Y 4
.H 88
L 12

1043

95Y4
H 88
L-12

BANNING OF THE DRUG LAETRILE FROM INTERSTATE COMMERCE BY FDA

GOVERNMENT
Storage
DOCUMENTS
DEC 21 1977
FARRELL LIBRARY
KANSAS STATE UNIVERSITY

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH

OF THE

COMMITTEE ON HUMAN RESOURCES UNITED STATES SENATE

NINETY-FIFTH CONGRESS

FIRST SESSION

ON

EVALUATION OF INFORMATION WHICH THE FDA BASED ITS DECISION TO BAN THE DRUG LAETRILE FROM INTERSTATE COMMERCE

JULY 12, 1977

KSU LIBRARIES
A11900 803163

Printed for the use of the Committee on Human Resources

AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

BANNING OF THE DRUG LAETRILE FROM INTERSTATE COMMERCE BY FDA

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH

OF THE

COMMITTEE ON HUMAN RESOURCES UNITED STATES SENATE

NINETY-FIFTH CONGRESS

FIRST SESSION

ON

EVALUATION OF INFORMATION WHICH THE FDA BASED ITS DECISION TO BAN THE DRUG LAETRILE FROM INTERSTATE COMMERCE

JULY 12, 1977

Printed for the use of the Committee on Human Resources

U.S. GOVERNMENT PRINTING OFFICE

96-492 O WASHINGTON : 1977

COMMITTEE ON HUMAN RESOURCES

HARRISON A. WILLIAMS, JR., New Jersey, *Chairman*

JENNINGS RANDOLPH, West Virginia
CLAIBORNE PELL, Rhode Island
EDWARD M. KENNEDY, Massachusetts
GAYLORD NELSON, Wisconsin
THOMAS F. EAGLETON, Missouri
ALAN CRANSTON, California
WILLIAM D. HATHAWAY, Maine
DONALD W. RIEGLE, JR., Michigan
JACOB K. JAVITS, New York
RICHARD S. SCHWEIKER, Pennsylvania
ROBERT T. STAFFORD, Vermont
ORRIN G. HATCH, Utah
JOHN H. CHAFEE, Rhode Island
S. I. HAYAKAWA, California

STEPHEN J. PARADISE, *General Counsel and Staff Director*
MARJORIE M. WHITTAKER, *Chief Clerk*
DON A. ZIMMERMAN, *Minority Counsel*

SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH

EDWARD M. KENNEDY, Massachusetts, *Chairman*

CLAIBORNE PELL, Rhode Island
GAYLORD NELSON, Wisconsin
WILLIAM D. HATHAWAY, Maine
HARRISON A. WILLIAMS, JR., New Jersey
(ex officio)
RICHARD S. SCHWEIKER, Pennsylvania
JACOB K. JAVITS, New York
JOHN H. CHAFEE, Rhode Island

LAWRENCE HOROWITZ, *Professional Staff Member*
DAVID WINSTON, *Minority Counsel*

CONTENTS

CHRONOLOGICAL LIST OF WITNESSES

TUESDAY, JULY 12, 1977

Kennedy, Donald, M.D., Commissioner, Food and Drug Administration, accompanied by Donald Frederickson, M.D., Director, National Institutes of Health; Guy Newell, M.D., Director, National Cancer Institute; Lewis Thomas, M.D., director, Memorial Sloan-Kettering Cancer Center; and Joseph Ross, M.D., professor of medicine, UCLA ..... Page 2

Hoffman, Herbert B., assistant U.S. attorney, San Diego, Calif.; John Keeney, Deputy Assistant Attorney General, Department of Justice; Louis Castro, deputy attorney general, State of California; Joseph Cosentino, chief medical director, board of medical examiners, State of California; and Carol Hehmeyer, assistant district attorney, San Francisco, Calif., a panel 189

Richardson, John A., M.D., Albany, Calif.; Robert Bradford president, Committee for Freedom of Choice in Cancer Therapy, Los Altos, Calif.; Ernst T. Krebs, Jr., San Francisco, Calif.; and Bruce Halstead, M.D., Loma Linda, Calif., a panel 242

STATEMENTS

American Cancer Society, Robert C. Eyerly, M.D., prepared statement 370

American Medical Association, prepared statement 328

Board of Medical Quality Assurance, Department of Consumer Affairs, State of California, Joseph P. Cosentino, M.D., chief medical consultant, prepared statement 231

Burk, Dean, president, Dean Burk Foundation, Inc., prepared statement 385

Committee for Freedom of Choice in Cancer Therapy, Inc., Robert W. Bradford, president, prepared statement 280

Ermer, Walter, D.D., executive director, International Health Council, Cleveland, Ohio, prepared statement 375

Hoffman, Herbert B., assistant U.S. attorney, San Diego, Calif.; John Keeney, Deputy Assistant Attorney General, Department of Justice; Louis Castro, deputy attorney general, State of California; Joseph Cosentino, chief medical director, board of medical examiners, State of California; and Carol Hehmeye, assistant district attorney, San Francisco, Calif., a panel 189

Prepared statement 231

International Health Council, Cleveland, Ohio, Walter Ermer, D.D., executive director, prepared statement 378

Kennedy, Donald, M.D., Commissioner, Food and Drug Administration, accompanied by Donald Fredrickson, M.D., Director, National Institutes of Health; Guy Newell, M.D., Director, National Cancer Institute; Lewis Thomas, M.D., director, Memorial Sloan-Kettering Cancer Center; and Joseph Ross, M.D., professor of medicine, UCLA 2

Prepared statement 26

Memorial Sloan-Kettering Cancer Center, Lewis Thomas, M.D., president, prepared statement 56

National Cancer Institute, Guy R. Newell, M.D., Acting Director, prepared statement 46

National Council on Drugs, John A. Owen, Jr., M.D., prepared statement 334

National Institutes of Health, Donald S. Fredrickson, M.D., Director, prepared statement 40

ADDITIONAL INFORMATION

Richardson, John A., M.D., Albany, Calif.; Robert Bradford president, Committee for Freedom of Choice in Cancer Therapy, Los Altos, Calif.; Ernst T. Krebs, Jr., San Francisco, Calif.; and Bruce Halstead, M.D., Loma Linda, Calif., a panel ..... Page 242

Prepared statement 275

UCLA School of Medicine, Joseph F. Ross, M.D., professor of medicine, prepared statement (with attachments) 62

Articles, publications, etc.:

Adverse Effects of Laetrile Therapy in Patients with Cancer Who Were Observed at the UCLA Hospital 141

An Objective Refutation of David M. Greenberg, Ph.D. and his article entitled, "The Vitamin Fraud in Cancer Quackery" by John A. Richardson, M.D., from the Western Medical Journal, April 1975 312

Articles, publications, etc.—Continued
Anti-Tumor Effects of Amygdalin in Walker 256 Carcinoma 420
Before the Board of Medical Quality Assurance, Division of Medical Quality for the State of California, in the Matter of the Accusation against John A. Richardson, M.D., respondent, October 28, 1976 199
Brief on Foods, Vitamins, and Vitamin B–17 (Amygdalin, Nitriloside, Laetrile), by Dean Burk, president, Dean Burk Foundation, Inc 391
Chronic Cassava Toxicity, by Barry Nestel and Reginald MacIntyre, from Arch. Neurol., vol. 21, November 1969 116
Clinical Ineffectiveness of Laetrile: Abuses of Objective Response or of Extension of Life Span in Fifteen Patients, by Wallace I. Sampson, M.D., and Lawrence A. Williams, M.D 179
Cyanide Poisoning From the Ingestion of Apricot Kernels, Weekly Report from the Bureau of Communicable Disease Control, State Department of Public Health:
September 1, 1972, No. 34 109
November 14, 1975, No. 45 110
December 26, 1975, No. 51 111
Evaluation of case reports submitted to the California State Department of Health by the McNaughton Foundation as Evidence of the Efficacy of Laetrile in the Treatment of Cancer 144
Fatal Cyanide Poisoning Following Acidental Ingestion of Amygdalin (Laetrile) 104
Hazards to Health—Cyanide Poisoning From Apricot Seeds Among Children in Central Turkey, from the New England Medical Journal, vol. 270, No. 21 107
Laetrile Toxicity: A report of two cases, by Frederick P. Smith, M.D.; Thomas P. Butler, M.D.; Stanley Cohen, M.D.; and Philip S. Schein, M.D., division of medicine and department of neurology, Georgetown University School of Medicine, Washington, D.C 338
Little Cyanide Cook Book—Delicious Recipes Rich in Vitamin B17, by June de Spain 113
Open Letter to the Pennsylvania House of Representatives, from Thomas H. Mansell, chairman, Committee for Freedom of Choice in Cancer Therapy 377
Reports of Human Poisonings From Laetrile and From Cyanogenic Fruit Kernels 101
Some Qualifications of Dr. Kanematsu Sugiura, article 414
Title 21—Foods and Drugs 412
Treatment of Cancer with "Laetriles," a report by the Cancer Commission of the California Medical Association 172
Communications to:
Burk, Dean, president, Dean Burk Foundation, Inc., from Dr. Kanematsu Sugiura, April 13, 1975 414
DeVitta, Vincent, M.D., Director, Division of Cancer Treatment, National Cancer Institute, Bethesda, Md., from Robert W. Bradford, president, Committee for Freedom of Choice in Cancer Therapy, Inc., Los Altos, Calif., July 7, 1977 267
Henderson, Kathleen M., staff person, Subcommittee on Health and Scientific Research, U.S. Senate, from Joseph P. Cosentino, M.D., medical consultant, Board of Medical Quality Assurance, Department of Consumer Affairs, State of California, July 14, 1977 (with enclosure) 347
Kennedy, Hon. Edward M., a U.S. Senator from the State of Massachusetts, from:
Page
Burk, Dean, president, Dean Burk Foundation, Inc., Washington, D.C., November 16, 1977 384
Ermer, Walter, D. D., executive director, International Health Council, Cleveland Ohio, October 3, 1977, and July 17, 1977 ..... 381, 383
Eyerly, Robert C., M.D., chairman, Committee on Unproven Methods of Cancer Management, American Cancer Society, Inc., New York, N.Y., July 11, 1977 369
Owen, John A., Jr., M.D., National Council on Drugs, Chicago, Ill., July 8, 1977 333
Sammons, James H., M.D., executive vice president, American Medical Association, Chicago, Ill., July 8, 1977 327
Stout, Gregory, attorney, from Dean Burk, president, Dean Burk Foundation, Inc., February 16, 1977 413

BANNING OF THE DRUG LAETRILE FROM INTERSTATE COMMERCE BY FDA

TUESDAY, JULY 12, 1977

U.S. SENATE,
SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH
OF THE COMMITTEE ON HUMAN RESOURCES,
Washington, D.C.

The subcommittee met, pursuant to notice, at 9:13 a.m., in room 4232, Dirksen Senate Office Building, Senator Edward M. Kennedy (chairman of the subcommittee) presiding.

Present: Senators Kennedy, Nelson, Schweiker, Chafee, and Hayakawa.

Senator KENNEDY. We will come to order.

There is no disease that the American people fear more than cancer. The very word terrifies many, and conjures up images of pain, suffering and terminal illness. Families fear it when it strikes a loved one because, in some cases, there is so little one can do. There is a feeling of hopelessness and helplessness and, of course, a feeling of guilt.

I know these feelings first hand. I remember how I felt when the diagnosis was made on my son. What I remember about those first terrible days was the sense of outrage and of injustice that it had happened to him. I remember the search for the cure—the answer that would save my son's life. I wanted to know every possibility. I wanted to see if there was a special treatment hidden somewhere in the vast array of medical resources available in the country.

I know how very vulnerable people are in the circumstances—how willing they are to grasp at any straw—to try any approach—to effect a cure.

This is the time when people need the best information they can get; when they need to be able to understand realistic alternatives. It is not a time when people are capable of sifting fact from fancy themselves.

The emotions of the moment make a fully rational choice difficult enough and could tip the balance toward "quick-fix" panaceas if they were presented as comparable alternatives to proven therapy.

The role of the Food and Drug Administration in this tragic moment is to guarantee that the available drug therapies are the best and most effective that science can devise. Their role is to protect both the patient and his family from remedies that are neither safe nor effective. The elimination of useless treatments is a valid Federal role. It is a humanitarian role. It reduces the burden on cancer patients and their families and allows them to exercise their freedom of choice on the basis of informed judgments among viable alternatives.

These issues are brought into dramatic focus by the subject of today's hearing—Laetrile. Is it a useful addition to the armamentarium against cancer or is it a useless compound which has gained some acceptance because of the vulnerability of the people who decide to use it?

We all have a high stake in the answers, and today's hearing is designed to provide them.

Senator Schweiker.

Senator SCHWEIKER. I do not have any statement.

Senator KENNEDY. We have 3 hours and 15 minutes for this hearing, and we are going to try, in order to be fair in terms of the hearing, to give each panel an hour and 5 minutes. I will mention when we are getting close after an hour to try to see if we cannot conclude.

Also this morning, because of the nature of the hearing and the statements that will be made and the importance of it, we are going to swear all of the witnesses, all of the governmental witnesses, the researchers, and all the panelists, so that all the testimony will be sworn testimony.

I will ask our first panel if they would rise.

Do you swear that the testimony you will give is the truth, the whole truth and nothing but the truth, so help you, God?

[Drs. Kennedy, Fredrickson, Newell, Thomas and Ross answered in the affirmative.]

Senator KENNEDY. We will start with our first panel this morning consisting of Dr. Donald Kennedy, Commissioner of the Food and Drug Administration.

With him is Dr. Donald Fredrickson, Director, National Institutes of Health; Dr. Guy Newell, Director, National Cancer Institute; Dr. Lewis Thomas, Director, Memorial Sloan-Kettering Cancer Institute; and Dr. Joseph Ross, Professor of Medicine, UCLA.

I will start with Dr. Kennedy.

STATEMENT OF DONALD KENNEDY, M.D., COMMISSIONER, FOOD AND DRUG ADMINISTRATION, ACCOMPANIED BY DONALD FREDRICKSON, M.D., DIRECTOR, NATIONAL INSTITUTES OF HEALTH; GUY NEWELL, M.D., DIRECTOR, NATIONAL CANCER INSTITUTE; LEWIS THOMAS, M.D. DIRECTOR, MEMORIAL SLOAN-KETTERING CANCER CENTER; AND JOSEPH ROSS, M.D., PROFESSOR OF MEDICINE, UCLA

Dr. KENNEDY. Mr. Chairman, I would like to begin with a very short statement.

I know that there are people who believe in their hearts that Laetrile will cure them, and I have deep sympathy for these people. But there are 198 million people whose health and safety depend on some measure on the integrity of the FDA. The Commissioner of Food and Drugs has neither the moral nor the legal right to disregard the laws of Congress and the evidence of science. We cannot and will not permit the introduction of Laetrile into interstate commerce.

Mr. Chairman, that statement was actually made by then FDA Commissioner James Goddard 12 years ago, and in reading it to you, I have only substituted the name "Laetrile" for the name "Krebiozen," the cancer fraud of that time.

Before Krebiozen was proven worthless by FDA, it gave false hopes to thousands of American cancer victims and milked them of millions of dollars.

Before that, Dr. Hoxsey's medicine, the Koch treatment, and even something called Dr. Johnson's mild cancer cure, did the same. It is important to view the Laetrile question in this historical perspective because in its pattern of promotion, in its reliance on people's frustration with the medical establishment and its use of testimonials, Laetrile is retracing precisely the course of these earlier remedies.

Mr. Chairman, FDA has been asked to provide a district court in Oklahoma with an administrative record on which that court can review the basis for FDA's contention that Laetrile is a new drug under the Food, Drug, and Cosmetics Act, thus requiring premarket approval by the agency before it can be lawfully distributed.

In compiling that record, FDA has received written submissions from proponents of Laetrile and from the scientific and medical community. In addition, we held 2 days of public hearings in Kansas City on May 2, and 3, 1977.

We have now prepared our analysis of that record, and it will be published in the Federal Register later this month and delivered to the court in Oklahoma City.

I now want to summarize for the subcommittee members a central finding from this extensive record. They indicate beyond serious question, first, that Laetrile is not generally recognized by qualified experts as a safe and effective cancer drug and, second, that Laetrile is not exempt from the premarket approval requirements for new drugs by virtue of the grandfather provisions of the Food, Drug, and Cosmetics Act.

To the contrary, all the evidence shows that both now and in the past, Laetrile has been regarded by the overwhelming majority of qualified experts as being of unproven safety and of no effectiveness whatever.

The evidence regarding efficacy brought to us by the proponents consists entirely of hearsay arguments in patient's testimonials.

The subcommittee is familiar with the long experience we have had with such testimonials. Time after time, persons or corporations wishing to introduce new drugs onto the market have tried to persuade us that general clinical experience or the subjective judgment of physicians, or the conviction of patients should substitute for controlled experiments in the approval process.

Time after time, my agency has insisted on the scientific data that results from controlled experiments. Time after time, the courts have upheld that position by confirming that the intent of the Congress in 1962 drug efficacy amendments was to insist that proof of efficacy requires more than personal belief. I know you share my view that Congress was wise to insist.

It is not uncommon for the course of cancer or of other diseases to fluctuate. Patients experience complete remission for causes that are unknown. Almost 20 percent of all patients with breast cancer will survive for 5 years without any treatment.

Senator KENNEDY. If they had taken Laetrile, I suppose they would attribute the cure to that?

Dr. KENNEDY. I think that is often the case, Mr. Chairman.

Many patients also are receiving several different therapies at the same time, under which conditions both patient and physician may be under serious temptation to believe that a cure which may only be a remission is attributable to a particular therapy. That is why we insist on control trials. That is why we cannot use testimonials, no matter how poignant they are and no matter how deeply we may sympathize with those who provide them.

We did not find any evidence that Laetrile is exempt from premarket approval requirements for new drugs by virtue of being grandfathered. No evidence was presented to us that experts in 1962 recognized Laetrile to be safe and effective in the treatment and management of cancer. None of the experts who submitted testimony knows of scientific reports on which such recognition could have been predicated, or knows of medical textbooks or medical schools where the use of substances are recommended or taught, or knows of medical experts who were then or are now of the view that Laetrile has any useful effect in treating cancer.

I think the most important outcome of our analysis of this lengthy administrative record is one that emerges entirely from the assertions of Laetrile's proponents. It is simply this: Those who wish us to legalize Laetrile cannot give us a consistent picture of what it is or what it does. It is either Amygdalin or a substance called laevo-mandelonitrile betaglucuronoside, from which Laetrile was originally named, or it is a mixture of these and other compounds, or it is these plus some enzymes depending on who and when you ask.

Senator KENNEDY. I think that is important. You mean it is a variety of different compounds and substances?

Dr. KENNEDY. Yes. It is an extraction procedure, Mr. Chairman, that, as far as we can tell, is subject to a great deal of variation from place to place. Its identity has been claimed in very different terms by proponents at different times in its history, and it is now not easy for us to dredge out of our administrative records a consistent pattern of agreement as to its identity.

Senator KENNEDY. You mean people in different parts of the country are taking different compounds?

Dr. KENNEDY. That is very clear from the examinations using chemical and analytical techniques.

Senator KENNEDY. And all the names are under the general name of Laetrile?

Dr. KENNEDY. Not entirely, Mr. Chairman.

Some are called Laetrile with a capital L, and some are called laetrile with a small l.

The most common designation now is Laetrile, but under that name different compounds that we have seized and analyzed have different chemical compositions.

Senator KENNEDY. It is spelled the same, is that correct?

Dr. KENNEDY. Yes; it is spelled the same.

Senator KENNEDY. But it can be different in terms of substance and makeup of the substance, is that correct?

Dr. KENNEDY. That is correct.

Senator KENNEDY. While we are on this point, is there any scientific information that has been submitted to you that you know about that indicates the efficacy of any of these compounds that you have just mentioned here that go under the name of Laetrile?

Have you got any scientific information on the effectiveness of any?

Dr. KENNEDY. We have not tested them all ourselves, or indeed have not tested any of them ourselves, Mr. Chairman. We have subjected them to chemical analysis which allows us to say that they are often different, one from another.

The tests that have been performed on animals by the National Cancer Institute, by Dr. Thomas' Memorial Sloan-Kettering Institute, and by others, have shown that it is without effect on animal tumors. It has not been subjected to anything that one would call a scientific test in human beings.

I might just mention, Mr. Chairman, that, also depending on who you talk to, it is either a drug or a vitamin.

In the latter case, it would be unique, because I know of no deficiency disease nor does anyone else that is associated with it. It is either to be taken by injection or orally, depending on who you talk to. And if it is taken orally, we have very serious doubts about its safety, and you will hear more from other members of the panel on that subject later.

Senator KENNEDY. I think that is an important point because there are those who say that perhaps Laetrile does not have the effectiveness in terms of curing, but since it is safe, why not let people take it?

Your testimony is that you have reason to believe that Laetrile, taken orally, may not be safe?

Dr. KENNEDY. I think there are very good reasons for believing that, Senator.

In summary then, there is a substance that has no fixed identity in the literature of its own components. It also has no fixed identity in the hands of our analytical chemists who find the amount of Amygdalin and the ratio of its isomeric forms varies widely in the samples of the material we had seized.

I do not know of any honest therapy that lacks an identity to this degree.

Indeed, in sifting the strange mixture of nomenclature, alleged chemical identity, and proposed mechanism of action that comprises Laetrile's record over the past 25 years, one becomes gradually convinced that these uncertainties are not entirely accidental.

Senator KENNEDY. Are you suggesting intentional deceit?

Dr. KENNEDY. I think the fact that Laetrile is such a moving target, makes it extraordinarily effective as a cover for the promoters, because failure to achieve a result can always be attributed to having used the wrong material. Arguments against one hypothesis of action can always be met by taking refuge in another.

As you will hear later this morning, there is a substantial incentive to cover one's tracks well in such a business because Laetrile pays and pays well.

Mr. Chairman, I would like to conclude my testimony with a few words about the freedom of choice argument.

I think the importance of that freedom was underscored in 1962 by President Kennedy in his consumer message of that year, and it is important to remember that in his list of four basic consumer rights, the right to choose directly followed another right, the right to be informed. President Kennedy knew, and we should all be reminded, that the only free choices are informed ones.

To say that the Laetrile promoters are offering cancer patients free choices is to debase the concept of freedom beyond all recognition.

Mr. Chairman, if I sound a little angry, it is because I am. I hope, however, that I am not seen as unsympathetic, because, in fact, my anger derives from the sympathy I feel for those cancer patients who turn to Laetrile. They are being victimized twice—once by their disease and once by the profiteers.

