

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 Montgomery)
State of Maryland) ss

AFFIDAVIT OF LEROY G. KERNEY

Before me personally appeared LeRoy G. Kerney, who being first duly sworn, deposes and says:

At the present time I am the Chief of the Department of Spiritual Ministry at the Clinical Center, National Institutes of Health, Bethesda, Maryland. Attached is my curriculum vitae. The comments and opinions expressed in this statement come largely out of my experience as a Protestant chaplain ministering directly to cancer patients and their families and from my experience in serving on several clinical research review committees which evaluate the ethics and the science of medical research protocols. These opinions are not to be construed as opinions and policies of the National Institutes of Health but are to be viewed as my personal views.

I am informed that the legal status of Laetrile is being considered by the Food and Drug Administration. I am further informed that Laetrile is not recognized by medical experts as safe and effective treatment of cancer. I am further informed that the proponents of Laetrile are seeking to make Laetrile available to cancer victims throughout the country.

I would like to make four general statements that guide my ethical thinking in this matter and then state my conclusion in regard to the question of the approval or denial of approval by the Food and Drug Administration of the use of Laetrile.

First, at the heart of medical care is the element of trust. A doctor-patient relationship is a professional relationship in which the person being treated has an implicit faith or trust that the doctor is working for the patient's best interest. Furthermore, it is assumed that because the doctor is an expert and a specialist in medical care, the doctor has knowledge and information -- at least has access to such knowledge and information -- that the patient does not have nor never can have due to the lack of medical education. This stands in contrast to a commercial relationship in which the caveat -- the buyer beware -- is involved.

The importance of the element of trust is heightened when individuals are discovered to have cancer which to most persons carries with it an implicit or sometimes explicit threat of death. At these points, patients and their families often out of ignorance, desperation, or fear may seek forms of treatment that they might not otherwise seek in less threatening diseases. Too often I have seen false hopes raised or good treatment delayed because the intense anxiety of patients and their families has propelled them to seek spurious forms of therapy. Because of the potential and often real threats to life that cancer brings, society in its wisdom has entrusted to physicians a relationship in which trust is the most basic ethical ingredient. To betray this trust by using worthless drugs is a betrayal of the doctor-patient relationship.

Second, our society has established a system of regulation whereby threatened receivers can be protected from unscrupulous givers of medical care. Any system of regulation has its gaps and blind spots. But the alternative of no regulation or regulation based on opinions contraindicated

by expert scientific opinion is unthinkable. Freedom of the individual is important. But when the freedom to accept any drug for treatment and the freedom to injure oneself collide, a judgment must be made. Stop signs or restrictions on turning at certain corners restrict my freedom in driving but, at the same time, they protect my freedom from hurting myself or others in traffic.

Third, in medical care there is a "placebo effect". In the giving of experimental drugs sometimes a placebo — an inactive drug — is given to test the effectiveness of the drug being tested. A change in the patient's response to the disease may result, not from the placebo, but from other real but often unidentified factors involved. This placebo effect can also be generalized to the personal care given a patient, the setting in which treatment is given, and the availability of psychosocial and spiritual support, all of which can and do effect the course of an illness. Conceivably even a drug like Laetrile may have this effect on some patients.

As an observer of patients in a hospital, I cannot help but notice the change in a person's attitude and even the course of the disease when it is accompanied with the hopes and expectations expressed by the physician in charge. Although there are cases of "spontaneous remission" of cancer described by scientists, or "miracles" cited by faith healers, the actual numbers of these are very rare. Too many times, I have seen patients who have delayed treatment or have been treated ineffectively, inevitably subjected to the painful and anguished consequence of dashed hopes and resentment of botched and mishandled medical care. Good psychosocial and spiritual support and caring health care specialists are one thing. However, it is inexcusable to administer ineffective drugs and treatment even when these drugs and treatments are accompanied with care and concern. Such course of action will undoubtedly delay and prevent the administration of acceptable drugs and therapies. Such a consequence is abhorrent.

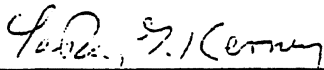
Fourth, in our society we are beginning to give patients and their families the right to refuse drugs and treatments that appear to prolong death rather than prolong life. But this is a far cry from allowing patients to receive drugs and treatments that are purported to be "cure alls" when the best scientific minds see them as ineffective at best, particularly when they cause delay in or rejection of proven drugs and treatment.

Turning to the specific question of the approval of the use of Laetrile in the treatment of cancer, my personal opinion is that it is unethical and immoral to offer what I view as an illusory form of treatment to cancer victims and their families.

Because cancer victims and their families are often desperate in looking for help to cure their disease, they are highly vulnerable to quick solutions offered by friends and by false hopes raised by advocates of what I consider to be ineffective and useless drugs. Cancer victims need protection from such resources. I consider it immoral and highly unethical to subject cancer victims and their families to the propaganda and false advertising generated by proponents of worthless drugs such as Laetrile.

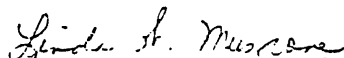
I view persons who expose the cancer patient and his family to false hopes of recovery and survival — whether the motives are misguided or financial — as engaging in a highly unethical practice.

As such I consider it to be necessary that there be public regulation of drugs in the marketplace to protect the victims of life-threatening illnesses from misguided and/or irresponsible purveyors of purported miracle drugs such as Laetrile.



LeRoy G. Kerney

Subscribed and sworn to before me by the said LeRoy G. Kerney on this 22nd day of April, 1977, in the County and State aforesaid.



