

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

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

County of Erie)
State of New York) ss

AFFIDAVIT OF HAROLD JAMES WALLACE, JR., M.D.

Before me personally appeared Harold James Wallace, Jr., M.D., who being first duly sworn, deposes and says:

1. I am a physician, licensed to practice in the States of New York and Vermont.

2. I received a Bachelor of Arts Degree from the University of Vermont in 1954 and a Doctor of Medicine Degree, Cum Laude, from the University of Vermont College of Medicine in 1958.

3. I was Assistant Professor of Medicine and Instructor in Clinical Pharmacology at the University of Vermont College of Medicine from 1967-1970 and have been Research Assistant and Professor of Medicine at the State University of New York at Buffalo, School of Medicine, since 1971.

4. I was Senior Cancer Research Internist (1970-1972), Associate Cancer Research Internist (1972-1974), Acting Chief, Department of Medicine A (1972-1973), Associate Chief, Department of Medicine A (1974-1975), and have been Director of Cancer Control and Rehabilitation Program since 1976, all at Roswell Park Memorial Institute, Buffalo, New York.

5. From September-December 1975, I was Program Director for Oncology Treatment and from December 1975 - September 1976, Acting Chief of the Treatment, Rehabilitation, and Continuing Care Branch, Division of Cancer Control and Rehabilitation, National Cancer Institute, Bethesda, Maryland.

6. I am a member of the American Association for Cancer Research, American Association for Cancer Education, American Cancer Society, and American Society for Clinical Oncology.

7. My curriculum vitae and bibliography are attached as Exhibit 1. They provide a summary of my education, training, and experience and a list of my publications and abstracts.

8. 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. Some are well known; others are not.

9. 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 rapidly and may quickly cause death. Others grow very slowly and may be present for years before producing seriously adverse or lethal effects. The vast majority of cancers begin in a single cell or a small group of cells in a localized area of the body before metastasizing to other parts of the body. It is during this localized period in the natural history of a cancer that it is curable. Once it has spread to other parts of the body the chance for cure diminishes markedly. Cure is directly related to the stage of disease.

10. 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 are the only known methods to controlling cancer. Some forms of cancer can be cured and others controlled for many years through swift use of effective therapy. Delay can be fatal.

11. The claim that any single 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. We know how to prevent most of the lung cancers in this country and that is by eliminating cigarette smoking and a few other inhaled environmental toxins, not by taking another chemical which in itself may have some carcinogenic effects. It is well known that cyanide containing compounds are goiterogenic and the risk of developing cancer is higher in those patients having thyroid nodules than in those not having nodules. Therefore, prolonged use of a cyanogenic compound may increase the incidence of at least one form of cancer.

12. My duties now and during 1975-1976 when I was Acting Chief of the Treatment, Rehabilitation and Continuing Care Branch of the Division of Cancer Control of the National Cancer Institute required that I be, and I am, familiar with those drugs that are generally recognized as safe and effective in the prevention, treatment and management of cancer. I keep informed about the status of current research 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.

13. 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 was generally recognized as safe for any such uses on October 10, 1962. 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 qualified expert in cancer chemotherapy in any country in the world who is of the view that there is evidence these substances have any useful effect in treating cancer. 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.

14. 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 all preventions, treatments, and procedures used in the management of cancer should undergo careful scientific scrutiny and evaluation so that we can choose only those interventions which have a beneficial effect, low risk, and will conserve our health care resources. Amygdalin, in either its parenteral or oral forms, does not meet these scientific criteria. There is no evidence in either

animal models or in the large numbers of patients who have received amygdalin that it is effective in any way in preventing cancer, causing a regression or remission of cancer, or improving the life expectancy of the cancer patient. Neither has there been any evidence that it decreases the symptoms of pain, weakness or depression from cancer in any direct way. It is not analgesic or antiemetic in character. The anecdotal evidence claimed by amygdalin proponents has not been presented to me or to any scientific forum for critical review and these claims have not been substantiated by documentation in medical records available for review.

15. The safety of amygdalin in its various forms has not been tested in the usual scientific methods of clinical pharmacology and there is evidence that the crude oral form can and has caused toxicity in humans and may cause death. There has been no documentation of blood levels achieved, activation, clearance, metabolism or excretion of amygdalin compounds as is usually required in the preclinical and clinical evaluation of potential drugs for human use. It must meet these criteria of safety and efficacy by law before it can be used as an anti-cancer agent. I have no indication that it can now or even in the future meet these requirements.

16. Amygdalin and other unproven methods of cancer prevention and treatment do not conserve our health care resources in several obvious ways:

a. This compound of no proven worth costs money and time for administration.

b. It has contributed to the personal wealth of a few people at the cost of many cancer patients and their families.

c. It diverts the attention and resources of the medical and scientific community away from the very important work of finding new and better methods for preventing and treating cancer.

d. Most importantly, it delays the institution of curative treatment in some patients to the point where they are no longer curable. This fact alone more than triples the cost of treating a

cancer patient.


e. Curative treatment costs about one third as much as treatment which does not result in cure and requires additional treatment for palliation or control of the cancer.

17. One can make a case for using anything in the terminal cancer patient if it holds out any hope of making them feel better even if it does not prolong life or cause a cure. I challenge anyone to document this palliation in any patient in which the same effect could not be achieved by a simpler, less costly, method. It takes considerable experience and judgment to determine which treatments may be effective in relieving patients of various discomforts and no one agent will accomplish this. Patients take the risk of missing an extremely effective treatment for their cancer by dealing on the fringes of medicine rather than the traditional and scientific health care system.