The conviction of cancer patients who believe firmly that they are being helped by Laetrile is real. They present powerful and moving appeals. One can understand why they do. Cancer, the disease Americans fear more than they fear war, has for decades resisted the best efforts of science to provide a cure.

We now think we know why. It is not a single disease, but a whole set of diseases, many of them are a complex of largely environmental origin. Cancer possibly does not have a single cure. Yet a single cure is exactly what the afflicted person hopes for most desperately.

The convincing salesperson who offers one for a price is likely to make a sale, not only with the patient but with the family and loved ones.

When I hear testimonials from such patients, it is hard for me to avoid anger at their exploiters, and I think it is a deplorable suggestion that this Government should, on the falsified issue of freedom of choice, stand aside and allow vulnerable people to be treated by therapy that is unproven in merit, false in its promise, and even uncertain in its identity.

Senator KENNEDY. If I understand the sense of your testimony, it is that Laetrile cannot be generally recognized as safe, and certainly not effective in treating cancer. The Laetrile promoters stand to make a lot of money by taking advantage of the fears and hopes and feelings of helplessness of cancer victims and their families, and that in many cases they prevent these victims from seeking legitimate therapy.

Would you say that is a fair summary of your position?

Dr. KENNEDY. Yes; Mr. Chairman.

I provided a more extended set of views for the record to you. The statement I read is necessarily brief. I would emphasize that no evidence was presented to us that suggests that it be regarded as a grandfathered drug. It is a new drug under the definition of the Federal Food, Drug, and Cosmetics Act. No evidence has been offered as to its efficiency. It has never been generally recognized as safe.

Indeed, the shifting view now says miraculously it is a vitamin is dangerous and troublesome because vitamins are characteristically taken orally. Taken orally, most of the stuff that is offered for sale as Laetrile is dangerous.

Senator KENNEDY. Why do you not do a test and resolve this issue once and for all?

Dr. KENNEDY. Well, Mr. Chairman, I think my colleagues on the panel will probably be responding to that.

I would only say that from my personal perspective that clinical tests on the efficacy of Laetrile would have to be done in such a way that the material was of proven authenticity and analyzed prior to the test. And then, of course, a whole set of ethical problems involving access of human subjects to other modes of therapy would have to be solved.

I am not suggesting these are impossible.

Dr. Fredrickson, Dr. Newell and Dr. Thomas know more than I about those kinds of problems.

I would, I think, concentrate—in communicating my own concerns to you—on the question of identity, because I think I can predict if this is done with one kind of Laetrile, and if, as we all expect, it would fail in an experiment to demonstrate its efficacy, then there would be quick resort to the explanation that, well, we did not have the best kind of material to work with.

Senator KENNEDY. Dr. Fredrickson.

Dr. FREDRICKSON. Mr. Chairman, as has already been made clear this morning, the problem of Laetrile that we are discussing today has several very important dimensions. In the public policy area, the principle that drugs must be efficacious as well as safe in order to be approved by the FDA is at stake.

The issue simply put is: Are useless nostrums to be substituted for treatments shown to be safe and useful by scientific methods?

We are dicussing today, therefore, a problem far greater than cancer or any other disease.

I am aware, Mr. Chairman, of the limits of the scientific method. It often cannot provide the comfort sought by those beyond the help of its restricted power. I sympathize with the frustration and grief which have led so many cancer patients and their families to try Laetrile and do not ignore the emotional dimension of this problem.

It is my purpose, however, to discuss certain of the ethical and moral problems surrounding the application of the scientific method to the clinical testing of drugs for efficacy against cancer—another important dimension of the Laetrile problem. Specifically, I would like to limit my remarks to the moral and ethical issues that have arisen from the National Cancer Institute's decision to consider conducting a clinical trial of Laetrile—a trial that by definition would involve human beings. My statement will be brief. Dr. Guy Newell, Acting Director of the National Cancer Institute, will provide details, which expand on my summary.

The present food and drug law requires that drugs be proved safe and effective before they can be marketed. This proof of safety and effectiveness must be demonstrated by precise and thorough testing.

The precedent which underlines the implementation of this law has been that a drug shall not be tested in man without a reasonable scientific basis for assuming that it might be efficacious in man. Usually this has meant that it has been necessary to develop proof that the drug had antitumor activity in animals.

As you know, Laetrile, in one or another formulation, has been known for more than 25 years. Over this extended period of time, no scientifically acceptable evidence has been presented of Laetrile's effectiveness against cancer, in either animals or man, for either prevention or cure. In his statement, Dr. Newell will amplify this point.

Let me now discuss what I consider to be the critical issue from the perspective of the scientific community, the possibility that a clinical trial of Laetrile be mounted by the National Cancer Institute using public funds. This is a critical issue because, based on past experiences there is no valid scientific reason to put Laetrile into a clinical trial.

Faced with this, the first question is, should public demand or legis-

lation by individual States force us to break a precedent which, we believe, has served society and the public well?

It is estimated that more than 50,000 individuals in this country are receiving Laetrile, some undoubtedly in lieu of other treatment known to be beneficial or curative.

Do mere numbers of people, unaccompanied by a shred of necessary scientific proof that they have been, or can be, helped by Laetrile, override those precedents that have served so well?

What would be overriden is the reasonable basis that has been constructed to protect those patients who would be recruited to a clinical trial. Central to this reasonable basis is the good faith on the part of the physician and the patient both that the drug or technique to be studied has a chance—some chance—of helping the patient.

Simply stated, clinical trials have been based on the principle that drugs are tried in patients only when there is scientific evidence to believe they might help those patients. Have we ever the right to deprive a patient of a potentially useful drug and provide, instead, a compound for which there is no reasonable probability of usefulness?

In any clinical trial of Laetrile, two key conditions must be met, I believe. First, no patient can be deprived of any proven therapy that might help that patient.

Any individual entered into such a trial must be clearly beyond any beneficial therapy known to be effective against cancer, including surgery, radiotherapy, and chemotherapy.

The second condition to be met is the principle of informed consent. Each patient must have a meticulous explanation of what is known and not known about the compounds being tested, and must have full understanding of the choices available to him when consent is given.

Trials of anticancer drugs in man present trying ethical dilemmas at best and Laetrile, backed as it is by no scientific evidence of efficacy, compounds these dilemmas.

In considering what should be its next step, the National Cancer Institute has discussed several possible courses of action.

One option is to do no clinical trial of Laetrile, and thereby maintain that important precedent we have been discussing. The dimensions of the Laetrile problem are such that this is not a comfortable position for us.

A second option is to defer a decision on a clinical trial, and for the NCI to offer its services, in collaboration with the Food and Drug Administration, in the collection and review of clinical evidence of a kind necessary to support the effectiveness of Laetrile as an anticancer agent. If the use of Laetrile continues in a number of States, it is at least possible that evidence meeting scientific standards could be developed by responsible physicians who are prescribing Laetrile for certain of their cancer patients. Such evidence could support the conduct of further more structured trials. This, too, will be a very difficult course of action, but we need not consider it impossible.

The third option is that NCI begin a clinical trial without undue delay. In preparation for such a trial, it must thoroughly discuss and lay out those ethical issues alluded to above, as well as the considerable technical problems that would attend such a trial.

The expenditure of public money on members of the public requires no less. The probability of a clinical trial of Laetrile providing an

unequivocal result seems to be small. The possibility is considerable that even an unequivocal negative result would still not convince some proponents of this substance.

We will very shortly come to a decision about which of these options to adopt.

Mr. Chairman, that completes my statement. You may wish to proceed to Dr. Newell's statement now or, if you prefer, I would be happy to answer questions.

Senator KENNEDY. I think it would be wise to go on to Dr. Newell.

Dr. NEWELL. Thank you, Mr. Chairman.

The substance Laetrile, derived from apricot pits, has been exhaustively tested in laboratory animals, both by the National Cancer Institute and other prestigious institutions of this country.

The results of these tests conclusively show that Laetrile has no significant anticancer activity. Based on these tests, we feel that Laetrile is unlikely to be active against cancer in man.

In spite of this, as you have heard, we estimate approximately 50,000 cancer patients in the United States are taking this drug each year, at great cost to themselves and their families.

The Food and Drug Administration bans Laetrile from interstate commerce because it has not been shown to be effective for the treatment of cancer. Yet, 11 States have enacted legislation recently to legalize the use of the substance within those States. Without doubt, these new State laws will increase use of Laetrile.

The average citizen in this country does not have the resources and technical skills necessary to select, develop, and test materials for the treatment of disease. Neither does he have the background that will enable him to make enlightened decisions concerning the selection and use of therapeutic agents. The selection, development, testing, evaluation, marketing, prescribing, and administration of materials for disease treatment is an area in which large institutions and skilled professionals are uniquely qualified to take the measures necessary to protect the interests of the public.

Accordingly, society has established and endorsed rigorous procedures through which new drugs are tested and certified for use in clinical medicine. After many years of experience, a number of animal tumor systems have been found useful in predicting the activity of new drugs in cancer patients.

Mr. Chairman, I would like to describe for the committee the development and use of the procedures employed by the National Cancer Institute for evaluating compounds for anticancer activity.

Although our experience in this area dates back to 1937, it was not until the birth of modern chemotherapy in the post-World War II era that great interest was generated in screening new compounds for anticancer activity. Screening is the process by which a large number of materials are evaluated in an experimental test system to quickly eliminate the vast majority of inactive compounds and identify the few materials having the greatest potential for clinical activity.

Between 1955 and 1976, more than 275,000 synthetic compounds and 200,000 natural product extracts have been evaluated for anticancer activity by NCI at a cost of about $400 million. Today, NCI's drug research and development program tests potential anticancer drugs in a system that consists of seven well-defined steps.

1. Acquiring materials for evaluation.—About 15,000 synthetic compounds and 250 purified natural products are selected each year.

2. Screening.—NCI's prescreen, using mice with a transplanted leukemia, has demonstrated sensitivity to most classes of clinically effective anticancer drugs, and is sufficiently discriminating to avoid overloading the testing system with inactive compounds. Before a compound is tested beyond the prescreen, a 20-percent increase in the lifespan of treated mice over untreated controls must be shown. If this criterion is met, the prescreen is repeated and confirmed, preferably in another laboratory. The prescreen may be bypassed if a compound has particular properties or if it has shown activitiy in another screen or assay.

Compounds active in the prescreen are next tested against a number of different types of tumors. Criteria for activity here is either increase in survival or inhibition of tumor growth in the test animals.

3. Detailed drug evaluation.—The timing and route of administration of the drug—either oral or intravenous—is determined in animals. Studies are also carried out to determine the feasibility of producing large quantities of drugs and formulating it for clinical trial.

4. Toxicology in large animals.—The highest nontoxic dose is determined in dogs and monkeys. The major organ toxicity in both species is noted, as well as the ability to predict toxicity.

Following passage of this stage, an investigational new drug, IND, application is filed with FDA. Data showing the compound to be both safe and effective against cancer in animals are presented. Approval of the IND marks the beginning of studies with cancer patients.

5. Phase I clinical trials.—The maximum tolerated dose is established in advanced cancer patients who have not responded to conventional therapies, and the predictability of the major organ toxicity is noted. Antitumor activity is not required at this stage but is recorded if it occurs.

6. Phase II clinical trials.—The drug is evaluated for anticancer activity in patients with measurable disease in each of 10 forms of cancer. An objective response must be clearly established in a group of 15 to 30 patients with any one of the tumors.

At the completion of phase II studies, a judgment is made regarding the degree of efficacy of the compound and the nature of its adverse effects. If the risk-benefit ratio is acceptable, the compound goes into large-scale clinical studies with cancer patients.

7. Phase III and phase IV clinical trials.—Phase III trials evaluate in detail the activity of the compound against the one or more cancers in which it had shown activity and, in particular, compare it with the established drugs of choice. Phase IV trials evaluate the use of the drug in combination with other active forms of therapy—surgery and radiation therapy.

These studies provide definitive answers on the value of a given drug or combined modality therapy, and based on the accumulated data, a new drug application is filed with FDA.

Mr. Chairman, only 1 drug out of every 5,000 screened goes as far as clinical trials, and only 1 of every 50,000 is eventually marketed.

I would like now to summarize for you the results of a series of animal tests we have conducted of Laetrile. It should be noted that

of all the compounds that have been submitted to NCI's drug research and development program, Laetrile is the most tested inactive substance.

Laetrile is variously described as a form of Amygdalin, as a nitriloside, or as vitamin B–17. Supporters of the compound have used the names Laetrile and Amygdalin synonymously. The compound actually used in all tests at NCI and elsewhere has been Amygdalin. Amygdalin occurs in the seeds of many plants. It is not necessary for the normal functioning of the body; therefore, it is not regarded as a true vitamin.

The National Cancer Institute has tested Laetrile in rodents with transplanted tumors in the same systems routinely used to screen compounds for anticancer activity. Six different samples of Laetrile have been tested, beginning in 1957, and continuing as new animal tumor systems have become available. All tests have failed to demonstrate that Laetrile has any anticancer activity and provide no basis for predicting that Laetrile might act against cancer in humans.

It should be noted that all of the drugs of demonstrable benefit in various forms of human cancer have displayed activity against one or more animal tumors.

Mr. Chairman, if you wish, I will submit for the record a more detailed account of all NCI tests of Laetrile.

As I have indicated earlier, the final definitive evaluation of the effectiveness of a cancer drug can be determined only in carefully conducted clinical trials. Because of the animal test results, Laetrile never reached this stage of NCI testing. In addition, the many patients treated legally with Laetrile in other countries and illegally in this country have not been studied in a fashion that permits any objective conclusions to be made concerning either antitumor effect or toxicity.

The claims of clinical effectiveness made by Laetrile proponents have been based on incomplete case histories or anecdotal and testimonial reports which cannot be evaluated objectively.

The current promotion of Laetrile flies largely under the flag of "freedom of choice" in cancer treatment. Yet the choice presented to the often frightened, confused, and anxious patient is specious and serves actually to narrow the real choices.

Laetrile proponents tell patients they can either accept Laetrile, which they call a "harmless, natural, effective" remedy—even though Laetrile is known to be poisonous if taken incorrectly by mouth—or submit to surgery, X-ray, and chemotherapy, which they characterize as "cutting, burning, and poisoning." In these terms, it is not difficult to appreciate the appeal of Laetrile to cancer patients.

In truth, the proven cancer treatments—surgery, radiotherapy, and chemotherapy—are often attended by unpleasant side effects, but they do indeed cure. The side effects are manageable, however, and nearly always of brief duration. All of the advances made in cancer treatment—abundantly documented in the medical literature—are due to the use of these treatment methods.

The cancer patient should have freedom of choice to seek out the best qualified physician or physicians and to obtain more than one opinion. He should and does have the freedom to demand information about his problems and the solutions proposed. This will constitute the basis for informed consent. I do not believe that cancer patients are

afraid to make tough choices, if they have an honest appraisal of what those choices mean for them.

At the National Cancer Institute, we have been gravely concerned that so many cancer patients in this country have chosen to use this unproven remedy for cancer. We are concerned that the number of patients who do so will increase as more and more States legalize the substance. Many of these patients have used and will use Laetrile as a substitute for known medical treatments that might cure their cancers or prolong their lives. Because of this situation, medical experts at NCI and elsewhere have reluctantly concluded that a clinical trial of Laetrile should be considered. The results of such a trial, if negative as we expect they would be, would not convince the most avid proponents of Laetrile, but would be of value to State legislators and to physicians who care for cancer patients.

The ethical, moral, and legal implications of testing in humans a compound proved to be of no value in animals has made even consideration of a clinical trial of this compound controversial. Dr. Fredrickson has discussed these implications in detail in his testimony.

As we have considered a trial of Laetrile in humans, many alternative approaches have been discussed. These range from the view that we should do nothing beyond the animal tests already conducted to the view that a clinical trial be conducted immediately.

Another alternative is to oversee, but not finance, independent trials conducted by major cancer centers.

So far, our thinking leads us to favor a fourth option. This would lead us to establish a group of experts who would assess the ethical issues and feasibility of mounting a clinical trial by the National Center Institute. This group would grapple with the ethical issue of conducting a clinical trial of a compound that does not meet current scientific standards of acceptability.

The cost of taking this approach should be relatively low, and it should not take an inordinate amount of time. In addition, the issues to be examined are worthy of scrutiny by the research and medical community, as well as by the public, even if there ultimately is a decision not to go ahead with a clinical trial.

If the group's deliberations result in recommendation of a clinical trial, such a trial could be undertaken with FDA approval. As support for the deliberations of this group, we could also attempt to acquire and analyze clinical data from reputable physicians who will use Laetrile in therapy because their States have legalized it.

Mr. Chairman, that completes my prepared statement. I will be happy to answer any questions from you and members of the committee.

Senator KENNEDY. Dr. Thomas, Memorial Sloan-Kettering Cancer Institute.

Dr. THOMAS. Mr. Chairman, although there is nothing new about the Laetrile phenomenon—in the sense that other purported "cancer cures" have periodically achieved wide publicity and some measure of public credibility—the outstanding example in recent years was recent legalization by several State legislatures have created a unique and unprecedented situation.

The number of cancer patients now under "treatment" with Laetrile is not known with any accuracy, but reports in the press have suggested that it is already in excess of 100,000. Moreover, the public

relations effort on behalf of Laetrile seems to have convinced some people—the number is entirely unknown—that the material is somehow to be classed as a vitamin and cancer-preventive properties. If this effort at deception succeeds, the number of people who will be buying Laetrile is simply incalculable.

Meanwhile, there is not a particle of scientific evidence, as this term is customarily understood, to suggest that Laetrile possesses any anticancer properties at all. I am not aware of any scientific papers published in any of the world's accredited journals of medical science, presenting data in support of the substance, although there are several papers, one of these recently made public by the Sloan-Kettering Institute, reporting the complete absence of anticancer properties in a variety of experimental animals.

The public testimonials attesting to the value of Laetrile which have been circulated by its supporters are all in the form of isolated anecdotes about individual patients, unaccompanied by any of the sorts of detailed information required for scientific evaluation.

Generally lacking are such details as the histological classification of the neoplasm, the precise nature of other treatments—surgery, radiation, chemotherapy—received by the same patients, and the clinical prognosis which each case would have carried in the absence of Laetrile. Moreover, there is no information whatever concerning the long-term outcome in the vast majority of the patients for whom beneficial effects have been claimed.

It is not difficult to explain the existence of individual testimonials favoring Laetrile. Cancer is a much more variable disease in its clinical course than the public has been led to believe. A great many patients with the diagnosis have been totally cured by today's conventional therapy, and in many others in whom cure is not possible, the disease may persist in arrested form for periods of several years without symptoms.

Moreover, cancer is not usually a painful illness, and when there is pain associated with cancer, it is often controllable by conventional analgesic drugs.

However, cancer is something very different in the minds of a great many people. For many patients and their families, the very word cancer is perceived as a death sentence. It is widely believed to be an inexorable and agonizing process, with no way out but death. Moreover, there are the wildest misconceptions about the current methods for treating cancer, especially with respect to the side effects of chemotherapy, which tend to be grossly exaggerated in the literature disseminated by the advocates of Laetrile.

Because of these misapprehensions about the nature of cancer and its treatment, many people are vulnerable to propaganda by vendors of various cancer "cures." Since large numbers of patients who have been treated by conventional therapeutic methods are inevitably going to do well, some for periods of a few years and some for a normal life span, and since some of these same patients have been persuaded to take Laetrile as well, their testimonials are added to the pro-Laetrile propaganda.

It is noteworthy that the marketers of Laetrile have tended to moderate their claims for the substance in recent years. It is no longer openly claimed that Laetrile cures cancer, although some of the leaflets and public releases hint broadly in this direction. Currently, the major

96-402 O - 77 - 2

claims seem to be that pain is dramatically relieved, and that patients undergo a marked improvement in their general sense of well-being.

It is often asserted that since Laetrile is not a particularly toxic substance, it should be made available to all patients who wish to use it as a matter of free choice. There is, however, a very real danger here. If, for example, children with early leukemia or sarcoma, or women with cancer of the breast, or young men with Hodgkin's disease, are persuaded to give Laetrile a trial before doing anything else, the outcome will almost certainly be death, in circumstances where appropriate therapy could be lifesaving.

There are already instances where this is known to have happened, in various parts of the country, and they will very likely increase if the material becomes more widely used. In this sense, Laetrile can fairly be regarded as a lethal drug.

In normal circumstances, one would not advocate clinical studies in human beings for any drugs unless scientific research in experimental animals or cell cultures gave some reason for expecting benefit. This is not the case with Laetrile but these are not normal circumstances.

The material is already in wide use, and its use appears to be spreading further each week. It has received official sanction from several State governments; an increasing segment of the public has been persuaded that it may be beneficial and is therefore worth a try. All this has happened in the absence of any real data. There exists no solid information about its effects on humans, beyond the likelihood that it is not, in itself, toxic.

For these reasons, it is now essential that the public is provided with solid information about Laetrile based on scientific facts.

There are two possible courses that could be taken rather quickly.

1. An epidemiological study of a statistically significant sample of patients who have already been treated with Laetrile should be launched. Many such patients are known to their private physicians, and information is probably available for some of them concerning the microscopic nature and extent of the tumor, the stage of the disease, and the details of other treatments, if any, including surgery, radiation and chemotherapy.

If a sufficient sample of cases with this level of information can be located, it should be possible to determine whether the course of the illness was or was not significantly altered by Laetrile.

This kind of retrospective study could not in itself be conclusive, because of the absence of controls within the same study. Nevertheless, it might be capable of revealing whether or not there is any basis in truth for the most strident of the claims made by the sellers of Laetrile, for example, the disappearance of tumors, the prolongation of active life, relief of intractable pain, and restoration of a feeling of good health.

2. A clinical trial of Laetrile in cancer patients should be planned under sponsorship and supervision by the National Cancer Institute. This ought to involve at least three major cancer centers. It should be a "double-blind" study, in which neither the patients nor physicians will know whether Laetrile or another substance are being administered. It should be aimed at answering the central questions about Laetrile, does it relieve pain, prolong life, cure cancer?

On ethical grounds, it would not be possible to treat any patient with Laetrile alone, if there are other forms of therapy conceivably beneficial for that patient. Therefore, for most of the patients to be studied, any clinical trial would have to involve Laetrile as an add-on to another treatment. This is a serious but unavoidable limitation. Even so, the key questions about pain relief and well-being could undoubtedly be answered, and such answers would tell us, at least, whether the substance provides any clinical benefits at all.

