epsilon  
Medical Fraternity, 1972
  - n. Alumni Lecture Award, College of  
Dentistry Alumni Association, New York  
University, 1972
  - o. Distinguished Service Award, American  
Friends of Hebrew University, 1972
  - p. Other lectures and testimony before  
governmental bodies and academic  
societies
  
- 8. Licensure:
  - Ohio, California, District of Columbia,  
Maryland, Minnesota, Virginia
  
- 9. Board Certification:
  - Internal Medicine, 1958

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Negative Effects of Some Metabolic Analogs in Human Neoplasms  
Cancer Res., 14:315-318, May, 1954
2. Melcher, L. R., Steinfeld, J. L., Reed, R.  
Studies on I-131 Red Blood Cell Antibodies  
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3. Steinfeld, J. L., Paton, R. R., Flick, A. L., Milch, R. A., Beach, F. E.  
Distribution and Degradation of Human Serum Albumin Labeled with  
I-131 by Different Techniques  
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Clin. Sci., 16:651-661, November, 1957
5. Fahey, J. L., Steinfeld, J. L.  
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Preparations and Normal Human Serum Albumin  
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7. Flick, A. L., Steinfeld, J. L.  
The Effect of Fever and Corticotropin on the In Vivo Degradation  
of Albumin in Man as Measured with Iodinated Human Serum Albumin  
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Circulating Leukocyte Level  
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9. Steinfeld, J. L.  
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Frozen Red Cells  
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12. Steinfeld, J. L.  
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  14. Steinfeld, J. L., Davidson, J. D., Gordon, R. S., Jr., Green, F. E.  
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Am. J. Med., 29:405-415, September, 1960
  15. Steinfeld, J. L.  
I-131 Albumin Degradation in Patients with Neoplastic Diseases  
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  16. Waldmann, T. A., Steinfeld, J. L., Dutcher, T. F., Davidson, J. D., Gordon, R. S., Jr.  
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Knowles, H., Jr., Rosenow, E., Sebrell, H., Van Itallie, T.  
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the Medical Advisory Group on Cyclamates  
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The Door is Open Wide  
J. Am. Pharm. Assoc., 10:398-399, July, 1970
41. Steinfeld, J. L.  
The Workplace as a Health Care Resource  
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42. Steinfeld, J. L.  
Progress in the Federal Medical Services - United States Public  
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43. Steinfeld, J. L.  
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Cigarette Smoking is on the Increase Among Women  
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47. Steinfeld, J. L.  
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