Linda St. Muscare
Notary Public
My Commission Expires: My Commission Expires 10/1/78

(3/28/72)

CURRICULUM VITAE - LEROY G. KERNEY

EDUCATION:

Bachelor of Arts, cum laude, 1945 Westmar College, LeMars, Iowa
Bachelor of Divinity, 1947, The Evangelical Theological Seminary,
Naperville, Illinois
Master of Arts, 1963, Divinity School, University of Chicago, in the
field of "Religion and Personality"

ECCLESIASTICAL RELATIONSHIPS:

Ordained an Elder in the Iowa Conference of the former Evangelical
Brethren Church (now the United Methodist Church), May 8, 1948
• Member of the National Capitol Union Presbytery of the United Presbyterian
Church in the U.S.A. and the Presbyterian Church in the U.S.
Ecclesiastically endorsed as a Protestant Chaplain at the Clinical Center,
NIH, Bethesda, Maryland, by National Capitol Union Presbytery and
the Council of Churches of Washington City, June 3, 1964

PARISH EXPERIENCE:

Grew up in a parsonage of the Evangelical United Brethren Church
Assistant Minister during two years of seminary at the First Evangelical
United Brethren Church of Naperville, Illinois
Minister of the First United Brethren Church of Manhattan, Illinois,
May 1947 to May 1948
Supply Minister in the United Presbyterian Church in the U.S.A.

CLINICAL PASTORAL TRAINING:

Clinical Pastoral Training was received under the auspices of the Council
for Clinical Training, Inc. Training was received at:

Summer 1945 - Elgin State Hospital, Elgin, Illinois
Summer 1946 - Episcopal Hospital, Louisville, Kentucky
Summer 1948 - Manteno State Hospital, Manteno, Illinois
June 1948 - February 1949 - Assistant Chaplain and Supervisor-in-
training, St. Elizabeths Hospital, Washington, D.C.

TRAINING, RECOGNITION, AND EXPERIENCE AS A CHAPLAIN-SUPERVISOR:

Accredited as a Chaplain-Supervisor in 1949 by the Council for Clinical
Training, Inc.
Conducted training programs at Manteno State Hospital during 7 years for
approximately 60 students
Professor of Pastoral Care and a Supervisor at the Institute of Religion,
Texas Medical Center, Houston, Texas, February 1956 - August 1963.
The programs included work with community clergy, seminarians, and
graduate students in pastoral care.
Chaplain-Supervisor, Clinical Center, N.I.H., Bethesda, Maryland

EXPERIENCE AS A CHAPLAIN:

- St. Elizabeths Hospital, Washington, D.C., Assistant Chaplain,
June 1948 - February 1949
Manteno State Hospital, Protestant Chaplain, February 1949 - October 1955
Methodist Hospital, Houston, Texas, Guest Chaplain 1956-1963
University of Texas M. D. Anderson Hospital Research and Tumor Institute,
Houston, Texas, Guest Chaplain 1957-1961
• Clinical Center, National Institutes of Health, Bethesda, Maryland,
Chief, Department of Spiritual Ministry, September 3, 1963 to present

EXPERIENCE AS A PROFESSOR AND LECTURER:

- McCormack Theological Seminary, Chicago, Illinois, 1953-54 and 1954-55
Lecturer in Pastoral Counseling
Texas Medical Center, Institute of Religion, Houston, Texas, 1956 - 1963
Professor of Pastoral Care, Institute of Religion. Work included
teaching community clergy, seminarians, and graduate students
in the field of Pastoral Care and Counseling
Baylor School of Medicine, Lecturer in "Religion and Medicine"
Methodist School of Nursing, Lecturer in "Religious Aspects of
Nursing"
George Washington University, Washington, D.C., Lecturer in the M.A. degree
program in Religion and Medical Care in the field of "Advanced Pastoral
Care"
Professional and Community Groups, on the themes of "Pastoral Care of Cancer
Patients," "Ministering to the Dying Patient," "Religion in the Hospital,"
"Abortion," "Pain," and other related subjects

PUBLICATIONS:

- But Not to Lose, Simon and Schuster, 1969, "A New Choice: Medical Research
Hospitals"
American Hospital Association, Manual on Hospital Chaplaincy, 1970,
"Establishing and Implementing a Chaplaincy Program"
Bulletin of the A.P.H.A., 1970, "Ministering to Cancer Patients"
Bulletin of the American Protestant Hospital Association, Special Edition
on Pastoral Care, 1972, "Preface," and "The Hospital Chaplain and
the Nation's Health Care System"
Pastoral Psychology, Vol. 23, No. 223, 1972, "By the Pools of Bethesda"
Foundation of Thanatology, (to be published), "Pastoral Use of 'The Seven
Last Words' in Terminal Care"

PROFESSIONAL MEMBERSHIPS:

- Association for Clinical Pastoral Education, Inc., member and Certified
Chaplain Supervisor
College of Chaplains, American Protestant Hospital Association, member and
Certified Professional Chaplain
Association of Mental Hospital Chaplains, former member

HONORS:

College of Chaplains, American Protestant Hospital Association,
Secretary 1966, 1967
President-Elect 1970
President 1971
Past President 1972
Member of the Board of Trustees, American Protestant Hospital
Association, 1971, 1972

FAMILY SITUATION:

Present address: 11507 Parkedge Drive
Rockville, Maryland
Phone: 891-7425

Wife: Virginia Ann Kerney
Children: Suzanne, born in 1953
Sarah, born in 1957