But there is one overriding problem which will have to be settled before any sort of clinical testing can be undertaken by anyone. What exactly is it that is to be tested under the name of Laetrile?

There are, by some accounts, any number of quite different preparations carrying this label out in the marketplace, and they differ from each other chemically in fundamental respects. They cannot all be tested.

Unless the advocates of the treatment can provide a single standardized preparation on which they will agree to base their claims of benefit to cancer patients, the prospects for scientific evaluation of Laetrile are so remote and the results would be so inconclusive that the undertaking is hardly worth the considerable effort that would be involved.

If there is to be a clinical trial of Laetrile, the data should eventually be reviewed and evaluated by a special committee composed both of clinicians with general experience in clinical science and lay persons with sagacity and good commonsense. It is of importance that this committee be recognized as fair minded and without vested interest one way or the other, for if the results are negative, there will surely be accusations of bias from the marketers of Laetrile.

It has to be remembered that an enormous amount of money is being made from Laetrile and the stakes for those who now control this market are very high indeed.

Thank you, Mr. Chairman.

Senator KENNEDY. Thank you, Dr. Thomas.

We will go on to Dr. Ross before questioning.

Would you proceed and then we will come back to the questions.

Dr. Ross. Yes, Senator Kennedy.

I would like to skip to page 2 of my statement.

Senator KENNEDY. I have no objection to that, other than page 1 gives your biography and your history, which is enormously impressive in terms of the degree of experience and research and attention that you have given generally into the area of cancer research.

We will make that a part of the record. I know you are reluctant to read it.

We will make note of it and make it a part of the record. We will start with page 2.

Dr. Ross. I have been concerned with the problems caused by the advocacy of Laetrile as a cancer treatment since 1959 and have assessed a large amount of factual information concerning Laetrile and related compounds and their effects on human beings, and their ineffectiveness as therapeutic agents in humans and in animals with cancer. I have observed and studied many patients who had been treated by others with Laetrile.

Today I will comment on the effects of Laetrile and related materials—apricot kernels, "Vitamin B–17," and other cyanogenic materials—on human beings.

There is a vast literature of studies which have been done on animal systems. I am not going to talk about them. They have all indicated Laetrile to be ineffective in controlling cancer.

First, I will discuss the dangerous nature of these materials and their potential for causing serious illness and death. Second, I will comment on my observations and studies indicating the ineffectiveness of these materials in the treatment of cancer. I hope that this information will be helpful to the subcommittee in its consideration of the problems relating to legitimization of Laetrile as a cancer therapeutic or preventive substance. I believe the best interests of the American people will be served by support of the position of the U.S. Food and Drug Administration concerning these materials.

The dangerous effects of Laetrile and cyanogenic plant materials on human beings:

ACUTE POISONING

Laetrile or Amygdalin is one of several chemically related compounds occurring naturally in the kernels and seeds of certain plants and in the tubers of the cassava. These compounds are similar in their effects on the body. They contain cyanide as a constituent part of their structure, and when these compounds in the presence of betaglucosidase enzymes contained in foodstuffs are subjected to digestive processes in the gastrointestinal tract of human beings or animals, they release cyanide—hence, the generic name "cyanogenic" compounds.

When released in the gastrointestinal tract, cyanide is rapidly absorbed into the body and interferes with the body's ability to use oxygen, producing cyanosis, dizziness, stupor, coma, nausea, vomiting, drop in blood pressure, shock, and death.

When given by intravenous injection, the fate of these materials is obscure and they are less toxic than when ingested. This is a subject which needs investigation. We do not know actually what happens to these materials in their ultimate disposal in the body when they are injected.

However, some of the symptoms described above follow intravenous injection.

The proponents of Laetrile have stated that it is harmless. This statement is contrary to fact as illustrated by the following tabulation, which you have before you, indicating a collection of 37 cases of severe poisoning, and of these 37, 17 died.

These cases have occurred sporadically since the materials involved have been proscribed by law, or are recognized as poisonous by the populations of foreign nations. Should they be made generally available and advocated as beneficial to humans, the number of cases may be expected to increase. An example of such advocacy of these materials is given in appendix 3.

I would like to call your attention to this publication which is a "cyanide cookbook." It says here this lady fed her husband cyanide last night, and on the next page it says she will do it again, and she has prepared a cookbook of cyanogenic materials, which she says should be used by all housewives in the United States in the proper nutrition of their families.

This is an example of the advocacy which is used by the proponents of these materials.

Senator KENNEDY. What are the health indications of that?

Dr. Ross. The health indication is that if this advice is followed and many people insert these materials there will be large numbers of poison cases attributable to this material, not only acute poisoning, but as I will tell you later, also chronic poisoning from continued ingestion of these materials.

Senator KENNEDY. Dr. Ross, why do you not move on—this is very important testimony—I would like for you to summarize.

Would you summarize the latter part of your testimony?

Dr. Ross. Surely, sir.

Summarizing the published and reported literature relating to the use of these materials, more than 1,000 cases have been published on or reported, competent authorities indicate that there is not evidence that these are effective in the treatment of disease.

Also there is evidence that when taken on a long-term chronic basis, a material similar to Laetrile materials apricot pits and amygdalin will produce poisoning in human subjects. These materials are contained in the cassava root which constitutes a major food staple for some 200 million people in the world. I believe that continued long-term ingestion of large amounts of Laetrile or amygdalin will produce similar poisoning in American citizens.

My summary statement, Senator Kennedy: There is ample scientific evidence that Laetrile is a toxic material which is potentially lethal when ingested, and may produce adverse symptoms when injected.

Observation of patients treated with Laetrile and review of cases purported to show the benefits of such therapy indicate that there is no scientific evidence of objective or unequivocal subjective benefit of cancer patients subjected to this therapy. There is ample evidence that administration of Laetrile therapy instead of conventional therapy results in needless deaths and great suffering.

I have provided an appendix detailing some of the cases I have observed in which this has happened.

It is my opinion that legitimization of Laetrile and its related compounds would be deleterious to the health and well being of the American people, and that the regulations of the FDA in regard to these materials are wise and should be continued.

Thank you very much, Senator.

Senator KENNEDY. Thank you very much, Dr. Ross.

If I understand the fundamental conclusion of the members of this panel that represent the different agencies of obviously Government, some of our important research institutions and a distinguished researcher who has spent the better part of his lifetime in the areas of cancer research and particularly in the area of Laetrile, that you can say to us unequivocably that there is not a shred of scientific information or evidence that is available or that has been submitted to any of you that would indicate Laetrile is an effective agent in meeting the problems of cancer.

Is that a fair statement, is it a reasonable statement and will each of the panelists just give or indicate whether they agree with that or they differ?

[The members of the panel responded affirmatively.]

Senator KENNEDY. Dr. Ross has brought important information and it has been testified by other members, although it was not the substance of their particular testimony, that Laetrile or the substances or the various compounds that go under the names of Laetrile may very well be a toxic substance that the ingestion of which can be hazardous to your health, irrespective of any other complications, health complications, that you might have.

Dr. Ross. That is correct.

Senator KENNEDY. That is correct from Dr. Ross—and how about Dr. Thomas and Dr. Newell?

[Dr. Thomas and Dr. Newell responded affirmatively.]

Senator KENNEDY. Given the reluctance among the American people in understanding basic scientific information which is so complete in terms of its failure to show that Laetrile is an effective substance, why do not the American people either understand it or why do they not believe it, and why do you not believe that they support the kind of testimony that you have given here?

Dr. KENNEDY. Senator Kennedy, I think one of the reasons here is perhaps we have not stated it effectively enough or often enough or publicly enough, and perhaps reiteration will do some good.

There obviously is something else at work here though. The American people have come to trust their physicians. That web of trust, it depends on a lot of things, but among other things it depends upon the fact that we have always worked in a system—since 1962, we have worked in a system in which physicians prescribed drugs, which were efficacious as well as safe, because Federal laws required that FDA subject them to the kind of scrutiny that guarantees that.

I think in that kind of environment where people are advised by some doctors to try a different therapy, that their belief in the wisdom of their own physicians may exceed in its impact on them their understanding of the broader scientific issues that are involved.

That is why I think it is so unfortunate that physicians are promoting Laetrile because they are capitalizing on a kind of faith that has been built up over many years by many people in the health care system.

Senator KENNEDY. Dr. Fredrickson.

Dr. FREDRICKSON. I think, Mr. Chairman, that I agree with Dr. Kennedy in the sense that there are real limits to the scientific method and power of anecdotal evidence, of belief, even myth, is very great when there is nothing else to offer hope to patients. And thus we have a situation created where it is very difficult to maintain that everyone remain rational and not subject himself to a last wave of hope. I think it is indeed most unfortunate, totally understandable about the patients themselves, but it is unfortunate when physicians who are trained in this country now in a medicine which has a rational base that they might themselves be the ones who really ignore the requirements for reasonable scientific proof in prescribing this compound.

Senator KENNEDY. I have a couple questions finally.

Do you think any scientific information can change the nature of this debate or discussion now, given what you have just said, Dr. Kennedy and Dr. Fredrickson?

Would anything turn this around?

Dr. KENNEDY. Yes, I do, Senator. I think repeated explanations of such facts as the shifting identity of the substance, the difficulty of finding a single magic treatment for cancer, the vexing problem that cancer is probably a disease of multiple origins and perhaps significant environmental and lifestyle related causes is going to begin taking hold and that people will understand enough so that they can, I hope, tolerate the frustrations that cancer as a disease presents to us.

But the fact which is so frightfully difficult for us to accept is that we just do not know enough about this disease to offer, even through conventional therapies, any kind of therapies of success. It is that which promoters are capitalizing on.

We have got to be honest about that. Tell people what we do and what we do not know.

Dr. FREDRICKSON. I think it is not likely that there will be new scientific evidence that will be in itself as convincing as reiteration of the principles that we have been talking about today.

I would add to that one important one, that is we, as the establishment, must recognize that we have to continue to be openminded and flexible ourselves and always credible in the eyes of the public to trust us to structure the tests upon which these decisions of safety and efficacy must be based.

Senator KENNEDY. Senator Schweiker.

Senator SCHWEIKER. Thank you, Mr. Chairman.

I would like to ask Dr. Thomas some questions.

Dr. Thomas, as I read some of the medical news accounts of several experiments conducted at Sloan-Kettering, it seems that your laboratory has become one of the focal points of this controversy.

Could you explain for the record exactly what was involved in the experiments conducted by Dr. Sugiura?

As I understand it, Dr. Sugiura initially had favorable results with Laetrile, and apparently you tried to duplicate his tests to reproduce his results.

I will let you tell the story. I think the record, in fairness, ought to show exactly what happened here. This is an important part of what the argument is all about.

Dr. THOMAS. I will be glad to.

The experiment you are referring to began a few years ago in Sloan-Kettering Institute under the direction of Dr. Sugiura, who has had a very long experience in evaluation of proposed, and many of them ultimately successful, anticancer drugs.

The model that was selected at the outset of this particular line of experiments involved a strain of mice prone to development of spontaneous breast cancer.

This line of mice is difficult to maintain. The numbers that could be obtained through the 3-year period were always limited to numbers far fewer than investigators themselves would have liked to have had. The experiments did take a longer time than would have been the case had these been mice from a freely available stock.

In the very first experiments that were put on, these were the experiments done under Dr. Sugiura's personal direction, and it appeared, although there was no evidence of significant extension of life in the mice once they developed cancer, nor was there any evidence on the size

or the extent of the cancers of the breast when they did develop, there did appear to be at the time of death of animals or at the time they were sacrificed, a difference in the numbers of metastatic nodules in the lungs.

Senator SCHWEIKER. Would you put that in layman's terms?

Dr. THOMAS. In this disease, when it terminates in mice, it is common to find large numbers of small aggregates of cancer cells that are nodules, little nodules throughout the lungs.

Senator SCHWEIKER. Small tumors?

Dr. THOMAS. No. Visible to the naked eye and more easily visible by microscopic section of the lungs. Anyway, it appeared in the first experiments there at least this difference between Laetrile or Amygdalin treated animals, and controls—however, the numbers were small.

Over the next 3 years, much of the effort was to find out whether this was a valid observation or whether it was not, and ultimately, after the launching of a number of experiments, including finally a double-blind—because of the subjective element involved in reading numbers of metastatic nodules through one's naked eye, it was finally decided that the safest way to do this experiment was to have the investigators not know whether the mice they were looking at had received the Laetrile.

The final conclusion of the people in charge of these studies, and certainly my final conclusion, was that Laetrile was without any effect at all in these particular animal models.

It ought to be mentioned, too, that other animal models have been tested for the effect of Laetrile against cancer, and many other kinds of animals, including rats and mice, and always to date with negative results.

Senator SCHWEIKER. What you were saying, in essence, is after the first experiment, which seemed to open up some new possibilities——

Dr. THOMAS. There was more than one first experiment. There were two or three occasions when it looked as though the number of metastatic nodules—well, not in the survival of animals, but simply in that one aspect of the terminal disease.

Senator SCHWEIKER. In essence, you tried to duplicate the initial results, or repeat the tests and explore further, and further tests were negative?

Dr. THOMAS. Could not confirm it, yes. That is not an uncommon event by the way in this kind of research. It is not at all unusual to have something turn up early on that we cannot prove later.

Senator SCHWEIKER. What is Dr. Sugiura's present position on these tests?

At one point, he was disagreeing with the subsequent tests which had negative results.

Dr. THOMAS. Dr. Sugiura, I think, still has a hunch that there was something there, that he was observing in those first two experiments. But he is unable to provide any explanation nor can the rest of us provide any explanation for why it was seen then and never turned up again.

My own feeling about it, and this is the feeling of biostatisticians who have looked at the problem, the model itself is a lot more variable with respect to this one question than had been anticipated at the outset.

In order to do this kind of experiment, you have to have a larger number of animals that were available for that particular series.

Senator SCHWEIKER. In a Washington Star article, dated May 2, Dr. Sugiura was asked if he felt the Laetrile experiment should be tried in human beings.

He responded that Laetrile "is not a cancer cure. It did not destroy the cancer completely, but just stopped the growth. Surgery still comes first, chemotherapy, * * * then maybe Amygdalin [Laetrile]."

What does it mean to say that it stops cancer growth, but does not kill cancer?

What does that mean, and how can we do that in other ways if, in fact, we can?

Dr. THOMAS. I had not heard that before. In point of fact, the evidence from the animal experiments has been that Laetrile or Amygdalin does not stop growth. It did seem in Dr. Sugiura's experiment it would inhibit the number of metastatic lesions in the lungs. But the primary tumor in other parts of the body were unchanged.

I should say, Senator Schweiker, that if we could find a drug or set of drugs that would simply stop cancer in its tracks, that would be a nearly ideal therapeutic remedy. Not remedy, because it would not make cancer go away, but if we could find a way that would hold things where they were for a longer period of time, that would be an ideal drug.

Senator SCHWEIKER. In view of all of this, Doctor, what again is your position on whether we should run a clinical trial?

I realize you have already addressed yourself a little bit to that question.

Where are we in your mind—should we be running a clinical trial or not?

Dr. THOMAS. I have had a feeling that until a clinical trial is done or until—if it was possible to do so—someone who can get epidemiologic data on what the effects have actually been on Laetrile patients in the past, unless one or both of those things are done, the use of this material will continue to spread.

I think one reason for it is that there is widespread public misapprehension about what cancer is like as a disease.

Cancer is deeply feared, as has already been said. But a great many people think that it is absolutely inexorable, that once the diagnosis is made, it is clearly the end of the game and that it is very painful.

In point of fact, a good many patients with cancer are, as you know, totally cured, and in many others treated by today's method of treatment, the disease can be held in abeyance for a period of as long as 4 or 5 or 6 years.

In this circumstance, the public is thinking that it is bound to go quickly and that it is bound to be associated with pain which, by the way, is not the case. Most of the patients with cancer, even terminal cancer, are not affected by severe pain. Some of them have no pain whatever. But with this fear of the disease, it is not difficult to understand why testimonials for patients who believe that they have been helped by Laetrile are available.

At any rate, I think if a clinical trial could be done by several centers, it would be worth doing. But I am quite aware of the problems raised by Dr. Fredrickson and Dr. Kennedy and Dr. Newell.

There are educational problems. One can certainly not treat patients with Laetrile by itself, and there is often the problem raised by Dr. Kennedy of not knowing what it is that we would be testing.

Senator KENNEDY. Senator Nelson.

Senator NELSON. No questions.

Senator KENNEDY. Senator Chafee.

Senator CHAFEE. It seems to me that the problem we are confronted with is the freedom of choice argument, namely that there is no evidence, scientific, let us assume, that Laetrile does any good.

But the people say, well, why should we not have our choice?

Now, each of you have addressed this, but it seems to me that Dr. Ross went a little further than the others did, and I would like to see if others agree, and I think Senator Kennedy touched on this in his summation, but Dr. Ross says there is scientific evidence that Laetrile is a toxic material which is potentially lethal when ingested.

Let us assume you are not meant to ingest it anyway, and may reduce adverse symptoms when injected.

Now, could you amplify a bit on that, Dr. Ross?

In other words, what we have got to do is have a good answer to that freedom of choice discussion.

Dr. Ross. Senator Chafee, the proponents of the material advocate it be taken by mouth. They advocate it be taken by mouth on a continuing basis by those who have the disease, and they also advocate that as a cancer preventive, everybody should take this material by mouth.

Senator CHAFEE. That is news to me. I thought it was not. I thought it was meant to be injected.

Dr. Ross. There just appeared in print a little paper book entitled Laetrile Case Histories, Richardson Cancer Clinic Experience, John Richardson and Patricia Griffin.

In the detailed regimen, which they advise be followed—is included the oral ingestion of this material. The book also reports some 90 cases out of the 4,000 which they say they have treated. These are the only 90; apparently they were able to get adequate followup data and then only for a period of about 1 year. The case reports do not indicate to me that Laetrile is effective in the control of cancer.

When Laetrile is given by injection, it also produces symptoms. In Mexico, the Contreras group reports some 3 percent of the cases that they treat die within 3 weeks of the time they start treatment. It is a question whether this is due to the injections they are given or not. But the patients who were given such injections, to whom I have spoken, indicate that they have flushing, they feel weak, they have some drop in their blood pressure. How many of them expire as a consequence of these injections is not known, since the proponents who use this material are not going to report what happened in terms of the immediate effects, and how many patients might die as a consequence of the intravenous injections.

Does that answer your question, Senator?

Senator CHAFEE. It does. Is there any comment from Dr. Kennedy? I appreciate the argument that has been given on freedom of choice that you might be deferring a better—not a better—a potentially satisfactory care as is mentioned on page 2 of Dr. Thomas' testimony. I wish we would get the proper pronunciation of this thing. How do you pronounce it?

Dr. THOMAS. We do not know.

Senator KENNEDY. It depends on whether it is a big L or a little l.

Dr. KENNEDY. The subject is full of mystery, Senator, but let me try to approach the problem of toxicity. Dr. Ross clearly knows better than we, because of his extensive clinical experience with it. I think one of the most alarming public health aspects of this problem among a lot of alarming aspects, is the recent shift to the vitamin promotion, which essentially means that however unregulated Laetrile therapy used to be, it will be more unregulated now, and I think that we are apt to have more accidental deaths like the one in New York State 10 days or 2 weeks ago as a consequence of the accidental ingestion of Laetrile tablets by an infant who subsequently died of cyanide poisoning.

I think we are going to see as the vitamin promotion gathers steam more and more of that kind of troublesome incident. Would you agree?

Dr. Ross. That is my belief.

Senator CHAFEE. Fine. I think the points that were made of the elaborate testing that has gone through, I guess Dr. Newell touched on that, the elaborate testing they have gone through with mice, that this has been given a fair trial, not clinically, but in comparison with every other drug, it has been given more than its fair shake.

So, plus the point that Dr. Thomas made that cancer is a more variable disease than the public believes, and there are cures through chemotherapy and surgery, that we can stress that. I think these hearings are going to be valuable in getting across to the public the points that you gentlemen have made.

Thank you, Mr. Chairman.

Senator KENNEDY. Thank you.

Just before calling on Senator Hayakawa, I want to carry on one point which Senator Chafee started, and I would like to have your attention. Even if we were not to accept Dr. Ross' statement and comment, and others, in terms of the danger, do we not also reach the issue of the efficacy of various drugs for which we talk about? Does that not also reach a question of whether, as a matter of public policy, that even if you do not find this, what would be the situation where perhaps any drug company could create a groundswell for any particular kind of Krebiozen or any other drug that was not necessarily dangerous, but not necessarily effective either, and would we not be going back to the old snake oil salesman period in the 1890's and early 20th century, which really gouged the American consumer?

Is that not an unrelated subject that is underlying at least part of the issue that we are considering here?

Just a brief comment.

Dr. KENNEDY. Yes; I think that was the main issue up until recently. I think that the toxicity questions have only enlarged in our mind as a consequence of this new strategy, relatively new strategy, and promotion as a vitamin.

The efficacy questions are equally troubling. I do not know—if we can make a hole in the efficacy requirements for Laetrile—and why other things could not follow on the same basis. And I think that would be a very regressive step in public health in this country.

Senator KENNEDY. Senator Hayakawa.

Senator HAYAKAWA. I do not suppose, gentlemen, I really have a question. I am concerned very, very much by that fact that there is

no "cure" for cancer. One of the peculiarities of the disease is that the patient knows it is fatal, relatives know it is fatal, it may be fatal, in 6 months, or 1 year, or 6 years, and during that time, what are you supposed to do?

This is the problem since the medical profession has no immediate cure, very few palliatives even, the patient, especially the relatives, are madly scrounging around looking for something to do besides prayer. Of course they pray. One cannot help but be very sympathetic and full of compassion for the people who realize that father is dying, grandmother is dying, there is nothing we can do about it except sit around and wait for it to happen.

How do you fill in that gap? Of course, whatever shortcomings there may be to Laetrile, it has the function of poorly filling in that psychological gap for those people for whom prayer is simply not enough.

Therefore, I think we cannot but approach this problem with considerable compassion for those who advocate Laetrile.

At the same time we recognize its uselessness.

Now, I am sufficiently respectful of the medical profession, and science in general, to put a great deal of weight into your findings, and especially Dr. Ross' statement about the toxicity, the contents of Laetrile. I think we are all of us confronting a really impossible situation until medical research makes further progress in the search for, as I say, either a cure, or at least the palliative, or to put it bluntly, something you can do while you wait for the patient to die.

Is it a gap that cannot be filled? Is there any way of filling it?

