Henry Ford Hospital
2799 West Grand Boulevard
Detroit, Michigan 48202

DIVISION OF ONCOLOGY
Robert W. Talley, M.D.
Robert M. O'Bryan, M.D.
Robert W. Brownlee, M.D.
Robert A. Huseby, M.D., Ph.D.

March 21, 1977

Food and Drug Administration
Rockville, Maryland 20857

Re: FDA Docket #77N-0048

Dear Hearing Clerk:

I am Robert W. Talley, M.D., currently Chief of the Division of Oncology of Henry Ford Hospital, Detroit, Michigan 48202. I am attaching hereto a copy of my curriculum vitae which contains details of my education, training, experience and publications. I have been asked to state my opinions on: (1) the safety and effectiveness of Laetrile, and (2) the public health significance of permitting cancer patients to receive and use Amygdalin or other unproven remedies, etc.

I would like to state at this point that the opinions I am expressing here are those of my own and do not in any way represent the opinions of the Henry Ford Hospital with which I am associated. These are my opinions as a physician involved in the oncologic management of patients with cancer.

Regarding the safety of Amygdalin, it is apparent from all I can read and from the few patients I have talked to who have taken the drug there can be no significant side effects, at least in the dosage of preparation administered. I could imagine that if large enough doses of any cyanogenic glycoside were used it could result in respiratory inhibition and possibly death, but I would think this is very much dose-related as well as related to the pharmacology of the cyanogenic material. I personally have never seen any patient who has materially benefitted from the administration of this agent. I have no knowledge of any studies being carried out with regards to the use of this agent nor any knowledge of its value in the prevention of cancer; I doubt that it does have any value.

With regard to the public health significance of permitting cancer patients to receive and use Amygdalin, I think this is a very detrimental situation, particularly under the current program where there is no control, of which I am aware, of the state of the disease or knowledge by the people administering the drug as to the importance of other methods of therapy. This, in many instances, could lead to disease and suffering which could possibly have been prevented by other programs of therapy which have definitely been proven to be effective.

From my own knowledge of patients who have received Laetrile under the program administered by Dr. Contreras in Tijuana and perhaps other places, though I am not certain just where the Laetrile was administered, I can supply the following information: the first, and perhaps the most disheartening, is the case of a 21 year old man who had testicular malignancy which was quite large and had been removed surgically but it was felt because of extensive abdominal node involvement that he should undergo radiotherapy and chemotherapy. At the advice of his mother the patient left our institution and did not appear in the office of an oncologist in another city to whom I referred him for continued care and management but did undergo Laetrile therapy. The only information I have is from our Tumor Registry followup which advised that the patient's death occurred within less than six months after the time of diagnosis. Even though patients presenting with such advanced disease as testicular cancer have a poor prognosis, approximately 10% can expect a prolonged remission and perhaps even cure of their disease with our current radiotherapy and chemotherapy. Another 30% or 40% can expect a palliation of their disease for many months or years. I think this is an example in which there was actually damage to the health of this individual when he was subjected to Laetrile therapy.

Another patient had been under our care for some time for metastatic colon carcinoma. She had received chemotherapy and had responded for a period of time, but was no longer regressing. The family then elected to take her to Tijuana against our advice where, I understand, she received therapy. Less than six weeks after her return from a therapeutic attempt with Laetrile, the patient expired with increasing liver and abdominal metastases. In such instances I have no particular comment other than that it was an expense which should have been avoided if the patient and family had heeded our advice.

Another patient with whom I am very familiar was referred to us because of recurring fibrosarcoma of the right femur. His initial treatment some ten years prior to his being seen here was that of surgical excision and radiotherapy. When it recurred several years later, the patient on his own initiative sought treatment with Laetrile. He underwent several courses of Laetrile therapy over at least a three-year period and because of slowly progressive disease was referred to our Division for specific therapy. He was found to have multiple nodules in his upper thigh at the time of his visit here with evidence of old surgical excision. He was placed on a combination chemotherapy program which we felt was most effective for sarcomas and all of his disease disappeared for about 2-1/2 years. Upon recurrence of a single nodule recently he was given radiotherapy to this local area. I cannot say that in this particular individual's case that the Laetrile altered his course as some of the drugs we had used which had a good effect on him were not available when he sought Laetrile therapy. However, it is possible that had he sought medical advice upon recurrence following his initial surgery and radiotherapy that more effective treatment, other than Laetrile, might have been introduced.