18. As a cured cancer patient and an expert in cancer chemotherapy, I firmly believe that the recommendations of the amygdalin proponents are fraudulent and can only lead to more deaths from cancer at a time when the scientific-medical community is beginning to see real progress in our goal of preventing or curing most forms of cancer.


HAROLD JAMES WALLACE, JR., M.D.

Subscribed and sworn to before me by the said Harold James Wallace, Jr., M.D., this 22nd day of March, 1977.


Notary Public
My Commission Expires:
SANDRA M. DANNEY
Notary Public, State of New York
Qualified in Erie County
My Commission Expires March 30, 1979

CURRICULUM VITAE

NAME: Harold James Wallace, Jr., M.D.

SOCIAL SECURITY NUMBER: 009-20-1967

BORN: August 15, 1930

PLACE: South Hadley Falls, Mass.

PRESENT ADDRESS: (Home) 160 Elmwood Avenue
East Aurora, New York 14052.

(Office)

Roswell Park Memorial Institute
Cancer Control Office
Research Studies Center
Room 520
666 Elm Street
Buffalo, New York 14263

MARITAL STATUS: Married July 4, 1959

Spouse's Name: Dorothy G.

Children: Harold James III December 2, 1960
Elizabeth Marie June 28, 1963
John Hill December 4, 1965

EDUCATION: University of Vermont, B.A., 1954
University of Vermont College of Medicine, M.D. (cum laude) 1958

MEDICAL TRAINING:

7/58 - 6/59 Intern, Mary Fletcher Hospital, Burlington, Vt.
7/59 - 6/61 Medical Resident, Mary Fletcher Hospital, Burlington, Vt.
7/61 - 6/62 Trainee in Metabolism, University of Vermont College of Medicine
7/62 - 6/64 Senior Research Fellow in Medicine A, Roswell Park Memorial
Institute, Buffalo, New York

PROFESSIONAL EXPERIENCE:

9/63 - 6/64 Research Instructor in Medicine, State University of New York
at Buffalo
7/64 - 6/67 Instructor in Medicine and Clinical Pharmacology, University
of Vermont College of Medicine
7/67 - 1/70 Assistant Professor of Medicine (Full Time) and Instructor
in Clinical Pharmacology, University of Vermont College of
Medicine
7/64 - 1/70 Assistant Attending in Medicine, Medical Center Hospital of
Vermont, Burlington, Vermont

2/70 - Consulting Attending, Medical Center Hospital of Vermont,
Burlington, Vermont

2/70 - 6/72 Senior Cancer Research Internist, Roswell Park Memorial
Institute, Buffalo, New York

6/72 - 1/74 Associate Cancer Research Internist, Department of Medicine A,
Roswell Park Memorial Institute, Buffalo, New York

7/72 - 4/73 Acting Chief, Department of Medicine A, Roswell Park
Memorial Institute, Buffalo, New York

1/74 - 9/75 Associate Chief, Department of Medicine A, Roswell Park
Memorial Institute, Buffalo, New York

2/70 - 8/74 Executive Secretary, Acute Leukemia Cooperative Group B
3/71 - Research Asst. Prof. of Medicine, State University of New
York at Buffalo, School of Medicine

4/71 - 6/75 Associate Chairman, Gynecology-Oncology Group

2/70 - 9/75 Medical Oncology Training Program Director, Roswell Park
Memorial Institute, Buffalo, New York

12/74 - 9/75 Chairman, New Drug Committee, Acute Leukemia Group B
9/75 - 12/75 Program Director for Oncology Treatment, National Cancer
Institute, Division of Cancer Control and Rehabilitation

12/75 - 9/76 Acting Chief, Treatment, Rehabilitation, and Continuing
Care Branch, Division of Cancer Control and Rehabilitation,
National Cancer Institute

9/76 - Director of Cancer Control and Rehabilitation Program,
Roswell Park Memorial Institute, Buffalo, New York

9/76 - Director, Adolescent Program, Roswell Park Memorial
Institute, Buffalo, New York

LICENSURE: Vermont and New York

HONORS: Alpha Omega Alpha, 1957
Appleton-Century Croft Prize, 1956
American Cancer Society National Division Award, Vermont, 1969

SOCIETIES: Certified, American Board of Internal Medicine (1965)
Certified, American Board of Internal Medicine - Medical
Oncology (1974)
Fellow, American College of Physicians
American Society for Clinical Oncology, Chairman, Cancer
Care Standards Committee
American Association for Cancer Research
American Association for Cancer Education
~~International Association for the Study of Lung Cancer~~
~~International Society for Experimental Hematology~~
~~Society for Computer Medicine~~
American Cancer Society
Erie County Unit, Chairman, Professional Education
Committee (1972 - 1974); Service and Rehabilitation
Committee (1974 - 1975)
New York State Division, Service and Rehabilitation
Committee (Chairman), Board of Directors, Executive
Committee, Finance Committee, Uterine & Breast Cancer
Task-Force
Honorary Member, Board of Trustees, American Cancer
Society, Vermont Division

Member, Joint Cancer Education
Committee of Medical School
University of Vermont + RPAH