Dr. KENNEDY. Well, Senator, I will ask for some help from my colleagues from the National Institute of Health, but I think it is not exactly fair to say that there is nothing that can be done. As Dr. Fredrickson and Dr. Thomas both pointed out, a number of patients who discover that they have a cancer, and even in some cases make the frightening discovery that they have a recently advanced one, are cured by radiation therapy, by chemotherapy, by surgery. These modes of intervention are not as successful as we would like them to be. But they do often succeed.

I think you have put in a beautiful way the problem that the loved ones of the cancer patient have. It is those people who are especially moved to seek therapies, and it is those people who are especially easy to victimize by promoters. I want to emphasize that my annoyance here is clearly restricted to the promoters. No one wishes to blame the victims. But the difficulty is that a promotion like Laetrile can be a very seductive form of therapy, and can take a patient away from something that could do serious good.

We are not promising that conventional forms of therapy succeed anything like as much as we would like them to. But they have a chance, a realistic chance, and to take that chance away from a person with a cancer I think is almost the worst thing you can do to that person.

Senator HAYAKAWA. Dr. Ross?

Dr. Ross. Senator, I spend much of my time taking care of patients who have cancer. I would like to tell you that many of these patients can be cured of cancer. Some of them cannot be cured but many can be.

Also, I would like to comment that the care and the management of the patient and his family, of those who cannot be cared, is one of the major jobs of oncologists, doctors who dedicate themselves to the treatment of cancer. There are many things that can be done to help these patients. They are done by good physicians, and they are most helpful to these patients. I consider it to be a cruel and delusive procedure to give somebody false hope by saying, "OK, we are going to use Laetrile, and this is going to make you feel great." Maybe temporarily it will make you feel great if I tell you it is going to make you feel great, but then subsequently it does not help you and your false hopes have been destroyed. I think false hope is not a desirable thing for mankind. I think mankind must confront reality. He has to be supported by all measures that modern medicine can give him, even though he has a terrible disease, and this can be done.

I think it is a cruel delusion to let somebody rely on something that we know is not effective. I do not think that this is the way to take care of patients.

Senator HAYAKAWA. You are very persuasive, doctor. I know I agree with you essentially, but getting mankind to face reality, whether about their illness, or about political, economic system, or about their spouse's infidelity or shortcomings, that is a very difficult task altogether, is it not?

Thank you very much.

Senator KENNEDY. Thank you very much.

Dr. KENNEDY. Thank you.

[The prepared statements of Dr. Kennedy, Dr. Fredrickson, Dr. Newell, Dr. Thomas, Dr. Ross, and additional material submitted for the record follow:]

STATEMENT

BY

DONALD KENNEDY

COMMISSIONER

FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

BEFORE THE

SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH

COMMITTEE ON HUMAN RESOURCES

UNITED STATES SENATE

July 12, 1977

Mr. Chairman:

I should like to begin with a statement:

> "I know that there are...people who believe in their hearts that Laetrile will cure them, and I have deep sympathy for these people. But there are 198 million people whose health and safety depend on some measure on the integrity of the FDA...The Commissioner of Food and Drugs has neither the moral nor the legal right to disregard the laws of Congress and the evidence of science. We cannot and will not permit the introduction of Laetrile into interstate commerce."

The statement I have just read you was not my own; it was made by then-Commissioner James Goddard twelve years ago; in reading it to you I have substituted one name--Laetrile--for another--Krebiozen. Only some of the people in this hearing room will recall that Krebiozen was "the" cancer fraud of the late 1950's and early 1960's. Its sponsorship by Dr. Andrew C. Ivy, a distinguished physiologist at the University of Illinois School of Medicine, gave it substantial credibility among cancer patients; and despite the universal skepticism with which it was treated by the scientific community and organized medicine, thousands of cancer victims eagerly sought the drug and thousands of doctors prescribed it as an investigational drug--at a cost of $9.00 per ampoule.

Both the politics and the science of Krebiozen provide historical lessons that are worth remembering at the present time. The treatment attracted a highly organized, emotional group of supporters. Like many present-day advocates of

Laetrile, they were genuinely convinced that the scientific establishment was suppressing the use of a drug which could save lives. They drew some support from some major public figures--including the distinguished senior Senator from the State of Illinois, Paul Douglas. The Food and Drug Administration, the American Medical Association, and the academic scientific community were all attacked for their role in suppressing the freedom of choice of cancer patients to use Krebiozen. Some newspapers wondered editorially why, if the scientific establishment was right, it was being so defensive.

Why did the Krebiozen boom collapse? The first crack came when a team of FDA chemists analyzing the only sample of the substance ever obtained from the sponsors, found it to contain only minute quantities of a common chemical known not to have value in the treatment of cancer. Similar analyses of samples packaged for injection showed that only mineral oil was present. As a result, Federal Grand Jury indictments for fraud and conspiracy were handed down against a number of Krebiozen promoters. A panel of cancer experts examined a selected group of cases submitted by Dr. Ivy and found the drug without effect as an anti-cancer agent. Wide public understanding of the fraudulent nature of the promotional enterprise and the convincing quality of the expert testimony ultimately supplied with regard to Krebiozen's effectiveness, eventually combined to destroy public confidence in the remedy.

Krebiozen was not, of course, the last popular cancer nostrum, nor was it the first. Because it is such a dreaded and baffling disease, cancer has always been a seed bed for quackery. Some of the supposed remedies have had an air of plausibility; others are so outlandish that it seems incredible that people once believed in them. In its seventy year history, FDA has put hundreds of such "cures" out of business. About every decade, however, one of them takes hold in a convincing enough way to attract a large following, and then it becomes a public health problem because significant numbers of people forego other treatment to rely on it.

In the early 1940's and 1950's, Dr. William F. Koch successfully promoted one of the great medical hoaxes of all time. Koch's treatment actually involved distilled water of extraordinary purity; but Koch claimed it contained one part per trillion of an active ingredient called glyoxylide. Despite the lack of any evidence that glyoxylide had a therapeutic effect, a great many people believed in it--and over 3,000 health practitioners of various kinds across the country were charging patients as much as $300 per injection.

The disappearance of Koch's treatment was followed shortly by the appearance of another; the Hoxsey treatment consisted of two medicines, one comprised primarily of various plant products and the other of lactated pepsin and potassium iodide. At the peak of the Hoxsey boom,more than 10,000 people were receiving the treatment at an individual cost of $400 each. Its sale was stopped in 1960, after 10 years of litigation. But old swindles never die; even patients who attempt to arrange trips to Mexico for Laetrile treatment are sometimes told that, for a slightly lower price, they can still get Dr. Hoxsey's medicine.

What is different about Laetrile? The short answer is: not very much. The pattern of promotion is similar; its advocates rely heavily on castigation of the medical and scientific establishment and emphasize the "freedom of choice" of patients, the support of a few major public figures, and the obviously sincere conviction of cancer patients and their relatives who feel they have been helped by the treatment. The Laetrile movement has also been aided by other forces that are unique to it or to the times. These include, I suspect, a feeling on the part of some people that Government and in particular regulatory agencies have too much control over people's lives, and a sense of frustration over the failure of biomedical research to provide a single, comprehensive solution to the cancer problem. To these social forces, Laetrile promoters have added a set of biological arguments that have a superficial ring of plausibility.

Mr. Chairman, as you and your colleagues from the Subcommittee are aware, FDA has been asked to provide a District Court in Oklahoma with an administrative record on which the Court could review the basis for FDA's contention that Laetrile is a "new drug" under the Federal Food, Drug and Cosmetic Act, thus requiring premarket approval by the Agency before it can be lawfully distributed. In compiling that record, FDA has received written submissions from proponents of Laetrile and from the scientific and medical community; in addition, we held two days of public hearings in Kansas City, Missouri, on May 2 and 3, 1977. We have now prepared our analysis of that record; and it will be published in the Federal Register later this month and simultaneously delivered to the Court in Oklahoma City. I now want to summarize for the Subcommittee our central findings from this extensive record. They indicate beyond serious question (1) that Laetrile is not generally recognized by qualified

experts as a safe and effective cancer drug; and (2) that Laetrile is not exempt from the premarket approval requirements for new drugs by virtue of the "grandfather" provisions of the Food, Drug and Cosmetic Act. To the contrary, the evidence shows that both now and in the past Laetrile has been regarded by the overwhelming majority of qualified experts as being of unproven safety and of no effectiveness whatever. The evidence brought to us by the proponents in the course of compiling the administrative record and the evidence cited earlier consists essentially of hearsay arguments and patients' testimonials.

Mr. Chairman, your Subcommittee is familiar with the long experience FDA has had with such testimonials. Time after time, persons or corporations wishing to introduce new drugs onto the market have tried to persuade us that general clinical experience, the subjective judgments of physicians, or the conviction of patients should substitute for controlled experiments in the approval process. Time after time, my Agency has insisted on the scientific data that result from controlled experiments. And time after time, the courts have upheld that position by confirming that the intent of Congress in the 1962 drug efficacy amendments was to insist that proof of efficacy requires more than personal belief.

I know you share my view that Congress was wise so to insist. It is not uncommon for the course of cancer, or that of other diseases, to fluctuate. Patients experience complete remission for causes that are unknown. Almost 20 percent of all patients with breast cancer will survive for five years without

any treatment whatever. Many patients who receive one therapy are receiving others at the same time. Both patient and physician are under serious temptation to believe that a "cure"--which may be only a remission--is attributable to a particular therapy. This is why we insist on controlled clinical trials; this is why we cannot trust testimonials, no matter how poignant they are and no matter how deeply we may sympathize with those who provide them.

Nor did we, in our examination of the record, find any evidence that Laetrile is exempt from the premarket approval requirements for new drugs by virtue of being "grandfathered." No evidence was presented to us that experts in 1962 recognized Laetrile to be safe and effective in the treatment and management of cancer; none of the experts who submitted testimony knows of scientific reports on which such recognition could have been predicated, or knows of medical text or medical schools where use of the substance(s) are recommended or taught, or knows of medical experts who were then or are now of the view that Laetrile has any useful effect in treating cancer. Furthermore, numerous variations in the identity of Laetrile, which I will discuss in a moment, make it certain that before 1938--and probably even in 1962--the material now understood to be "Laetrile" was a different compound or compounds entirely.

The voluminous record that we sifted in order to reach the conclusions I have just announced provides, among other things, the largest single body of material available regarding the identity and properties of Laetrile <u>as defined by its proponents</u>.

In order to evaluate the questions that the administrative proceeding sought to answer, we had to undertake a careful analysis of that information because we could hardly decide if Laetrile were a new drug or a grandfathered drug without first defining what it was. All of the written materials and the transcript of testimony presented at the hearing were examined by scientific and legal members of my staff. We wrestled conscientiously with the problem of Laetrile's identity.

The resulting analysis of the claims offered in support of Laetrile consitutes in many ways the most important set of findings we are presenting to the court. These are best expressed as a series of statements:

> First, Laetrile as it is offered for sale in the treatment of cancer is not one preparation, but several different ones;
>
> Second, Laetrile and Amygdalin are not the same compound, although they are often claimed to be; and
>
> Third, proponents of Laetrile do not agree as to the identity of the substance bearing that name.

These differences in identity relate to shifting theories that attempt to explain the alleged anti-cancer activity of the drug or drugs. The original claim was that Laetrile would be broken down by an enzyme (beta-glucosidase) in cancerous tissue to liberate cyanide, which would "kill the cancer." This concept must contend with at least three difficulties: (1) there are

only traces of beta-glucosidase in animal tissues, and even less in experimental tumors; (2) cyanide diffuses rapidly and would poison the surrounding normal tissues or be transported to cause systematic poisoning; and (3) the chemical differences between normal cells and cancerous cells that proponents claim to exist have not been demonstrated. More recently, the supporters of Laetrile have offered the theory that Laetrile is not a drug at all, but rather the source of vitamin B-17, which cures and prevents cancer; and that cancer is thus a manifestation of a vitamin B deficiency. No evidence that vitamin properties are associated with any such compound has been presented, nor is a deficiency disease associated with its lack.

Throughout its history, there has been uncertainty about the identity of the substance promoted and distributed as "Laetrile." Ernest T. Krebs, Jr. claimed to have prepared synthetically a compound named "Laetrile" in the 1950's. He coined the name from the compound's chemical name, laevo-mandelonitrile beta-glucuronoside. It should be noted that this identity is inconsistent with the then-prevalent enzyme theory; a beta-glucosidase would not attack the compound so named. But there are also serious conflicts among proponents about the real identity of "Laetrile." Dr. Ernest T. Krebs, Sr., for instance, stated in a 1965 affidavit that his son had developed the name Laetrile for the Amygdalin which Dr. Krebs, Sr. was producing, and that the name had in fact been so applied in 1949. Amygdalin and "Laetrile" are related compounds, but they are <u>not</u> identical. This confusion has extended from the early 1950's until the present time;

investigators have seldom identified the compound they used in tests or clinical practice in an unambiguous way. The "Laetrile" supplied by Mr. Krebs, Jr. to the Cancer Commission of the California Medical Association in 1953, for example, proved by analysis to be Amygdalin.

Furthermore, our own analyses on samples of products labeled as Laetrile give inconsistent results. For example, Amygdalin itself exists in two different isomeric forms. The biological activity--including the toxicity--of different optical isomers of the same substance often differ radically, so it is significant that the samples of "Laetrile" that we have analyzed vary widely not only in the amount of Amygdalin present but in the proportion of the two Amygdalin isomers.

A special feature of the identity problem relates to the question of safety. Amygdalin, "Laetrile" and related compounds all contain cyanide that can be released by certain enzymes. According to one of the proposals for Laetrile's mode of action, it is the differential release of cyanide in the vicinity of cancer cells that causes the action; but as I mentioned earlier, these enzymes are actually not found in appreciable amount within the body, either in normal cells or in cancer cells. They are, however, found in the digestive tract. That is why unextracted apricot pits, taken in large amounts, are toxic; and that is presumably why Laetrile proponents in 1962 indicated by labeling that their product was never to be taken orally.

The dangers of oral ingestion of Laetrile were dramatized by the recent tragic death of an infant in New York State who accidently ingested Laetrile tablets. In a report in press in the Journal of the American

Medical Association, this death is attributed by the attending physician to cyanide poisoning. Oral ingestion of Laetrile, or Amygdalin, or a related extract of apricot pits is, nevertheless, advocated by those Laetrile supporters who argue that it is a "vitamin." In this form, Laetrile and its congeners cannot conceivably be regarded as safe.

The most remarkable thing about the administrative record we have assembled is that it does not require reliance on the views of clinicians, biomedical researchers, or any of the other experts from the medical establishment who have testified against Laetrile. The startling contradictions about the drug's identity, the alarming uncertainty about its safety, and the mutually inconsistent theories brought forward to explain its alleged action against cancer are, by themselves, entirely adequate to defeat the proposition that Laetrile can possibly be an effective cure for anything. Its supporters have condemned it more effectively than the establishment ever could.

Indeed, in sifting the strange mixture of nomenclature, alleged chemical identity, and proposed mechanism of action that comprises Laetrile's record of the past twenty-five years, one becomes gradually convinced that these uncertainties are not accidental. They provide an effective cover for the promoters, since failure to achieve a result can always be attributed to having used the wrong material and arguments against one hypothesis of action can always be met by embracing another. As you will hear later this morning, there is substantial incentive to cover one's tracks in such a business. Laetrile pays, and pays well.

In my view, the evidence of fraud--and the lack of it about effectiveness--fully justify the prohibition against Laetrile. For some, however, the persistent notion of "freedom of choice" dominates the issue.

Of course, this general idea is deeply engraved on all of us who are proud of our American heritage; indeed, it is the essence of our political life. As one who is partly responsible for trying to cope with the complexities of our world within the framework of our free society, let me state my feelings about the limits of freedom on this issue.

(1) I do not believe that anyone has the right to debase the concept of freedom by swindling those who are desperate for their lives; and

(2) I do not believe that we should permit Laetrile to destroy a drug efficacy system that ensures free, informed choice among products that work. The "freedom" to promote Laetrile ultimately destroys every citizen's right to make intelligent choices.

Mr. Chairman, if I have sounded a little angry in these proceedings it is because I am. I hope, however, that I am not seen as unsympathetic, because in fact my anger derives from the sympathy I feel for those cancer patients who turn to Laetrile. They are being victimized twice--once by their disease and once by the profiteers.

I wish that everyone who feels that the Laetrile matter is a simple freedom of choice issue, in which Government should step aside and allow the marketplace to function, could meet as we have with some of the cancer patients who believe firmly that they are being helped by Laetrile. Their conviction is real, and they present powerful and moving appeals. One can understand why they do so; cancer, the disease Americans fear more than they fear war, has for decades resisted the best efforts of science to provide a cure. We now think we know why; it is not a single disease but a whole set of diseases--many of them of complex, largely environmental origin. Cancer probably does not even have a single cure; yet a single cure is exactly what the afflicted person hopes for most desperately. The convincing salesperson who offers one for a price is likely to make a sale--not only with the patient, but with family and loved ones.

When I hear testimonials from such patients, it is hard for me to control my anger at their exploiters. And I think it is a deplorable suggestion that this Government should, on the falsely applied issue of "freedom of choice" stand aside and allow them to be exploited by the purveyors of a therapy that is of unproven merit, and even of uncertain identity.

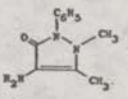
This concludes my statement. I will be happy to answer any questions you or members of the Subcommittee may have.

Merck Index 9th Ed

Bitter crystals, mp 142-145°. Freely sol in water; slightly sol in abs alcohol; insol in chloroform, ether. The aq soln is acid to litmus.

THERAP CAT: Anticholinergic.

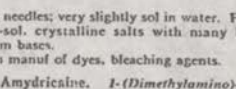
627. Ampyrone. *4-Amino-1,5-dimethyl-2-phenyl-3H-pyrazol-3-one; 4-amino-2,3-dimethyl-1-phenyl-3-pyrazolin-5-one;* 4-aminoantipyrine; 1,5-dimethyl-2-phenyl-4-aminopyrazolone. $C_{11}H_{13}N_3O$; mol wt 203.24. C 65.00%, H 6.45%, N 20.68%, O 7.87%. Prepn: Waser, *Helv. Chim. Acta* 8, 117 (1925); Freedman, Sherndal, U.S. pat. 1,877,166 (1933 to H. A. Metz Labs.); Turpechen, Kaltro, *C.A.* 36, 426 (1942); Takahashi, Ogyu, Japan. pat. 3663('54) (to Nippon New Drug), *C.A.* 50, 2687c (1956).



Pale yellow crystals from benzene, mp 109°. Sol in water, ethanol, benzene; sparingly sol in ether.

THERAP CAT: Antipyretic, analgesic.

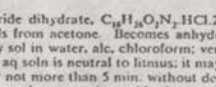
628. Amsonic Acid. *2,2'-(1,2-Ethenediyl)bis[5-amino-benzenesulfonic acid]; 4,4'-diamino-2,2'-stilbenedisulfonic acid.* $C_{14}H_{14}N_2O_6S_2$; mol wt 370.41. C 45.40%, H 3.81%, N 7.56%, O 25.92%, S 17.31%. Prepn: Bender, Schultz, *Ber.* 19, 3234 (1886); H. E. Fierz-David, L. Blangey, *Grundlegende Operationen der Farbenchemie* (Springer-Verlag, Vienna, 7th ed., 1947) p 161; Spiegler, U.S. pat. 2,784,220 (1957 to du Pont).



Yellow needles; very slightly sol in water. Forms sparingly water-sol. crystalline salts with many bisquaternary ammonium bases.

USE: In manuf of dyes, bleaching agents.

629. Amydricaine. *1-(Dimethylamino)-2-[(dimethylamino)methyl]-2-butanol benzoate;* 2-ethyl-1,3-bis(dimethylamino)-2-propanol benzoate; 2-benzoxy-2-dimethylaminomethyl-1-dimethylaminobutane; dimethylaminostovaine; Alypine; Benzopropyl. $C_{18}H_{30}N_2O_2$; mol wt 278.38. C 69.03%, H 9.41%, N 10.06%, O 11.50%. Prepd as the hydrochloride from 2-ethyl-1,3-bis(dimethylamino)-2-propanol and benzoyl chloride in 20% NaOH: Ger. pat. 173,631 (1906 to Bayer), *Frdl.* 8, 1027; U.S. pat. 808,748 (1906).



Hydrochloride dihydrate, $C_{18}H_{30}O_2N_2 \cdot HCl \cdot 2H_2O$, hygroscopic crystals from acetone. Becomes anhydr at 100°, mp 169°. Readily sol in water, alc, chloroform; very slightly sol in ether. The aq soln is neutral to litmus; it may be sterilized by boiling for not more than 5 min. without decompn. Two and four % aq solns are quite stable, but weaker solns are likely to become moldy. MLD s.c. in dogs: 70 mg/kg.

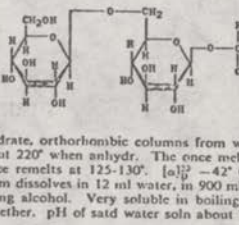
Nitrate. $C_{18}H_{30}N_2O_2 \cdot HNO_3$, nonhygroscopic cryst powder, mp 163°. Freely sol in water, alcohol; sparingly in ether. The aq soln is neutral to litmus. MLD s.c. in rats: 400 mg/kg.

Pharmaceutical Incompatibility: For the hydrochloride, iodides, caustic alkalies, alkali carbonates.

THERAP CAT: Hydrochloride as topical anesthetic.

THERAP CAT (vet): The hydrochloride has been used as topical anesthetic.