I personally have never seen a patient who had a documented malignancy which had not been treated adequately by other means respond to Laetrile therapy. I suspect many of the patients who give testimonial reports regarding this therapy have either had adequate treatment by surgery or other means before they present themselves to the various clinics who administer Laetrile.

Because of the markedly involved emotional impact of this disease and the vagaries associated with response of patients with malignancy, I would not think it would be bad science to conduct a well-controlled clinical trial of this material under rigid conditions by established investigators in the field of cancer therapy. I think that if such a program were carried out and patients utilized who could not be treated by effective means of therapy, a scientific appraisal of Laetrile would put to rest the problem. It is unfortunate that such a program would have to be done at a time when it may be unfair to ask any patient to participate in such a test. Of course these patients would participate only if they were fully aware of the fact that they were probably receiving a completely useless remedy.

I hereby verify, under penalty of perjury, that the foregoing facts are true and correct to the best of my knowledge.

(Signed): Robert W. Talley
Robert W. Talley, M.D.

RWT:dg
Enc.: Cur. Vitae

CURRICULUM VITAE

Robert W. Talley, M.D.

The Henry Ford Hospital, Detroit, Michigan

Department of Medicine -- Division of Oncology

PRESENT POSITION

Chief, Division of Oncology — 1966

BIOGRAPHIC DATA

Born - Fort Stockton, Texas — July 27, 1921

EDUCATION

Rice Institute
Degree: B.A. — 1939-1942

Baylor University School of Medicine — 1942-1944

Southwestern Medical College
Degree: M.D. — 1944-1945

INTERNSHIP

U.S. Naval Hospital
Philadelphia, Pennsylvania — 1945-1946

RESIDENCY

C & O Hospital
Huntington, West Virginia
Medical Resident — 1948-1949

University Hospital
Little Rock, Arkansas

Junior Medical Resident — 1949-1950
Senior Medical Resident — 1950-1951

CURRICULUM VITAE

Robert W. Talley, M.D.

HOSPITAL AND ACADEMIC APPOINTMENTS

Instructor, Department of Medicine University of Arkansas School of Medicine	1951-1952
Staff Physician University Hospital Little Rock, Arkansas	1951-1955
Assistant Professor, Department of Medicine Arkansas State Hospital Little Rock, Arkansas	1952-1955
Director of Research and Medical Consultant Arkansas State Hospital Little Rock, Arkansas	1952-1955
Director, Medical Outpatient Clinic University of Arkansas School of Medicine	1953-1955
Junior Consultant Veterans Administration Hospital Little Rock, Arkansas	1953-1955
Staff Physician, Medical Division, Department of Clinical Investigation (Section of Nutrition and Neoplastic Disease) The Upjohn Company Kalamazoo, Michigan	1955-1959
Associate Physician, Division of Oncology Department of Medicine The Henry Ford Hospital Detroit, Michigan	1959-1966
Chief, Division of Oncology Department of Medicine The Henry Ford Hospital Detroit, Michigan	1966-present
Research Coordinator and Chairman, Research Committee The Henry Ford Hospital Detroit, Michigan	1973
Clinical Professor of Internal Medicine University of Michigan Ann Arbor, Michigan	1973

CURRICULUM VITAE

Robert W. Talley, M.D.

BOARDS AND LICENSES

Diplomate
American Board of Internal Medicine — March, 1954

Licensed to practice medicine in

Texas
Arkansas
Michigan

MILITARY SERVICE

U.S. Navy (Flight Surgeon)
Active Duty — May, 1946-June, 1949

SOCIETIES

American Medical Association

Michigan Medical Association

Wayne County Medical Society

Fellow, American College of Physicians

American Federation for Clinical Research

American Therapeutic Society

American Association for Cancer Research

American Society of Clinical Oncology

American Society of Hematology

Detroit Physiological Society

Chairman, Committee on Cancer
Michigan State Medical Society

Detroit Cancer Club

Chairman, Adult Solid Tumor Committee
Southwest Cancer Chemotherapy Study Group (SWCCSG)

Executive Committee Member
Southwest Cancer Chemotherapy Study Group (SWCCSG)

Executive Committee Member
Cooperative Breast Cancer Group

Chairman of Committee for Protocols
Cooperative Breast Cancer Group

Executive Board Member
Detroit Institute for Cancer Research