630. Amygdalin. *(R)-α-[[6-O-β-D-Glucopyranosyl-β-D-glucopyranosyl]oxy]benzeneacetonitrile;* amygdaloside; mandelonitrile-β-gentiobioside; D-mandelonitrile-β-D-glucosido-6-β-D-glucoside; NSC-15780. $C_{20}H_{27}NO_{11}$; mol wt 457.42. C 52.51%, H 5.95%, N 3.06%, O 38.47%. Occurs in seeds of *Rosaceae;* principally in bitter almonds; also in peaches and apricots. Obtained by extracting defatted almond meal repeatedly with boiling 95% alcohol. Structure and synthesis: Haworth, Wylam, *J. Chem. Soc.* 123, 3120 (1923); Kuhn, *Ber.* 56, 857 (1923); Hudson, *J. Am. Chem. Soc.* 46, 483 (1924); Zemplén, Kunz, *Ber.* 57, 1357 (1924); Kuhn, Sobotka, *ibid.* 57, 1767 (1924); Baumann, Pigman in W. Pigman, *The Carbohydrates* (Academic Press, New York, 1957) p 550. Is split by emulsin: Amygdalase in emulsin produces glucose and mandelonitrile glucoside which are converted by prunase in emulsin to form benzaldehyde, glucose (2 mols), and HCN. Hydrolysis with hot dilute mineral acids gives same end products: Vichoever, Mack, *Am. J. Pharm.* 107, 397-450 (1935). Other enzymic hydrolysis studies: Haisman, Knight, *Biochem. J.* 103, 528 (1967). Although amydalin has been reported to have been used in cancer chemotherapy since 1845, there is an absence of published data substantiating its anticancer activity. *See* Wodinsky, Swiniarski, *Cancer Chemother. Rep.* (part 1) 59, 939 (1975); Laster, Schabel, Jr., *ibid.* 951. The term amygdalin is currently used interchangeably with Laetrile, *q.v.*



Trihydrate, orthorhombic columns from water, mp 200°; mp about 220° when anhydr. The once melted and solidif substance remelts at 125-130°. $[\alpha]_D^{25}$ −42° (anhydr basis). One gram dissolves in 12 ml water, in 900 ml alcohol, in 11 ml boiling alcohol. Very soluble in boiling water; almost insol in ether. pH of satd water soln about 7.

631. *n*-Amylamine. *1-Pentanamine; pentylamine;* 1-aminopentane. $C_5H_{13}N$; mol wt 87.16. C 68.90%, H 15.03%, N 16.07%. $CH_3(CH_2)_3CH_2NH_2$. Prepd by reduction of valeronitrile with $LiAlH_4$ and with $LiAlH_4$-$AlCl_3$: Nystrom, *J. Am. Chem. Soc.* 77, 2544 (1955).

Liquid. d^{19} 0.766. bp 104°. mp −55°. Very sol in water; sol in alcohol; miscible with ether.

Caution: A strong irritant.

632. Amylase. Enzymes catalyzing the hydrolysis of α-1→4 glucosidic linkages of polysaccharides such as starch, glycogen, or their degradation products. *Endoamylases* attack the α-1→4 linkage at random. A single type of endoamylase is known, *i.e.*, α-amylases (*α-1,4-glucan 4-glucanohydrolases*), so named, because the reducing hemiacetal group liberated by the hydrolysis has α optical configuration and mutarotates downward. The more common α-amylases include those isolated from human saliva, human, hog and rat pancreas, *Bacillus subtilis, B. coagulans, Aspergillus oryzae* (*Taka-amylase*), *A. candidus, Pseudomonas saccharophila,* and barley malt. *Exoamylases* attack the α-1→4 linkages only from the non-reducing outer polysaccharide chain ends. Those breaking every glucosidic bond to produce solely α-glucose are known as *glucamylases* (*γ-amylases*). Those breaking every alternate bond to produce maltose are known as *β*-amylases (*α-1,4-glucan maltohydrolases*). Exoamylases are exclusively of vegetable or microbial origin. *Reviews:* Fischer, Stein, "α-Amylases" and French, "β-Amylases", in *The Enzymes,* P. D. Boyer *et al.*, Eds., Vol. 4 (Academic Press, New York, 2nd ed., 1960) pp 313-343, 345-368.

633. α-Amylase (Bacterial). Agrozyme; Amylo-Liquifase; Biolase; Diastmen; Grozyme; Rapidase; Superclastase. Usually prepd using *Bacillus subtilis, e.g.*, by submerged fermentation of wheat bran and peanut meal medium by a strain of *B. subtilis*: Babbar *et al.*, *Biochim. Biophys. Acta* 65, 347 (1962). Purification and crystallization of α-amylase from *B. subtilis*: Stein, Fischer, *Helv. Chim. Acta* 40, 529 (1957). Babbar *et al.*, *loc. cit.*: from *B. subtilis* or *B. mesenter-*

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20014

STATEMENT BY

DONALD S. FREDRICKSON, M.D.

DIRECTOR, NATIONAL INSTITUTES OF HEALTH

ON

LAETRILE

BEFORE THE

SUBCOMMITTEE ON HEALTH SCIENTIFIC RESEARCH

COMMITTEE ON HUMAN RESOURCES

JULY 12, 1977

Mr. Chairman and Members of the Committee:

The problem of Laetrile, which we are discussing today, has several important dimensions. In the public policy area the principle that drugs must be efficacious as well as safe in order to be approved by the Food and Drug Administration is at stake. The issue simply put is: are useless nostrums to be substituted for treatments shown to be safe and useful by scientific methods? We are discussing today, therefore, a problem far greater than cancer or any other disease.

I am aware, Mr. Chairman, of the limits of the scientific method. It often cannot provide the comfort sought by those beyond the help of its restricted power. I sympathize with the frustration and grief which have led so many cancer patients and their families to try Laetrile and do not ignore the emotional dimension of this problem.

It is my purpose, however, to discuss certain of the ethical and moral problems surrounding the application of the scientific method to the clinical testing of drugs for efficacy against cancer--another important dimension of the Laetrile problem. Specifically, I would like to limit my remarks to the moral and ethical issues that have arisen from the National Cancer Institute's decision to consider conducting a clinical trial of Laetrile--a trial that by definition would involve human beings. My statement will be relatively brief. Dr. Guy Newell, Acting Director of the National Cancer Institute, will provide details, which expand upon my summary.

The present Food and Drug law requires that drugs be proved safe and effective before they can be marketed. This proof of safety and effectiveness must be demonstrated by precise and thorough testing. The precedent which underlies the implementation of this law has been that a drug shall not be tested in man without a reasonable scientific basis for assuming that it might be efficacious in man. Usually, this has meant that it has been necessary to develop proof that the drug had anti-tumor activity in animals.

As you know, Laetrile, in one or another formulation, has been known for more than 25 years. Over this extended period of time, no scientifically acceptable evidence has been presented of Laetrile's effectiveness against cancer, in either animals or man, for either prevention or cure. In his statement, Dr. Newell will amplify this point.

Let me now discuss what I consider to be the critical issue from the perspective of the scientific community: the possibility that a clinical trial of Laetrile be mounted by the National Cancer Institute. This is a critical issue because, based on past experiences, there is no valid scientific reason to put Laetrile into a clinical trial. Faced with this, the first question is: should public demand or legislation by individual states force us to break a precedent which, we believe, has served society and the public well? It is estimated that more than 50,000 individuals in this country are receiving Laetrile, some undoubtedly in lieu of other treatment known to be beneficial or curative.

Do mere numbers of people, unaccompanied by a shred of necessary scientific proof that they have been, or can be, helped by Laetrile, override those precedents that have served so well? What would be overridden is the reasonable basis that has been constructed to protect those patients who would be recruited to a clinical trial. Central to this reasonable basis is the good faith on the part of the physician and the patient both that the drug or technique to be studied has a chance of helping the patient.

Simply stated, clinical trials have been based on the principle that drugs are tried in patients only when there is scientific evidence to believe they might help those patients. Have we ever the right to deprive a patient of a potentially useful drug, and provide instead a compound for which there is no reasonable probability of usefulness.

In any clinical trial of Laetrile, two key conditions must be met, I believe. First, no patient can be deprived of any proven therapy that might help that patient. Any individual entered into such a trial must be clearly beyond any beneficial therapy known to be effective against cancer, including surgery, radiotherapy, and chemotherapy. The second condition to be met is the principle of informed consent. Each patient must have a meticulous explanation of what is known and not known about the compounds being tested, and must have full understanding of the choices available to him when consent is given.

Trials of anticancer drugs in man present trying ethical dilemmas at best, and Laetrile, backed as it is by no scientific evidence of efficacy, compounds these dilemmas. In considering what should be its next step,

the National Cancer Institute has discussed several possible courses of action.

One option is to do no clinical trial of Laetrile, and thereby maintain that important precedent we have been discussing. The dimensions of the Laetrile problem are such that this is not a comfortable position for us.

A second option is to defer a decision on a clinical trial, and for the NCI to offer its services, in collaboration with the Food and Drug Administration, in the collection and review of clinical evidence of a kind necessary to support the effectiveness of Laetrile as an anti-cancer agent. If the use of Laetrile continues in a number of states, it is at least possible that evidence meeting scientific standards could be developed by responsible physicians who are prescribing Laetrile for certain of their cancer patients. This will be a very difficult course of action, but we need not consider it impossible.

The third option is that NCI begin a clinical trial without undue delay. In preparation for such a trial, it must thoroughly discuss and lay out those ethical issues alluded to above, as well as the considerable technical problems that would attend such a trial. The probability of a clinical trial of Laetrile providing an unequivocal result seems to be small. The possibility is considerable that even an unequivocal negative result would still not convince some proponents of this substance.

We will very shortly come to a decision about which of these options to adopt. Mr. Chairman, that completes my statement. You may wish to proceed to Dr. Newell's statement now, or if you prefer, I would be happy to answer questions.

96-492 O - 77 - 4

STATEMENT OF

GUY R. NEWELL, M.D.

ACTING DIRECTOR

NATIONAL CANCER INSTITUTE

BEFORE THE

HEALTH AND SCIENTIFIC RESEARCH

SUBCOMMITTEE

OF THE

COMMITTEE ON HUMAN RESOURCES

July 12, 1977

Mr. Chairman and Members of the Committee, it is a pleasure to have an opportunity to present to you the National Cancer Institute's activities and position regarding the substance called Laetrile.

This substance, derived from apricot pits, has been exhaustively tested in laboratory animals by the National Cancer Institute and other scientists. The results of these tests conclusively show that Laetrile has no significant anticancer activity. Based on these tests, NCI's evaluation is that Laetrile is likely to be inactive against cancer.

In spite of the evidence that Laetrile does not have effect in treating cancer, approximately 50,000 cancer patients in the United States take Laetrile each year, at great cost to themselves and their families. The Food and Drug Administration bans Laetrile from interstate commerce because it has not been shown to be effective for the treatment of cancer. Yet, 11 states have enacted legislation recently to legalize the use of the substance within those states. Without doubt, these new state laws will increase use of Laetrile.

The average citizen in this country does not have the resources and technical skills necessary to select, develop and test materials for the treatment of disease. Neither does he have the background that will enable him to make enlightened decisions concerning the selection and use of therapeutic agents. The selection, development, testing, evaluation, marketing, prescribing and administration of materials for disease treatment is an area in which large institutions and skilled professionals are uniquely qualified to take the measures necessary to protect the interests of the public.

Accordingly, society has established and endorsed rigorous procedures through which new drugs are tested and certified for use in clinical medicine. After many years of experience, a number of animal tumor systems have been found useful in predicting the activity of new drugs in cancer patients.

Mr. Chairman, I would like to describe for the Committee the development and use of the procedures employed by the National Cancer Institute for evaluating compounds for anticancer activity. Although our experience in this area dates back to 1937, it was not until the birth of modern chemotherapy in the post World War II era that great interest was generated in screening new compounds for anticancer activity. Screening is the process by which a large number of materials are evaluated in an experimental test system to quickly eliminate the vast majority of inactive compounds and identify the few materials having the greatest potential for clinical activity.

Between 1955 and 1976, more than 275,000 synthetic compounds and 200,000 natural product extracts have been evaluated for anticancer activity by NCI as a cost of about $400 million. Today, NCI's Drug Research and Development Program tests potential anticancer drugs in a system that consists of seven well-defined steps:

1) Acquiring materials for evaluation. About 15,000 synthetic compounds and 250 purified natural products are selected each year.

2) Screening. NCI's prescreen, using mice with a transplanted leukemia, has demonstrated sensitivity to most classes of clinically effective anticancer drugs, and is sufficiently discriminating to avoid overloading the testing system with inactive compounds. Before a compound is tested beyond the prescreen, a 20 percent increase in the life span of treated mice over untreated controls must be shown. If this criterion is met, the prescreen is repeated and confirmed, preferably in another laboratory. The prescreen may be bypassed if a compound has particular properties, or if it has shown activity in another screen or assay.

Compounds active in the prescreen are next tested against a number of different types of tumors. Criteria for activity here is either increase in survival or inhibition of tumor growth in the test animals.

3) Detailed Drug Evaluation. The timing and route of administration of the drug--either oral or intravenous--is determined in animals. Studies are also carried out to determine the feasibility of producing large quantities of drug and formulating it for clinical trial.

4) Toxicology in Large Animals. The highest nontoxic dose is determined in dogs and monkeys. The major organ toxicity in both species is noted, as well as the ability to predict toxicity.

Following passage of this stage, an Investigational New Drug (IND) application is filed with FDA. Data showing the compound to be both safe and effective against cancer in animals are presented. Approval of the IND marks the beginning of studies with cancer patients.

5) Phase I Clinical Trials. The maximum tolerated dose is established in advanced cancer patients who have not responded to conventional therapies, and the predictability of the major organ toxicity is noted. Antitumor activity is not required at this stage, but is recorded if it occurs.

6) Phase II Clinical Trials. The drug is evaluated for anticancer activity in patients with measurable disease in each of 10 forms of cancer. An objective response must be clearly established in at least 15 to 30 patients with any one of the tumors.

At the completion of Phase II studies, a judgment is made regarding the degree of efficacy of the compound and the nature of its adverse effects. If the risk-benefit ratio is acceptable, the compound goes into large-scale clinical studies with cancer patients.

7) Phase III and Phase IV Clinical Trials. Phase III trials evaluate in detail the activity of the compound against the one or more cancers in which it had shown activity and in particular, compare it with the established drugs of choice. Phase IV trials evaluate the use of the drug in combination with other active drugs and with other active forms of therapy--surgery and radiation therapy.

These studies provide definitive answers on the value of a given drug or combined modality therapy, and based on the accumulated data, a New Drug Application is filed with FDA.

Mr. Chairman, only one drug out of every 5,000 screened goes as far as clinical trials, and only one of every 50,000 is eventually marketed.

I would like now to summarize for you the results of a series of animal tests we have conducted of Laetrile. It should be noted that of all the compounds that have been submitted to NCI's Drug Research and Development Program, Laetrile is the most tested inactive substance.

Laetrile is variously described as a form of Amygdalin, as a nitriloside, or as Vitamin B-17. Supporters of the compound have used the names Laetrile and Amygdalin synonymously. The compound actually used in all tests at NCI and elsewhere has been Amygdalin. Amygdalin occurs in the seeds of many plants. (It is not necessary for the normal functioning of the body; therefore, it is not regarded as a true vitamin.)

The National Cancer Institute has tested Laetrile in rodents with transplanted tumors in the same systems routinely used to screen compounds for anticancer activity. Six different samples of Laetrile have been tested, beginning in 1957 and continuing as new animal tumor systems have become available. All tests have failed to demonstrate that Laetrile has any anticancer activity, and provide no basis for predicting that Laetrile might act against cancer in humans. It should be noted that all of the drugs of demonstrable benefit in various forms of human cancer have displayed activity against one or more animal tumors. Mr. Chairman, if you wish, I will submit for the record a more detailed account of all NCI tests of Laetrile.

As I have indicated earlier, the final definitive evaluation of the effectiveness of a cancer drug can be determined only in carefully conducted clinical trials. Because of the animal test results, Laetrile never reached this stage of NCI testing. In addition, the many patients treated legally with Laetrile in other countries and illegally in this country have not been studied in a fashion that permits any objective conclusions to be made concerning either antitumor effect or toxicity. The claims of clinical effectiveness made by Laetrile proponents have been based on incomplete case histories or anecdotal and testimonial reports which cannot be evaluated objectively.

The current promotion of Laetrile flies largely under the flag of "freedom of choice" in cancer treatment. Yet the choice presented to the often frightened, confused and anxious patient is specious and serves actually to narrow the real choices. Laetrile proponents tell patients

they can either accept Laetrile, which they call a "harmless, natural, effective" remedy (even though Laetrile is known to be poisonous if taken incorrectly by mouth), or submit to surgery, x-ray and chemotherapy, which they characterize as "cutting, burning and poisoning." In these terms it is not difficult to appreciate the appeal of Laetrile to cancer patients.

In truth, the proven cancer treatments, surgery, radiotherapy and chemotherapy, are often attended by unpleasant side effects--but they do indeed cure. The side effects are manageable, however, and nearly always of brief duration. All of the advances made in cancer treatment--abundantly documented in the medical literature--are due to the use of these treatment methods.

The cancer patient should have freedom of choice to seek out the best qualified physician or physicians and to obtain more than one opinion. He should and does have the freedom to demand information about his problems and the solutions proposed. This will constitute the basis for informed consent. I do not believe that cancer patients are afraid to make tough choices, if they have an honest appraisal of what those choices mean for them.

At the National Cancer Institute, we have been gravely concerned that so many cancer patients in this country have chosen to use this unproven remedy for cancer. We are concerned that the number of patients who do so will increase as more and more states legalize the substance. Many of these patients have used and will use Laetrile as a substitute for known medical treatments that might cure their cancers or prolong

their lives. Because of this situation, medical experts at NCI and elsewhere have reluctantly concluded that a clinical trial of Laetrile should be considered. The results of such a trial, if negative as we expect they would be, would not convince the most avid proponents of Laetrile, but would be of value to state legislators and to physicians who care for cancer patients.

The ethical, moral and legal implications of testing in humans a compound proved to be of no value in animals has made even consideration of a clinical trial of this compound controversial. Dr. Frederickson has discussed these implications in detail in his testimony.

As we have considered a trial of Laetrile in humans, many alternative approaches have been discussed. These range from the view that we should do nothing beyond the animal tests already conducted to the view that a clinical trial be conducted immediately. Another alternative is to oversee, but not finance, independent trials conducted by major cancer centers.

So far, our thinking leads us to favor a fourth option. This would lead us to establish a Consensus Development Group that would assess the ethical issues and feasibility of mounting a clinical trial by the National Cancer Institute. This Group would grapple with the ethical issue of conducting a clinical trial of a compound that does not meet current scientific standards of acceptability.

The cost of taking this approach should be relatively low, and it should not take an inordinate amount of time. In addition, the issues to be examined are worthy of scrutiny by the research and medical community,

as well as by the public, even if there ultimately is a decision not to go ahead with a clinical trial. If the Group's deliberations result in recommendation of a clinical trial, such a trial could be undertaken with FDA approval. As support for the deliberations of the Consensus Development Group, we could also attempt to acquire and analyze clinical data from reputable physicians who will use Laetrile in therapy because their states have legalized it.

Mr. Chairman, that completes my prepared statement. I will be happy to answer any questions from you and members of the Committee.

A STATEMENT CONCERNING LAETRILE

Lewis Thomas, M.D.
President, Memorial Sloan-Kettering
Cancer Center, New York.
Professor of Medicine and Pathology,
Cornell University College of Medicine.
Member, National Academy of Sciences.

July 12, 1977

1.

Although there is nothing new about the Laetrile phenomenon in the sense that other purported "cancer cures" have periodically achieved wide publicity and some measure of public credibility (the outstanding example in recent years was "Krebiozen") - the increasingly widespread use of Laetrile and its recent legalization by several State legislatures have created a unique and unprecedented situation. The number of cancer patients now under "treatment" with Laetrile is not known with any accuracy, but reports in the press have suggested that it is already in excess of 100,000. Moreover, the public relations effort on behalf of Laetrile seems to have convinced some people - the number is entirely unknown - that the material is somehow to be classed as a vitamin and has cancer-preventive properties; if this effort at deception succeeds, the number of people who will be buying Laetrile is simply incalculable.

Meanwhile, there is not a particle of scientific evidence, as this term is customarily understood, to suggest that Laetrile possesses any anti-cancer properties at all. I am not aware of any scientific papers, published in any of the world's accredited journals of medical science, presenting data in support of the substance, although there are several papers, one of these recently made public by the Sloan-Kettering Institute, reporting the complete absence of anti-cancer properties in a variety of experimental animals.

The public testimonials attesting to the value of Laetrile which have been circulated by its supporters are all in the form of isolated anecdotes about individual patients, unaccompanied by any of the sorts of detailed information required for scientific evaluation. Generally lacking are such details as the histological classification of the neoplasm, the precise nature of other treatments (surgery, radiation, chemotherapy) received by the same patients, and the clinical prognosis which each case would have carried in the absence of Laetrile. Moreover, there is no information whatever concerning the long-term outcome in the vast majority of the patients for whom

beneficial effects have been claimed.

It is not difficult to explain the existence of individual testimonials favoring Laetrile. Cancer is a much more variable disease in its clinical course than the public has been led to believe. A great many patients with the diagnosis have been totally cured by today's conventional therapy, and in many others in whom cure is not possible the disease may persist in arrested form for periods of several years without symptoms. Moreover, cancer is not usually a painful illness, and when there is pain associated with cancer it is often controllable by conventional analgesic drugs.

However, cancer is something very different in the minds of a great many people. For many patients and their families, the very word cancer is perceived as a death sentence. It is widely believed to be an inexorable and agonizing process, with no way out but death. Moreover, there are the wildest misconceptions about the current methods for treating cancer, especially with respect to the side-effects of chemotherapy which tend to be grossly exaggerated in the literature disseminated by the advocates of Laetrile.

Because of these misapprehensions about the nature of cancer and its treatment, many people are vulnerable to propaganda by vendors of various cancer "cures". Since a large number of patients who have been treated by conventional therapeutic methods are inevitably going to do well, some for periods of a few years and some for a normal life span, and since some of these same patients have been persuaded to take Laetrile as well, their testimonials are added to the pro-Laetrile propaganda.

It is noteworthy that the marketers of Laetrile have tended to moderate their claims for the substance in recent years. It is no longer openly claimed that Laetrile cures cancer, although some of the leaflets and public releases hint broadly in this direction. Currently, the major claims seem to be that pain is dramatically

3.

relieved, and that patients undergo a marked improvement in their general sense of well-being.

It is often asserted that since Laetrile is not a particularly toxic substance it should be made available to all patients who wish to use it, as a matter of free choice. There is, however, a very real danger here. If, for example, children with early leukemia or sarcoma, or women with cancer of the breast, or young men with Hodgkin's disease, are persuaded to give Laetrile a trial before doing anything else, the outcome will almost certainly be death, in circumstances where appropriate therapy could be life-saving. There are already instances where this is known to have happened, in various parts of the country, and they will very likely increase if the material becomes more widely used. In this sense, Laetrile can fairly be regarded as a lethal drug.

In normal circumstances, one would not advocate clinical studies in human beings for any drugs unless scientific research in experimental animals or cell cultures gave some reason for expecting benefit. This is not the case with Laetrile, but these are not normal circumstances. The material is already in wide use, and its use appears to be spreading further each week; it has received official sanction from several State governments; an increasing segment of the public has been persuaded that it may be beneficial and is therefore worth a try. All this has happened in the absence of any real data. There exists no solid information about its effects on humans, beyond the likelihood that it is not, in itself, toxic.

For these reasons, it is now essential that the public is provided with solid information about Laetrile, based on scientific facts.

There are two possible courses that could be taken, rather quickly.

1. An epidemiological study of a statistically significant sample of patients who have already been treated with Laetrile should be

4.

launched. Many such patients are known to their private physicians, and information is probably available, for some of them, concerning the microscopic nature and extent of the tumor, the stage of the disease, and the details of other treatments if any, including surgery, radiation and chemotherapy.

If a sufficient sample of cases with this level of information can be located, it should be possible to determine whether the course of the illness was, or was not, significantly altered by Laetrile.

This kind of retrospective study could not in itself be conclusive, because of the absence of controls within the same study. Nevertheless, it might be capable of revealing whether or not there is any basis in truth for the most strident of the claims made by the sellers of Laetrile, e.g. the disappearance of tumors, the prolongation of active life, relief of intractable pain, and restoration of a feeling of good health.

2. A clinical trial of Laetrile in cancer patients should be planned, under sponsorship and supervision by the National Cancer Institute. This ought to involve at least three major Cancer Centers. It should be a "double-blind" study, in which neither the patients nor physicians will know whether Laetrile or another substance are being administered. It should be aimed at answering the central questions about Laetrile: does it relieve pain, prolong life, cure cancer?

On ethical grounds, it would not be possible to treat any patient with Laetrile alone, if there are other forms of therapy conceivably beneficial for that patient. Therefore, for most of the patients to be studied, any clinical trial would have to involve Laetrile as an add-on to other treatment. This is a serious but unavoidable limitation. Even so, the key questions about pain relief and well-being could undoubtedly be answered, and such answers would tell us, at least, whether the substance provides any clinical benefits at all.

But there is one overriding problem which will have to be settled before any sort of clinical testing can be undertaken by anyone.

5.

What, exactly, is it that is to be tested under the name of Laetrile? There are, by some accounts, any number of quite different preparations carrying this label, out in the marketplace, and they differ from each other chemically in fundamental respects. They cannot all be tested. Unless the advocates of the treatment can provide a single, standardized preparation, on which they will agree to base their claims of benefit to cancer patients, the prospects for scientific evaluation of Laetrile are so remote and the results would be so inconclusive that the undertaking is hardly worth the considerable effort that would be involved.

If there is to be a clinical trial of Laetrile, the data should eventually be reviewed and evaluated by a special committee, composed both of clinicians with general experience in clinical science and lay persons with sagacity and good common sense. It is of importance that this committee be recognized as fair minded and without vested interest one way or the other, for if the results are negative there will surely be accusations of bias from the marketers of Laetrile. It has to be remembered that an enormous amount of money is being made from Laetrile, and the stakes for those who now control this market are very high indeed.

96-492 O - 77 - 5

THE HARMFUL EFFECTS OF LAETRILE, APRICOT KERNELS AND OTHER CYANOGENIC FRUIT AND VEGETABLE MATERIALS ON HUMAN BEINGS; AND THE INEFFECTIVENESS OF LAETRILE AS A THERAPEUTIC AGENT IN PATIENTS WITH CANCER

SUMMARY STATEMENT

APPENDICES

1. J. F. Ross Curriculum Vitae and Bibliography
2. Acute Toxicity of Laetrile to Humans
3. "The Cyanide Cook Book"
4. Chronic Toxicity of Cyanogenic Material
5. Patients Treated with Laetrile Observed at UCLA Hospital
6. California Cancer Advisory Council Reports of Evaluation of Records of Laetrile Treated Patients Submitted by Proponents and of Published Reports
7. Cancer Commission of California Medical Association Evaluation of Patients Treated with Laetrile
8. Sampson & William manuscript Reporting Ineffectiveness of Laetrile Therapy of Cancer and Indicating Such Therapy May Shorten Life Span

THE HARMFUL EFFECTS OF LAETRILE, APRICOT KERNELS AND OTHER CYANOGENIC FRUIT AND VEGETABLE MATERIALS ON HUMAN BEINGS; AND THE INEFFECTIVENESS OF LAETRILE AS A THERAPEUTIC AGENT IN PATIENTS WITH CANCER

A Statement Presented to the
U.S. Senate Subcommittee on Health and Scientific Research
July 12, 1977

Joseph F. Ross, M.D.

INTRODUCTION

PERSONAL IDENTIFICATION AND CREDENTIALS: I am Joseph F. Ross, M.D., Professor of Medicine at the UCLA School of Medicine, Los Angeles, California. I am licensed to practice medicine in the states of California and Massachusetts. I received my M.D. Degree from Harvard Medical School in 1936 and received extensive training in cancerous diseases at the Huntington Memorial Hospital of the Harvard Cancer Commission, the Mallory Institute of Pathology and the Harvard Medical Service of the Boston City Hospital; and at the University of Rochester School of Medicine and Hospital. I am certified as a specialist in Internal Medicine by the American Board of Internal Medicine and as a specialist in Nuclear Medicine by the American Board of Nuclear Medicine. At present, I am a member of each of these Boards and also of the American Board of Medical Specialties. I was a member of the National Advisory Cancer Council from 1956 to 1960, and subsequently have served on numerous committees of the National Cancer Institute until the present time. I have been a member of the California State Department of Health Cancer Advisory Council since 1959 and was Chairman from 1963 to 1967, and from 1975 to 1977.

I have devoted my professional life to the diagnosis and treatment of neoplastic diseases, primarily of the hematopoietic system, and to research on the nature, mechanisms and treatment of these diseases. I teach medical students and physicians about cancer and the medical management of patients

with cancer. I am Director of the United States Public Health Service-funded Training Program in Hematology and Hematologic Oncology at UCLA. I am actively engaged in the treatment of patients with cancer. Details of my professional activities are provided in Appendix 1.

MY QUALIFICATIONS IN REGARD TO LAETRILE AS A CANCER TREATMENT: Since 1959, I have been concerned with the problems caused by the advocacy of Laetrile as a cancer treatment and have amassed a large amount of factual information concerning Laetrile and related compounds, and their effects on human beings, and their ineffectiveness as therapeutic agents in humans and in animals with cancer. I have observed and studied many patients who had been treated by others with Laetrile.

Today I will comment on the effects of Laetrile and related materials (apricot kernels, "Vitamin B-17," and other cyanogenic materials) on human beings. First, I will discuss the dangerous nature of these materials and their potential for causing serious illness and death. Second, I will comment on my observations and studies indicating the ineffectiveness of these materials in the treatment of cancer. I hope that this information will be helpful to the Subcommittee in its consideration of the problems relating to legitimization of Laetrile as a cancer therapeutic or preventative substance. I believe the best interests of the American people will be served by support of the position of the U.S. Food and Drug Administration concerning these materials.

THE DANGEROUS EFFECTS OF LAETRILE AND CYANOGENIC PLANT MATERIALS ON HUMAN BEINGS

ACUTE POISONING: Laetrile or Amygdalin is one of several chemically-related compounds occurring naturally in the kernels and seeds of certain plants and in the tubers of the cassava. These compounds are similar in their effects

on the body. They contain cyanide as a constituent part of their structure, and when these compounds in the presence of beta-glucosidase enzymes contained in food stuffs are subjected to digestive processes in the gastrointestinal tract of human beings or animals, they release cyanide (hence, the generic name "cyanogenic" compounds). When released in the gastrointestinal tract, cyanide is rapidly absorbed into the body, and interferes with the body's ability to use oxygen, producing cyanosis, dizziness, stupor, coma, nausea, vomiting, drop in blood pressure, shock and death. When given by intravenous injection the fate of these materials is obscure and they are less toxic than when ingested. However, some of the symptoms described above follow intravenous injection.

The proponents of Laetrile have stated that it is harmless. This statement is contrary to fact as illustrated by the following tabulation.

Summary of Cases of Poisoning
by Laetrile and Cyanogenic Fruit Kernels

Product	Cases of Poisonings	Death
Laetrile	1	1
Apricot Kernels	18	3
Bitter Almonds	5	5
Peach Kernels	4	4
Wild Choke Cherry Kernels	5	1
Sweet Cherry Kernels	2	1
Prune Kernels	2	2
Total	37	17

These cases have occurred sporadically, since the materials involved have been proscribed by law, or are recognized as poisonous by the populations of foreign nations. Should they be made generally available and advocated as beneficial to humans, the number of cases may be expected to increase. An example of such advocacy is given in Appendix 3. Additional documentation of these poisonings and deaths is provided in Appendix 2.

The most recent of these fatal cases is very informative of the tragic consequences of Laetrile poisoning, and the symptoms, mechanisms, and pathologic changes caused by Laetrile. A 10-month-old infant ingested

one to five of her father's 500 mgm Laetrile tablets, and rapidly became listless, developed symptoms of vomiting, stupor, coma and shock. Her blood contained significant amounts of cyanide. In spite of vigorous and informed therapy, she died 72 hours after the ingestion of the Laetrile. The medical examiner's autopsy findings of "extensive anoxic brain damage due to acute cyanide poisoning due to Amygdalin ingestion" describes the mechanism by which Laetrile causes death. Certainly an agent which causes tragic deaths such as this cannot be considered harmless. (With the permission of Dr. James R. Humbert, his letter to the editor of the JAMA is reproduced in Appendix 2A.)

CHRONIC POISONING BY CYANOGENIC MATERIALS: Proponents of Laetrile and "Vitamin B-17" and "Aprikern" (apricot kernels) now advocate continuing long-term ingestion of these materials as cancer preventatives. There is strong probability that such use, in addition to possibly causing acute toxic effects, will result in chronic poisoning similar to the poisoning produced by the ingestion of cassava root. Cassava contains a cyanogenic compound with chemical similarities to Laetrile and is believed to be responsible for a severe degenerative disease of the nervous system known as Tropical (Nutritional) Ataxia which frequently is seen in Nigeria and other areas where cassava root is a staple food. The release into the gastrointestinal tract over a prolonged period of time of cyanide from apricot kernels certainly has the potential for causing a similar neurological degenerative disease in American citizens (Appendix 4).

Chronic ingestion of cassave root also poisons the thyroid gland with resultant goiter and a potential for an increase in the incidence of thyroid cancer. Additionally, there is evidence that birth defects may develop in the offspring of mothers ingesting cyanogenic materials during pregnancy. (Appendix 4)

THE DANGER OF DEFERRAL OF EFFECTIVE CANCER THERAPY BY CANCER PATIENTS WHO UNDERGO LAETRILE THERAPY:

In the majority of cancer, the more promptly effective treatment is started the better is the chance of cure or prolongation of useful life. Thus deferral of conventional therapy to take Laetrile therapy costs lives and causes great misery. Examples of two such tragedies that I have personally observed are illustrated by cases R.L. and E.S. in Appendix 5. Both these patients had the alternative of accepting conventional therapy with a good expectancy of years of useful life but instead were persuaded to take Laetrile with resulting development of cord compression and paralysis from lymphoma in R.L. and of a fatal fungating cancer of the breast in E.S. Legitimization of Laetrile therapy will eventuate in many more such tragic cases. Active solicitation of cancer patients by the proponents of Laetrile diverts many unfortunate patients from conventional cancer therapy and preys most cruelly on the unsophisticated and underprivileged.

THE USELESSNESS OF LAETRILE
IN THE TREATMENT OF CANCER

Evidence that Laetrile is without benefit in the treatment of human cancer has been obtained by objective observation by qualified investigators of patients who have been treated with Laetrile and by review of records of patients who have been treated with Laetrile, which have been submitted by proponents of Laetrile therapy as exemplifying the benefits of such treatment, and by review of published reports of Laetrile treatment of cancer.

Such observations must be compared and weighed against the anecdotal and scientifically unsubstantiated claims of the proponents of Laetrile and of persons who claim that they have benefitted from such therapy.

OBSERVATIONS OF LAETRILE PATIENTS SEEN AT UCLA:

A representative sample of 5 cancer patients of the many who have been observed in the UCLA Hospital after having elected to take Laetrile rather than conventional therapy or who have elected to substitute Laetrile therapy or to take Laetrile in addition to conventional therapy , are tabulated in Appendix 5. Cases R.L. and E.S. (referred to above) exemplify the disastrous effects of electing Laetrile therapy rather than conventional therapy while cases S.C., N.P. and D.L. illustrate the uselessness of Laetrile to modify the course of the disease when used in conjunction with conventional therapy or when interspersed with such therapy.

EVALUATION OF CASE REPORTS SUBMITTED BY THE PROPONENTS OF LAETRILE AS EXEMPLIFYING THE BENEFICIAL EFFECTS OF LAETRILE THERAPY:

Table I presents a summary of 9 reports of evaluation of Laetrile in cancer therapy. 1009 patients have been reported, although many of these reports are inadequate for scientific clinical evaluation. No valid evidence of objective improvement of these patients attributable to Laetrile is presented. Some patients may have had subjective improvement, although this is very difficult to establish and if it occurred may have been attributable to placebo effect or to benzaldehyde. A report of the evaluation of such cases is presented in Appendix 6.

Fifty of these cases were carefully reviewed by competent oncologist members of the California Cancer Advisory Council. There is not one shred of evidence indicating that Laetrile therapy had any benefit in the alleviation, palliation, or control of cancer! And yet these were cases that the proponents of Laetrile provided as examples of the benefits to be expected from such therapy.

Similarly, an evaluation of 44 Laetrile cases by the Cancer Commission

of the California Medical Association in 1953 indicated that Laetrile had no beneficial effect on the patients so treated and that autopsy studies did not reveal any histological or cytological change that could be attributed to Laetrile treatment. A photocopy of this report is enclosed in Appendix 7.

Very recently Drs. Saunders and Williams in a preliminary report* to the FDA have provided evidence that patients treated with Laetrile have a shorter life span than a "control" group of patients who were not treated with Laetrile. These observations have not yet been confirmed by other investigators but they are suggestive that not only does Laetrile not prolong life, but may actually shorten it! Further studies are necessary to establish this observation.

*With Dr. Saunders' permission, a copy of this report is provided as Appendix 8.

SUMMARY

There is ample scientific evidence that Laetrile is a toxic material which is potentially lethal when ingested, and may produce adverse symptoms when injected.

Observation of patients treated with Laetrile and review of cases purporting to show the benefits of such therapy indicate that there is no scientific evidence of objective or unequivocal subjective benefit of cancer patients subjected to this therapy. There is ample evidence that administration of Laetrile therapy instead of conventional therapy results in needless deaths and great suffering. It is my opinion that legitimization of Laetrile and its related compounds would be deleterious to the health and well being of the American people, and that the regulations of the FDA in regard to these materials are wise and should be continued.

TABLE I

SUMMARY AND EVALUATION OF REPORTS OF CANCER PATIENTS TREATED WITH LAETRILE

Author	Reference	Year of Report	# of Cases	Comments
California Cancer Advisory Council	1	1963 1965	36 14	Review of case reports submitted by McNaughton Foundation as evidence of the efficacy of Laetrile in treatment of cancer. The Council found no evidence of therapeutic or palliative benefit from the Laetrile therapy.
Cancer Commission of the California Medical Association	2	1953	44	"All patients either have active disease or are dead of their disease, with one exception." (Cervical lesion probably entirely removed by biopsy.) Of those alive with disease, no patient has been found with objective evidence of control of cancer under treatment with Laetrile alone. Autopsy histological studies have shown no evidence of any chemotherapeutic effect."
Marco Tosco	3	1958	21	All patients died; some questionable evidence of subjective improvement. Little or no evidence of objective improvement. Duration of illness consistent with natural history of the disease. No prolongation of life.
Navarro	4	1956 1958 1959 1962 1970	17	Patients treated with conventional treatment as well as Laetrile; objective evidence of benefit from Laetrile is not presented. Not possible to corroborate report of subjective improvement.

TABLE I

Author	Reference	Year of Report	# of Cases	Comments
Morrone	5	1962	10	Inadequate reports: no histological diagnosis of cancer in two cases. Impossible to determine how much and how long Laetrile administered. Impossible to determine outcome of cases or duration of survival.
Contreras	6	1970	702	Sixty-two died of undetermined cause within three weeks of start of Laetrile therapy. Only 23 patients (3%) alive at end of one year. The author's claim of 30 - 35% "response rates" in certain cancers is not substantiated by data presented nor by the 97% deaths in one year.
Nieper	7	1971	60	Not possible to attribute any response or benefit to Laetrile, since multiple therapies employed simultaneously. Survival does not appear to be prolonged, but adequate control data not provided.
Richardson & Griffin	8	1977	90	These case histories were prepared and evaluated by Patricia Griffin, R.N., B.S. and do not fulfill criteria of objective clinical evaluation. They are presented as promotional material for Laetrile therapy for the Richardson Clinic. Many erroneous statements and unsupported claims are made and false conclusions are drawn. Patient testimonials are a major component of the reports. This cannot be considered an objective report.
Sampson & William	9	1977	15	Laetrile therapy in addition to conventional therapy. No remission, no objective improvement compared to controls. Life span less than controls. Other studies necessary to corroborate [illegible]

TABLE I

References

1. Report of Cancer Advisory Council: Treatment of Cancer with Beta-Cyanogenic Glucosides (Laetriles) 1963 and Supplement of 1965, State of California Department of Health.

2. California Medicine 8 320-326, 1953.

3. Gazetta Medico Italiano April 1958, p. 3.

4. Santo Tomas Journal of Medicine: 10 : 113, 1955;
   25 : 125, 1970.

   Acta Union Contra Cancer 15 : Suppl : 209, 1959.

5. Exp. Med. Surg 20 : 299, 1962.

6. Manuscript in preparation for publication.
   Copy in California State Department of Health.

7. Z. Blut u Geschwulstkrankh 3 H. 1, 7, 1971.
   also manuscript with California State Department of Health.

8. Laetrile Case Histories, Richardson & Griffin,
   Bantam Books, 1977.

9. Report to F.D.A., 1977, and manuscript appended.

APPENDIX 1

J O S E P H F. R O S S, M. D.

CURRICULUM VITAE

FEBRUARY, 1977

JOSEPH FOSTER ROSS, A.B., M.D.

ADDRESS: Office: Department of Medicine
School of Medicine
University of California, Los Angeles

Telephone: 213 - 825-6787

Home: 11246 Cashmere Street
Los Angeles, California 90049

Telephone: 213 - 472-9890

BORN: October 11, 1910
Azusa, California

PARENTS: Father: Verne Ralph Ross, A.B., A.M., Ed.D., Born Donnellson, Illinois
Occupation: High School Principal, Covina, California

Mother: Isabel Mills Bumgarner, A.B., A.M., Born McNabb, Illinois
Occupation: High School Teacher and Librarian

MARRIAGE: December 19, 1942. Eileen Sullivan, B.S., M.A. Born Boston, Massachusetts
Occupation: School Teacher

CHILDREN:

Louisa	-	Born April 21, 1944
Elisabeth	-	Born March 7, 1946
Joseph	-	Born July 21, 1948
Jeanne	-	Born October 2, 1951
Marianne	-	Born August 30, 1954

RELIGION: Presbyterian

EDUCATION: Covina Union High School, Covina, California, 1925-1929
Graduated "With Highest Honors" 1929

Leland Stanford Junior University, Palo Alto, California, 1929-1932
A.B. "With Great Distinction" 1933

Harvard Medical School, Boston, Massachusetts - 1932-1936
M.D. "Cum Laude - With Special Honors in Physiology" - 1936

CURRICULUM VITAE (Continued)

JOSEPH F. ROSS, M.D.

CLINICAL TRAINING:

Huntington Memorial Hospital of the Harvard Cancer Commission - Dr. Joseph C. Aub, Chief of Medicine, Boston, Massachusetts

House Officer, 1934-1935

Palmer Memorial, New England Deaconess Hospital - Dr. Elliot P. Joslin, Chief of Medicine, Boston, Massachusetts

House Officer, 1935-1936

Mallory Institute of Pathology, Boston City Hospital, Dr. Ted Parker, Jr., Director, Boston, Massachusetts

Resident in Pathology, 1936-1937

II Medical Service (Harvard) Boston City Hospital, Dr. Soma Weiss, Director, Boston, Massachusetts

House Officer, September 1937-April 1939

Strong Memorial Hospital of the University of Rochester School of Medicine, Dr. George H. Whipple, Dean and Chief of Pathology, Rochester, New York

Intern in Pathology, July 1939-July 1940

MEDICAL LICENSURE:

Massachusetts 1941 - License No. 19163

California 1954 - License No. C16521

SPECIALTY CERTIFICATION:

American Board of Internal Medicine - Certified 1943
Diploma No. 2231

American Board of Nuclear Medicine:

Founding Member, Secretary - 1971-1973

President and Chairman - 1973-1976

Certified - 1976

CURRICULUM VITAE (Continued)

JOSEPH F. ROSS, M.D.

ACADEMIC APPOINTMENTS:

Harvard Medical School:

Chief Prosector, 1933-1934
Assistant in Topographical Anatomy, 1934-1937
Tutorial Student in Physiology, 1935-1936
Research Fellow in Biochemistry, 1943-1946

University of Rochester School of Medicine:

Assistant in Pathology, 1939-1940

Boston University School of Medicine:

Instructor in Medicine, 1940-1942
Assistant Professor of Medicine, 1942-1945
Associate Professor of Medicine, 1945-1954

University of California at Los Angeles School of Medicine:

Associate Dean, 1954-1958
Professor of Medicine, 1954 to Present
Professor of Radiology (Radiobiology), 1954-1960
Professor of Biophysics and Nuclear Medicine, 1960-1965
Director, Laboratory of Nuclear Medicine and Radiation Biology, 1958-1965
Chairman, Department of Nuclear Medicine and Radiation Biology, 1958-1960
Chairman, Department of Biophysics and Nuclear Medicine, 1960-1965
Chief, Division of Hematology, 1969-1974
Director, Hematology Research Training Program, 1969 to Present
Coordinator for Hematology, 1974 to Present

SCHOLARSHIPS AND FELLOWSHIPS:

Leland Stanford Junior University
Cranston Scholar, 1929-1930

Harvard Medical School
Cheever Scholar, 1932-1933
Fellow in Biochemistry, 1943-1946

National Research Council, Division of Medical Sciences
Welch Fellow in Internal Medicine, 1943-1946

CURRICULUM VITAE (Continued)

JOSEPH F. ROSS, M.D.

TEACHING ACTIVITIES:

Harvard Medical School:

Instruction in Topographic Anatomy - 1934-1937
Tutorial Instruction in Physiology - 1936
Seminar Instruction in Biochemistry - 1943-1946

University of Rochester School of Medicine:

Instruction in General Pathology - 1939-1940

Boston University:

Director of Hematology & Nuclear Medicine Instruction - 1941-1954
Course Chairman, Clinical Pathology - 1948-1954
Director of American College of Physicians Graduate Course in Hematology - 1953

University of California, Los Angeles:

Instruction in General Internal Medicine and Hematology - 1955 to Present
Course Chairman, Biophysics, 1958-1965
Chairman, Graduate Education in Biophysics, Radiation Biology & Nuclear Medicine - 1958-1965
Course Chairman, Laboratory Medicine - 1968-1971
Course Chairman, Hematology Section, Pathophysiology of Disease - 1971 to Present
Director, Hematology Research Training Program - 1970 to Present
Instruction in Nuclear Medicine, Wadsworth VA Hospital - 1955 to Present
Director, American College of Physicians Graduate Course in Nuclear Medicine - 1964
Instruction in Society of Nuclear Medicine Graduate Course in Nuclear Medicine - 1972

CURRICULUM VITAE (Continued)

JOSEPH F. ROSS, M.D.

HONORS AND DISTINCTIONS:

Citation by the President of the United States -

Certificate of Merit, of the Medal for Merit Board, awarded by President Harry S. Truman, March 1948 - "Awarded in recognition of outstanding services from July, 1943 to December, 1945 in the field of blood preservatives under a research contract between the Office of Scientific Research and Development and the Massachusetts Memorial Hospitals, which was initiated at the request of the National Research Council and proved to be an invaluable contribution to the war effort of the United States."

Recipient of the Van Meter Prize of the American Goiter Society -

With Dr. Belton A. Burrows in 1953 for investigations of Thyroid Physiology and Pathology, Employing Radioactive Tracer Techniques.

Gordon Wilson Medalist of the American Clinical and Climatological Association for work on the Effects of Ionizing Radiation in Man - 1964

"Nuclear Pioneer Lecturer" of the Society of Nuclear Medicine - 1970

Boston City Hospital Centennial Citation for "Distinguished Achievement in Medicine" - 1964

Elected President or Chairman of the Following Organizations:

American Society of Hematology - 1961-1962
American Blood Club - 1957-1958
Western Association of Physicians - 1962-1963
Society of Nuclear Medicine - -
Southern California Chapter - 1962-1963
American Board of Nuclear Medicine - 1973-1976
State of California Cancer Advisory Council - 1963-1966; 1975-1977
NCI Cancer Special Programs Advisory Council - 1967-1971
National Colon-Rectal Cancer Advisory Council - 1972-1975
United Presbyterian Church, Westminster Foundation of Southern California - 1966-1968
United Ministry for Higher Education of Southern California - 1966-1968
Bay District Los Angeles County Medical Association - Vice President, 1975-1977

CURRICULUM VITAE (Continued)

JOSEPH F. ROSS, M.D.

HONORS AND DISTINCTIONS: (Continued)

Represented the United States Department of State and/or the United States Atomic Energy Commission on Five Official United States Missions to Foreign Countries:

A Scientific Member of the United States Delegation to the International Conference on Peaceful Uses of Atomic Energy in Geneva in 1955.

A Scientific Member of the "Atoms for Peace Mission" to Latin America in 1956.

A Scientific Member of "Health Sciences Mission" to the Governments of Greece and Turkey, 1961.

Member, "CENTO Science Mission" to Iran, Turkey and Pakistan - February-March 1963.

Member of the United States Atomic Energy Commission Scientific Mission to USSR. "Tracer Applications of Radioisotopes" - October 6-22, 1966.

HONORARY SOCIETIES:

Phi Beta Kappa, Leland Stanford University - 1933
Alpha Omega Alpha, Harvard Medical School - 1935
Boylston Society, Harvard Medical School - 1935
Begg Society, Boston University School of Medicine - 1942
Sigma Xi, Boston University - 1951
American Academy of Arts and Sciences - 1953.

SOCIAL FRATERNITIES AND SOCIETIES:

Theta Xi Fraternity, Leland Stanford University - 1930
Nu Sigma Nu Fraternity, Harvard Medical School - 1933
Aesculapian Club, Harvard Medical School - 1940
Harvard Club of Boston - 1940
Bel Air Country Club, Los Angeles - 1957
Cosmos Club, Washington, D.C. - 1960

CURRICULUM VITAE (Continued)

JOSEPH F. ROSS, M.D.

COMMUNITY AND CIVIC ACTIVITIES:

Lawrence School of Brookline - President of Family-School Association, 1953-1954
University Elementary School, University of California, Los Angeles Advisory Committee, 1957-1959
Beverly Hills Y.M.C.A., Board of Directors, 1959-1963
United Presbyterian Church in the U.S.A., Westminster Foundation of Southern California:
- Member, Executive Committee - 1962-1968
- Vice President - 1964-1966
- President - 1966-1967
- Chairman, Personnel Committee - 1965-1966
- Member, Advisory Committee to UCLA - 1959-1966
- Chairman - 1962-1964

United Ministry to Higher Education of Southern California, President - 1966-1968
Brentwood Presbyterian Church:
- Commission on Christian Education - 1964-1966
- Music Committee - 1964-1957
- Committee on Mission Programs - Chairman, 1966-1967

Westwood Presbyterian Church, Ruling Elder 1977 - 1980
Presbytery of the Pacific:
- Christian Education Committee - 1970-1973

Los Angeles Chamber Music Society - 1970 to Present
Los Angeles County Museum of Art - 1965 to Present

EDITORIAL ACTIVITIES:

"Blood: The Journal of Hematology"
- Assistant Editor - 1946-1950
- Abstract Editor - 1946-1955
- Associate Editor - 1950 to Present

"Journal of Nuclear Medicine"
- Member of Editorial Board - 1970-1974

Little, Brown and Company, Medical Book Division:
- Editorial Board - 1958-1968

"Annals of Internal Medicine"
- Editorial Board - 1960-1970

University of California Press, Medical Book Series:
- Advisory Committee - 1961-1971

DIRECTORY LISTINGS:

Who's Who in America
American Men of Science
Director of Medical Specialties
American Medical Association Directory
Who's Who in the West
Who's Who in American Education
Leaders in American Science

CURRICULUM VITAE (Continued)

JOSEPH F. ROSS, M.D.

SCIENTIFIC AND PROFESSIONAL ORGANIZATIONS (And Year of Election):

General Scholarly Organizations:

American Academy of Arts and Sciences - 1953

General Professional Organizations:

American Medical Association - 1941
Section on Experimental Medicine and Therapeutics,
Representative to Scientific Exhibit, 1952-1962

Massachusetts Medical Society - 1941

California Medical Association - 1958; Adv. Panel Int. Med., 1974-

Los Angeles County Medical Association - 1958

American Association for the Advancement of Sciences - 1943
Fellow - 1952

New York Academy of Sciences - 1944
Fellow - 1957

American Board of Medical Specialties - 1971 to Present

ACADEMIC AND RESEARCH ORGANIZATIONS:

Internal Medicine:

American Society for Clinical Investigation - 1942
Nominating Committee - 1957

Association of American Physicians - 1950

American Federation for Clinical Research - 1941

American College of Physicians - 1950
Chairman, Committee on Panels - 1950

American Society of Internal Medicine, Honorary Member - 1954

Western Association of Physicians:
Secretary-Treasurer - 1956
President - 1962-1963
Nominating Committee Chairman - 1964-1965; - 1967-1968

Western Society for Clinical Research - 1964

California Society of Internal Medicine, Honorary Member - 1956

Los Angeles Society of Internal Medicine - 1955

Los Angeles Academy of Medicine, Honorary Member - 1965

American Board of Internal Medicine - 1975- 1980

CURRICULUM VITAE (Continued)

JOSEPH F. ROSS, M.D.

ACADEMIC AND RESEARCH ORGANIZATIONS: (Continued)

Hematology and Oncology:

American Society of Hematology: - 1957
Executive Committee - 1957-1959
Vice President - 1959-1960
President-Elect - 1960-1961
President - 1961-1962
Advisory Council - 1962-1966
Chairman - 1962-1963
By-Laws Revision Committee - 1969-1973
Chairman - 1971-1973

European Society of Hematology - 1952

International Society of Hematology, Fellow - 1947
Constitutional Committee - 1947-1948

American Blood Club - 1946
Secretary-Treasurer - 1947-1948
Chairman - 1957-1958
Vice-Chairman - 1965-1966

Leukemia Society, Inc. - 1959-1964
National Medical Advisory Board - 1959-1964
Los Angeles Chapter, Medical Advisory Committee - 1961-1962

New England Cancer Society - 1958

Nuclear Medicine, Radiation Biology, Biophysics:

American Board of Nuclear Medicine:
Proponents of Board, Secretary - 1968-1971
Founding Member - 1971 to Present
Secretary of the Board - 1971-1973
President and Chairman - 1973-1976

Society of Nuclear Medicine: 1956
National Society:
Board of Trustees - 1962-1972
Committee on Legislation - 1963-1966
Program Committee, Chairman - 1966-1967
Committee on By-Laws, Chairman - 1966-1969
Committee on Publications - 1966-1970

Southern California Chapter:
Secretary-Treasurer - 1962-1963
Vice President - 1963-1964
President - 1964-1965
Executive Committee - 1965-1966
Nominating Committee, Chairman - 1964-1965; 1967-1968

CURRICULUM VITAE (Continued)

JOSEPH F. ROSS, M.D.

ACADEMIC AND RESEARCH ORGANIZATIONS: (Continued)

Nuclear Medicine, Radiation Biology, Biophysics: (Continued)

Radiation Research Society - 1960

Travel Grant Committee - 1962
Membership Committee - 1962-1963
Committee for Education in Radiation Research - 1963-1967
Chairman - 1966-1967
Program Committee - 1966-1967
Member of Council Representing Medicine - 1964-1965

Biophysical Society - 1962

Biology and Pathology:

Boston Society of Biologists - 1942

American Society for Experimental Pathology - 1941
Association of American Pathologists - 1976

CONSULTANCIES AND COMMITTEES:

National Agencies:

U.S. Veterans Administration:

Director Radioisotope Units, Framingham and Boston VA Hospitals - 1947-1954
Consultant in Radioisotopes, Los Angeles and Long Beach VA Hospitals - 1954 to Present
National Committee on Training in Nuclear Medicine:
Chairman - 1968-1972

National Cancer Institute of the U.S.P.H.S.:

The National Advisory Cancer Council - Member - 1956-1960
Planning Board, 1957-1958
Chemotherapy Review Board, 1958-1960
Training Grants Committee, 1960-1964
Consultant, 1964 to Present

The Cancer Chemotherapy National Service Center:

Clinical Studies Panel, 1958-1962
Contract Review Board, 1959-1960
Chemotherapy Review Board, 1959-1960

Cancer Special Programs Advisory Council, Chairman - 1966-1971

National Colon Rectal Cancer Program Advisory Council - Chairman - 1972-1975

CURRICULUM VITAE (Continued)

JOSEPH F. ROSS, M.D.

CONSULTANCIES AND COMMITTEES: (Continued)

United States Atomic Energy Commisssion:

Director, USAEC-UCLA - Laboratory of Nuclear Medicine and Radiation Biology, 1958-1965
Consultant, Medical Division, 1965-1967
Representative on Scientific Missions to:

Geneva, Switzerland, 1955; to Latin America, 1956; to Greece and Turkey, 1961; to Iran, Turkey and Pakistan in 1963; to the USSR in 1966.

U.S.P.H.S. Division of Radiological Health, Research Branch, Special Consultant, 1962-1963

U.S. Navy Special Consultant in Radiological Health - 1971 to Present

International Agencies:

International Atomic Energy Agency and World Health Organization Consultant;

Chairman, Panel on Studies on Erythrocyte Survival, Vienna, 1963.

International Survey of "Needs and Availability of Training in the Medical Uses of Radioisotopes." Responsible for Survey of Nations of Western Hemisphere - 1966.

Conference on "Training in Nuclear Medicine" - Vienna - 1974 Representative of the U.S.A..

Pan American Health Organization, Consultant 1962-1963:

Atomic Energy Commission of Peru - Advisor 1956-1960

Comitato Nazionale Ricerche Nucleari of the Government of Italy - 1957-1961

State Agencies:

State of California, Department of Health
Cancer Advisory Council, 1959 to Present;
Chairman, 1963-1966; 1975- 1977

Arizona State Medical School Study
National Advisory Committee, 1960-1961

CURRICULUM VITAE (Continued)

JOSEPH F. ROSS, M.D.

CONSULTANCIES AND COMMITTEES: (Continued)

Visiting Committees:

University of Chicago, Advisory Committee to the President of the University in Regard to the Argonne Cancer Hospital - 1965-1974

Oak Ridge Institute of Nuclear Studies of the Oak Ridge Associated Universities, Chairman - 1965-1966

Brookhaven National Laboratory of the Associated Universities Incorporated - 1968 & 1969; 1971-1975 - Chairman, 1974-1975

National Society Consultancies:

American Cancer Society, Committee on Institutional Grants - 1956-1958

Leukemia Society Inc.:

National Medical Advisory Board - 1959-1964
Los Angeles Chapter - Medical Advisory Committee - 1961-1962

College of American Pathologists, Advisory Committee to National Hemoglobin Survey - 1962

Other Committees:

City of Hope Medical Center, National Medical and Research Advisory Council - 1962-1972

Batelle Memorial Institute (Columbus, Ohio) - Consultant on Nuclear Energy Excavation Program 1965-1967

Hyland Laboratories of the Baxter Laboratories, Inc. - National Medical Advisory Board - 1965-1970

Southern California Edison Company - Special Consultant for Radiological Health, 1971 to Present

CURRICULUM VITAE (Continued)

JOSEPH F. ROSS, M.D.

HOSPITAL APPOINTMENTS:

Huntington Memorial Hospital, Boston, Massachusetts
House Officer, 1934-1935

Palmer Memorial, New England Deaconsess Hospital, Boston, Massachusetts
House Officer, 1935-1936

Mallory Institute of Pathology, Boston City Hospital, Boston, Massachusetts
Resident in Pathology, 1936-1937

II Medical Service (Harvard) Boston City Hospital
House Officer, September 1937-April 1939

Strong Memorial Hospital, Rochester, New York
Intern in Pathology, July 1939-July 1940

Robert Dawson Evans Memorial, Boston, Massachusetts
Assistant Physician, September 1940-February 1942
Associate Member, February 1942-February 1944
Member, February 1944-September 1954

Massachusetts Memorial Hospitals, Boston, Massachusetts

Assistant Visiting Physician, September 1940-February 1944
Visiting Physician, February 1944-September 1954
Director of Hematology Laboratories and Blood Bank,
March 1944-July 1946
Physician, Out-Patient Department and Director of Hematology Clinic,
September 1941-September 1954
Chief, Divisions of Hematology and Nuclear Medicine, 1940-1954

Cushing Veterans Administration Hospital, Framingham, Massachusetts
Consultant in Charge, Radioisotope Program, December 1947-March 1948
Director, Radioisotope Unit, March 1948-August 1952

Boston Veterans Administration Hospital, Boston, Massachusetts
Director, Radioisotope Unit, August 1952-September 1954

Consultant in Hematology:

Robert Breck Brigham Hospital, Boston, Massachusetts
December 1947-September 1954
Wellesley-Newton Hospital, Wellesley, Massachusetts
January 1949-September 1954
Framingham Union Hospital, Framingham, Massachusetts
March 1949-September 1954
Brighton Marine Hospital, USPHS, Boston, Massachusetts
March 1949-September 1954
New England Hospital for Women and Children, Boston, Massachusetts
August 1950-September 1954

CURRICULUM VITAE (Continued)

JOSEPH F. ROSS, M.D.

HOSPITAL APPOINTMENTS: (Continued)

Consultant in Radioisotopes:

Los Angeles Veterans Administration Hospital, Los Angeles
1954 to Present

Long Beach Veterans Administration Hospital, Long Beach, California, 1954-1973

University of California Hospital, Los Angeles, California
Attending Physician, 1954 to Present
Chief of Staff and Chairman, Hospital Executive Committee - 1954-1958
Chief of Hematology Clinic 1969-1974
Chief, Division of Hematology 1969-1974

PROFESSIONAL AND SCIENTIFIC ACTIVITIES:

Academic Medicine:

Medical Educational Administration as a Division Chief, Department Chairman and Associate Dean.

Medical Undergraduate and Graduate Instruction and Training in Internal Medicine, Hematology, Nuclear Medicine, Radiation Biology and Biophysics.

Medical Practice:

Consultation Practice of Medicine in University Medical Centers with the specialties of Internal Medicine, Hematology and Nuclear Medicine.

Clinical Investigation:

Investigation of the dynamic aspects of physiologic, metabolic and pathologic processes with tracer application of radioactive isotopes - specifically, radioactive iron, radioactive zinc, radioactive phosphorus and radioactive iodine.

Studies of the in vitro preservation and post transfusion survival of erythrocytes.

Studies of Blood Volume in health and disease.

Studies of the therapy of leukemia and lymphoma.

Studies of erythrocyte production and destruction.

Studies of thyroid physiology and disease.

Nuclear Medicine and Radiation Biology:

Development of radioisotopic methods of evaluating and treating human diseases.

Promotion and definition of training programs and residencies in Nuclear Medicine and establishment of the American Board of Nuclear Medicine to Certify specialists in Nuclear Medicine.

Director, U.S. Atomic Energy Research Laboratory of Nuclear Medicine and Radiation Biology.

BIBLIOGRAPHY

JOSEPH F. ROSS, M.D.

PUBLISHED MATERIAL

A. Research Papers

1. Ross, J. F.: The Effect of Piperidinomethylbenzodioxane (933F) and Yohimbine upon the Action of Certain Drugs and Ions on the Nictitating Membrane. Am. J. Physiol. 116, 574-576, August, 1936.

2. Ross, J. F.: Is the Transmission of the Nerve Impulses to the Cat's Uterus Electrical or Chemical? Am. J. Physiol. 119, 527-530, July, 1937.

3. Simeone, F. A. and Ross, J. F.: The Effect of Sympathectomy on Gestation and Lactation in the Cat. Am. J. Physiol. 122, 659-667, June, 1938.

4. Hahn, P. F., Ross, J. F., Bale, W. F. and Whipple, G. H.: The Utilization of Iron and the Rapidity of Hemoglobin Formation in Anemia Due to Blood Loss. J. Exper. Med. 71, 731-736, June, 1940.

5. Hahn, P. F., Bale, W. F., Ross, J. F., Hettig, R. A. and Whipple, G. H.: Radio-Iron in Plasma Does Not Exchange with Hemoglobin Iron in Red Cells. Science 92, 131-132, August, 1940.

6. Miller, L. L., Ross, J. F. and Whipple, G. H.: Methionine and Cystine, Specific Protein Factors Preventing Chloroform Liver Injury in Protein-Depleted Dogs. Am. J. Med. Sciences 200, 739-756, December, 1940.

7. Hahn, P. F., Balfour, W. M., Ross, J. F., Bale, W. F. and Whipple, G. H.: Red Cell Volume, Circulating and Total, as Determined by Radio-Iron. Science 93, 87-88, January, 1941.

8. Hahn, P. F., Ross, J. F., Bale, W. F., Balfour, W. M. and Whipple, G. H.: Red Cell and Plasma Volumes (Circulating and Total) as Determined by Radio-Iron and by Dye. J. Exper. Med. 75, 221-232, February, 1942.

9. Ross, J. F. and Chapin, M. A.: The Electrolytic Separation of Radioactive Iron from the Blood. Rev. of Scientific Instruments 13, 77-80, February, 1942.

BIBLIOGRAPHY (CONT.)

JOSEPH F. ROSS, M.D.

PUBLISHED MATERIAL (CONT.)

A. Research Papers (Cont.)

10. Chapin, M. A. and Ross, J. F.: The Determination of the True Cell Volume by Dye Dilution, by Protein Dilution, and with Radioactive Iron. The Error of the Centrifuge Hematocrit. Am. J. Physiol. 137, 447-455, September, 1942.

11. Hahn, P. F., Bale, W. F., Ross, J. F., Balfour, W. M. and Whipple, G. H.: Radioactive Iron Absorption by Gastro-Intestinal Tract. Influence of Anemia, Anoxia, and Antecedent Feeding Distribution in Growing Dogs. J. Exper. Med. 78, 169-188, September, 1943.

12. Ross, J. F. and Chapin, M. A.: Effect of Storage of Citrated Blood on the Survival of Transfused Erythrocytes. J.A.M.A. 123, 827-829, November, 1943.

13. Ross, J. F. and Paegel, B. L.: Acute Hemolytic Anemia and Hemoglobinuria Following Sulfadiazine Medication. Blood: The Journal of Hematology 1, 189-201, May, 1946.

14. Ross, J. F., Finch, C. A., Peacock, W. C. and Sammons, M. E.: The in vitro Preservation and Post-Transfusion Survival of Stored Blood. J. Clin. Investigation 26, 687-703, July, 1947.

15. Ross, J. F., Belding, H. and Paegel, B. L.: The Development and Progression of Subacute Combined Degeneration of the Spinal Cord in Patients with Pernicious Anemia Treated with Synthetic Pteroylglutamic (Folic) Acid. Blood: The Journal of Hematology 3, 68-90, January, 1948.

16. Ross, J. F., Crockett, Jr., C. L. and Emerson, C. P.: The Mechanism of Anemia in Leukemia and Malignant Lymphoma. J. Clin. Investigation 30, 668-669, June, 1951.

17. Ross, J. F.: Radioisotope Division. Boston Medical Quarterly 2, 38-41, June, 1951.

18. Finch, S. C., Crockett, Jr., C. L., Ross, J. F. and Bayles, T. B.: Hematologic Changes with ACTH and Cortisone Therapy of Rheumatoid Arthritis. Blood: The Journal of Hematology 6, 1034-1050, November, 1951.

BIBLIOGRAPHY (CONT.)

JOSEPH F. ROSS, M.D.

PUBLISHED MATERIAL (CONT.)

A. Research Papers (Cont.)

19. Lemon, H. M., Ravin, I. S., Ross, J. F., Sisson, J. H., Anglem, T. J. and Branca, A. W.: Testosterone Therapy of Metastatic Adenocarcinoma of the Thyroid, with Remission. Case Report. Cancer IV, 1176-1192, November, 1951.

20. Chodos, R. B. and Ross, J. F.: The Effects of Combined Folic Acid and Liver Extract Therapy. Blood: The Journal of Hematology 6, 1213-1233, December, 1951.

21. Ross, J. F., Chodos, R. B., Baker, W. H. and Freis, E. D.: The Blood Volume in Congestive Heart Failure. Trans. Assoc. Am. Physicians 65, 75-86, 1952.

22. Papper, S., Burrows, B. A., Ingbar, S. H., Sisson, J. H. and Ross, J. F.: The Effects of L-Thyroxine Sodium on Nontoxic Goiter, on Myxedema and on the Thyroid Uptake of Radioactive Iodine. New Eng. J. Med. 247, 897-899, December, 1952.

23. Ross, J. F., Barger, A. C., Finch, S. C., Ross, R. S., Price, H. L. and Freireich, E. J.: The Blood Volume Before and Following Experimentally Produced Congestive Heart Failure in Dogs. Trans. Assoc. Am. Physicians 66, 278-293, 1953.

24. Finch, S. C., Ross, J. F. and Ebaugh, Jr., F. G.: Immunologic Mechanisms of Leukocyte Abnormalities. J. Lab. and Clin. Med. 42, 555-569, October, 1953.

25. Burrows, B. A. and Ross, J. F.: The Thyroidal Uptake of Stable Iodine Compared with the Serum Concentration of Protein-Bound Iodine in Normal Subjects and in Patients with Thyroid Disease. J. Clin. Endocrinology and Metabolism 13, 1358-1368, November, 1953.

26. Ebaugh, Jr., F. G., Emerson, C. P. and Ross, J. F.: The Use of Radioactive Chromium-51 as an Erythrocyte Tagging Agent for the Determination of Red Cell Survival in vivo. J. Clin. Investigation 32, 1260-1276, December, 1953.

27. Hine, G. J., Burrows, B. A. and Ross, J. F.: Performance of Scintillation Counters in Measurement of I-131 Uptake by the Thyroid Gland. Tracerlog, No. 56, 2-11, December, 1953.

BIBLIOGRAPHY (CONT.)

JOSEPH F. ROSS, M.D.

PUBLISHED MATERIAL (CONT.)

A. Research Papers (Cont.)

28. Ross, J. F., Crockett, Jr., C. L., Finch, S. C. and Emerson, C. P.: The Mechanism of Anemia in Leukemia and Malignant Lymphoma. Boston Medical Quarterly 5, 8-10, March, 1954.

29. Ross, J. F., Finch, S. C., Street, Jr., R. B. and Strieder, J. W.: The Simultaneous Occurrence of Benign Thymoma and Refractory Anemia. Blood: The Journal of Hematology 9, 935-952, October, 1954.

30. Cajano, A., Miller, A., Finch, S. C. and Ross, J. F.: Autoimmunization to Blood Cells. Le Sang 26, 141, 1955.

31. Hine, G. J., Burrows, B. A., Apt, L., Pollycove, M., Ross, J. F. and Sarkes, L. A.: Scintillation Counting for Multiple-Tracer Studies. Nucleonics 13, 23-25, February, 1955.

32. Finch, S. C., Cajano, A. and Ross, J. F.: Leukocyte Response to Leukocyte Nuclear and Cytoplasmic Antisera. J. Lab. and Clin. Med. 46, 871-878, December, 1955.

33. Miller, A., Gaull, G., Ross, J. F. and Lemon, H. M.: Tissue Distribution of Parenteral Co^{60} Vitamin B_{12} in Mouse, Hamster, Rat and Guinea Pig. Proceedings of the Society for Experimental Biology and Medicine 93, 33-35, 1956.

34. Burrows, B. A. and Ross, J. F.: The Use of Radioactive Sodium and Potassium: Tracer Studies in Man. Boston Medical Quarterly 7, 54-57, June, 1956.

35. Peters, T., Giovanniello, T. J., Apt, L. and Ross, J. F.: A New Method for the Determination of Serum Iron-Binding Capacity. I. J. Lab. and Clin. Med. 48, 274-279, August, 1956.

36. Peters, T., Giovanniello, T. J., Apt, L. and Ross, J. F.: A Simple Improved Method for the Determination of Serum Iron. II. J. Lab. and Clin. Med. 48, 280-288, August, 1956.

37. Miller, A., Gaull, G., Lemon, H. M. and Ross, J. F.: Studies on the Uptake of Vitamin B_{12}-Co^{60} by the Hamster Methylcholanthrene-Induced Sarcoma and the Rat Walker Carcinosarcoma. Cancer Research 16, 842-847, October, 1956.

BIBLIOGRAPHY (CONT.)

JOSEPH F. ROSS, M.D.

PUBLISHED MATERIAL (CONT.)

A. Research Papers (Cont.)

38. Miller, A., Chodos, R. B., Emerson, C. P. and Ross, J. F.: Studies of the Anemia and Iron Metabolism in Cancer. J. Clin. Investigation 35, 1248-1262, November, 1956.

39. Hine, G. J., Burrows, B. A. and Ross, J. F.: Thyroid Uptake Measurements. Nucleonics 15, 54-57, January, 1957.

40. Chodos, R. B., Ross, J. F., Apt, L., Pollycove, M. and Halkett, J. A. E.: The Absorption of Radioiron Labeled Foods and Iron Salts in Normal and Iron-Deficient Subjects and in Idiopathic Hemochromatosis. J. Clin. Investigation 36, 314-326, February, 1957.

41. Freireich, E. J., Ross, J. F., Bayles, T. B., Emerson, C. P. and Finch, S. C.: Radioactive Iron Metabolism and Erythrocyte Survival Studies of the Mechanism of the Anemia Associated with Rheumatoid Arthritis. J. Clin. Investigation 36, 1043-1058, July, 1957.

42. Apt. L., Pollycove, M. and Ross, J. F.: Idiopathic Pulmonary Hemosiderosis. A Study of the Anemia and Iron Distribution Using Radioiron and Radiochromium. J. Clin. Investigation 36, 1150-1159, July, 1957.

43. Freireich, E. J., Miller, A., Emerson, C. P. and Ross, J. F.: The Effect of Inflammation on the Utilization of Erythrocyte and Transferrin Bound Radioiron for Red Cell Production. Blood: The Journal of Hematology 12, 972-983, November, 1957.

44. Ross, J. F., Ebaugh, Jr., F. G. and Talbot, Jr., T. R.: Radioisotopic Studies of Zinc Metabolism in Human Subjects. Trans. Assoc. Am. Physicians 71, 322-336, 1958.

45. Halkett, J. A. E., Peters, Jr., T. and Ross, J. F.: Studies on the Deposition and Nature of Egg Yolk Iron. J. Biol. Chemistry 231, 187-199, March, 1958.

46. Chodos, R. B. and Ross, J. F.: The Use of Radioactive Phosphorus in the Therapy of Leukemia, Polycythemia Vera and Lymphomas: A Report of 10 Years' Experience. Annals of Internal Medicine 48, 956-977, May, 1958.

BIBLIOGRAPHY (CONT'D.)
JOSEPH F. ROSS, M.D.

PUBLISHED MATERIAL: (CONT'D.)

A. Research Papers: (Cont'd.)

47. Talbot, T.R., Jr. and Ross, J.F.: The Zinc Content of Plasma and Erythrocytes of Patients with Pernicious Anemia, Sickle Cell Anemia, Polycythemia Vera, Leukemia, and Neoplastic Disease. Laboratory Investigation, 9, 174-184, January-February 1960.

48. Ross, J.F.: Atoms for Health. Amerika, No. 46, p. 40, 1960.

49. Libby, W.F., Berger, C.R., Mead, J.F., Alexander, G.V. and Ross, J.F.: Replacement Rates for Carbon in Human Tissues from Bomb Radio Carbon. Science, 146:1170-1172, November 1964.

50. Quastel, M.R. and Ross, J.F.: The Effect of Acute Inflammation on the Utilization and Distribution of Transferrin-bound and Erythrocyte Radioiron. Blood: The Journal of Hematology, 28, No. 5: 738-757, November 1966.

51. Krishnamurthy, G.T., Ross, J.F. and Blahd, W.H.: Prevention of Rh Immunization - Evaluation of Rh_0 (D) Antibody and Elaboration of Its Mechanism of Action by Chromium-51 RBC Clearing Method. Nuclear Medicine, 13, No. 3, 1974 - pp 236-244.

a. Government Reports:

1. Ross, J.F.: Report on First International Conference on Atoms for Peace, United States Atomic Energy Commission, 10 pp, 1955.

2. Ross, J.F.: Report on the Application of Atomic Energy to Medicine in the South and Central American Countries. United States Department of State and United States Atomic Energy Commission, 67 pp., 1956.

3. Ross, J.F.: Report of Travel to Participate in the U.S. Atomic Energy Commission Life Sciences Mission to Greece and Turkey; and to Inspect School of Medicine and National Research Institute, Madrid, Spain; and to Visit International Atomic Energy Agency in Vienna. U.S. Atomic Energy Commission, 7 pp., 1961.

4. Ross, J.F.: Report on the Second International Congress of Radiation Research, Harrogate, England, August 5-11, 1962. Report to U.S. Atomic Energy Commission, 4 pp., 1962.

5. Ross, J.F.: The Report of the CENTO Science Survey Mission. Report sent to the Central Treaty Organization and to the U.S. Department of State 42 pp., 1963.

BIBLIOGRAPHY (Cont'd.)

JOSEPH F. ROSS, M.D.

a. Government Reports: (Continued)

6. Ross, J.F.: Report of the United States Atomic Energy Commission Exchange Mission to the Union of Soviet Socialist Republics on the Tracer Applications of Radioisotopes. Report to the United States Atomic Energy Commission, 50 Pages, November, 1966. "For Official Use Only."

7. Ross, J.F.: Report of the International Survey of Needs and Availability of Training in the Medical Uses of Radioisotopes. Report to the World Health Organization and the International Atomic Energy Agency, 15 Pages, 1966.

8. Ross, J.F. and Others: Training in Nuclear Medicine. International Atomic Energy Agency and World Health Organization (In Press) 1975.

96-492 O - 77 - 7

BIBLIOGRAPHY (Cont'd)

JOSEPH F. ROSS, M. D.

PUBLISHED MATERIAL (Cont'd)

B. Reviews

1. Ross, J.F.: Artificial Radioactive Isotopes in Medicine and Biology. New Eng. J. Med. 226, 854-860, May 1942.

2. Ross, J.F.: Common Laboratory Aids to Diagnosis and Treatment. Medical Clinics of North America 26, 1391-1410, September 1942.

3. Ross, J.F.: Radioactive Iron in Experimental Medicine. Bulletin of the New England Med. Center, 4, 220-223, October 1942.

4. Ross, J.F.: Isotopes in Medical Investigation and Therapy. New Eng. J. Med., 228, 454-458 and 482-486, April 1943.

5. Ross, J.F.: Blood Banks and Blood Transfusion. New Eng. J. Med., 230, 171-175 and 195-198, February 1944.

6. Ross, J.F.: Hemoglobinemia and the Hemoglobinurias. New Eng. J. Med., 233, 691-696, 732-737 and 766-772, December 1945.

7. Paegel, B.L. and Ross, J.F.: The Diagnosis and Treatment of Anemia. Medical Clinics of North America, 30, 1042-1059, September 1946.

8. Belding, H.W. and Ross, J.F.: Recent Advances in Hematology. Medical Clinics of North America, 31, 1163-1184, September 1947.

9. Burrows, B.A. and Ross, J.F.: The Management of Hyperthyroidism. Medical Clinics of North America, 35, 1305-1321, September 1951.

10. Ross, J.F. and Ebaugh, F.G., Jr.: Current Trends in the Management of the Leukemias and the Malignant Lymphomas. Medical Clinics of North America, 35, 1381-1401, September 1951.

11. Ross, J.F.: Radioisotope Unit, Boston Veterans Administration Hospital. The Minute Man, 9, 14-16, 1952.

12. Ross, J.F.: Member of Panel V. The Use of Cobalt and Cobalt-Iron Preparations in the Therapy of Anemia. Blood: The Journal of Hematology, 10, 852-861, August 1955.

13. Ross, J.F.: Ionizing Radiation and the Development and Survival of Life. Trans. of the Amer. Clin. & Clim. Assoc., 77, April 1965. pp. 80-98

14. Weinstein, I.M. and Ross, J.F.: Therapy of Leukemia. Medical Science, 14, 56-66, May 1965.

15. Ross, J.F.: Radioisotope Scanning and Nuclear Medicine. Annals of Int. Med., 63, 538-9, September 1965. (Editorial)

BIBLIOGRAPHY (Cont'd.)

JOSEPH F. ROSS, M.D.

PUBLISHED MATERIAL (Continued)

B. Reviews (Continued

16. Ross, J.F.: Blood Volume Determination: Uses, Methods, Pitfalls pp. 589-591 in Polycythemia: Erythrocytosis and Erythremia. Annals of Internal Medicine, 69: 587-606, 1968.

17. Ross, J.F., Hewitt, Wm. L., Wahl, C.W., Okun, R. Shapiro, B.J. Slawson, P.F. & Shneidman, E.S., Ph.D: The Management of the Presuicidal, Suicidal, and Postsuicidal Patient. Annals of Internal Medicine 75:441-458, 1971.

18. Ross, J.F.: Laetriles - Not a Vitamin and Not a Treatment. The Western Journal of Medicine, Editorial, pp. 326-327, April 1975.

BIBLIOGRAPHY (CONT.)

JOSEPH F. ROSS, M.D.

PUBLISHED MATERIAL (CONT.)

C. Chapters and Books

1. Ross, J. F.: The in vitro Preservation and Post Transfusion Survival of Erythrocytes, pp. 726-731, 1943; pp. 1023-1026, 1267-1268 and 1296-1297, 1944; in Bulletin of Blood Substitutes of the Committee on Medical Research, Office of Scientific Research and Development, 1943 and 1944.

2. Ross, J. F.: Radioactive Isotopes in Medical Research and in the Treatment of Disease. Transactions of the Kansas City Academy of Medicine, 1948.

3. Ross, J. F.: The Use of Radioactive Isotopes in Evaluating the Viability and Survival of Formed Elements of the Blood, pp. 8-9, in The Preservation of the Formed Elements and of the Protein of the Blood, American National Red Cross, 1949.

4. Ross, J. F., Crockett, Jr., C. L., Finch, S. C. and Emerson, C. P.: The Mechanism of Anemia in Leukemia and Malignant Lymphoma, pp. 558-561, in Proceedings of the Second National Cancer Conference held in March, 1952, Vol. 1, American Cancer Society, Inc., New York, 1954.

5. Ross, J. F.: Experimental Applications of Radioactive Isotopes in Clinical Medicine, pp. 1633-1635, in Proceedings of the Second National Cancer Conference held in March, 1952, Vol. 2, American Cancer Society, Inc., New York, 1954.

6. Ross, J. F. and Miller, A.: The Dynamic Aspects of Erythropoiesis in Normal and Pathologic States as Indicated with the Radioactive Isotope Tracer Technique, pp. 255-263 and 402-408, in Proceedings of the International Conference on the Peaceful Uses of Atomic Energy - Radioactive Isotopes and Nuclear Radiations in Medicine, Vol. 10, United Nations, New York, 1956.

7. Chodos, R. B., Ross, J. F., Apt, L., Pollycove, M. and Halkett, J.: The Absorption of Radioiron-Labelled Foods and Inorganic Iron by Normal, Iron-Deficient and Hemochromatotic Subjects, pp. 373-377, in Proceedings of the International Conference on the Peaceful Uses of Atomic Energy - Radioactive Isotopes and Nuclear Radiations in Medicine, Vol. 10, United Nations, New York, 1956.

BIBLIOGRAPHY (CONT.)

JOSEPH F. ROSS, M. D.

PUBLISHED MATERIAL (CONT.)

C. Chapters and Books (Cont.)

8. Burrows, B. A. and Ross, J. F.: The Use of Radiosodium and Radiopotassium Tracer Studies in Man, pp. 430-434 and 534-536, in Proceedings of the International Conference on the Peaceful Uses of Atomic Energy - Radioactive Isotopes and Nuclear Radiations in Medicine, Vol. 10, United Nations, New York, 1956.

9. Ross, J. F.: The Diagnosis and Investigation of Disease with Radioactive Isotopes, pp. 33-48, in Progress in Nuclear Energy - Medical Sciences, Series VII, Vol. 1, Edited by J. C. Bugner, J. Coursaget and J. F. Loutit, Pergamon Press, London, 1956.

10. Ross, J. F.: Contributions of Atomic Energy to the Study of the Blood, pp. 259-281, in Progress Report on Atomic Energy Research in Medicine, Biology, Agriculture and Food Preservation Hearings before Subcommittee on Research and Development of the Joint Committee on Atomic Energy, 84th Congress of the United States, U S. Government Printing Office, Washington, D. C , 1956.

11. Ross, J.F.: Uso Diagnostico de Isotopos en Problemas Hematologicos, pp. 405-409, in Actas del Simposio Interamericano sobre la Aplicacion Pacifica de la Energia Nuclear, Libro 2, TID - 7554, Comision de Energia Atomica de los EE UU. Ampliacion del Servicio Informativo Tecnico, Oak Ridge, Tennessee, May, 1957.

12. Ross, J. F.: Nuclear Medicine - A Foreword, in The Practice of Nuclear Medicine, Authors - W. Blahd, F. Bauer and B Cassen, Charles C. Thomas, Springfield, Illinois, 1958.

13. Ross, J. F.: Radioactive Tracers in Hematologic Investigation, pp. 247-259, in Proceedings of the VI International Congress of the International Society of Hematology, Grune and Stratton, New York, 1958.

14. Ross, J. F.: Iron Metabolism - A Foreword, in Iron in Clinical Medicine, Edited by R. Wallerstein and S. R. Mettier, University of California Press, Berkeley and Los Angeles, California, 1958.

15. Berger, R.; Libby, W. F ; Mead, J F ; Alexander, G. V. and Ross, J. F.: Atmospheric Bomb Radiocarbon as a Tracer in Humans. III in Advances in Tracer Methodology, Plenum Press, 1965, New York, N.Y.

16. Ross, J. F.: Biological Effects of Ionizing Radiation. Chapter VI in Nuclear Medicine, Blahd, W. H., ed., McGraw-Hill, New York, October, 1965. (pp. 123-143)

BIBLIOGRAPHY (CONT.)

JOSEPH F. ROSS, M.D.

PUBLISHED MATERIAL (CONT.)

D. Abstracts

1. Ross, J. F. and Chapin, M. A.: The Selective Absorption of Radioactive Iron by Normal and Iron-Deficient Human Subjects. J. Clin. Investigation 20, 437, July, 1941.

2. Chapin, M. A. and Ross, J. F.: Factors Influencing the Metabolism of Radioactive Iron in Human Subjects. Federation Proceedings 1, 175, March, 1942.

3. Ross, J. F. and Chapin, M. A.: The Direct Determination of Erythrocyte Volume in Human Subjects with Radioactively Tagged Cells. Federation Proceedings 1, 183, March, 1942.

4. Ross, J. F. and Chapin, M. A.: The Absence of Erythrocyte Reserves in Human Subjects as Indicated with Radioactive Tagged Cells. J. Clin. Investigation 21, 640-641, September, 1942.

5. Ross, J. F.: The Metabolism of Inorganic and Hemoglobin Iron. J. Clin. Investigation 25, 933, November, 1946.

6. Wagley, P. F., Adams, M. and Ross, J. F.: The Iron Metabolism and Acid Fragility of Erythrocytes in Paroxysmal Nocturnal Hemoglobinuria. J. Clin. Investigation 28, 816-817, July, 1949.

7. Ross, J. F., Baker, W. H. and Freis, E. D.: The Blood Volume in Congestive Heart Failure. J. Clin. Investigation 29, 842, June, 1950.

8. Ebaugh, Jr., F. G., Ross, J. F. and Emerson, C. P.: The Use of Chromium-51 as an Erythrocyte Tagging Agent for Determining the Survival of Transfused and Autotransfused Erythrocytes. J. Clin. Investigation 32, 563, June, 1953.

9. Finch, S. C., Ross, J. F., Street, R. B. and Strieder, J. W.: Thymoma and Refractory Anemia. Clin. Research Proceedings 2, 29, March, 1954.

10. Halkett, J. A. E. and Ross, J. F.: The Incorporation of Radioactive Iron in Human Foodstuffs. Clin. Research Proceedings 2, 30, March, 1954.

BIBLIOGRAPHY (CONT.)

JOSEPH F. ROSS, M.D.

PUBLISHED MATERIAL (CONT.)

D. Abstracts (Cont.)

11. Chodos, R. B., Ross, J. F., Pratt, M., Donovan, J. and Halkett, J. A. E.: The Absorption of "Egg" and Inorganic Iron by Normal, Iron-Deficient, and Hemochromatotic Subjects. Clin. Research Proceedings 2, 30, March, 1954.

12. Pollycove, M., Chodos, R. B., Apt, L. and Ross, J. F.: The Use of Radioactive Iron in the Evaluation of Erythropoiesis and Ferrokinetics. Clin. Research Proceedings 2, 31, March, 1954.

13. Chodos, R. B., Ross, J. F., Apt, L., Halkett, J. and Pollycove, M.: The Absorption of Food Iron and Inorganic Iron by Normal, Iron-Deficient, and Hemochromatotic Subjects. Clin. Research Proceedings 2, 53, April, 1954.

14. Freireich, E. J., Ross, J. F., Bayles, T. B., Emerson, C. P. and Finch, S. C.: The Mechanism of the Anemia Associated with Rheumatoid Arthritis. Clin. Research Proceedings 2, 54-55, April, 1954.

15. Pollycove, M., Apt, L. and Ross, J. F.: The Pathologic Physiology of Hematopoiesis and Iron Metabolism in Chronic Myelogenous Leukemia before and after Radiophosphorus Therapy. Clin. Research Proceedings 2, 58, April, 1954.

16. Burrows, B. A., Hine, G. J. and Ross, J. F.: The Simultaneous Determination of Radiosodium, Radiopotassium and Radiosulphate Spaces. Clin. Research Proceedings 2, 81, April, 1954.

17. Burrows, B. A., Peters, T. and Ross, J. F.: The Tissue Utilization of Endogenous Thyroid Hormone in Human Subjects. J. Clin. Investigation 33, 921, June, 1954.

18. Peters, T., Apt, L. and Ross, J. F.: Iron-Phosphate Interactions Influencing Gastrointestinal Iron Absorption. Federation Proceedings 14, 415-416, March, 1955.

19. Burrows, B. A., Davis, D. J., Kelly, J. F., Lewis, A. A. G. and Ross, J. F.: The Effects of Surgical Procedures on Simultaneously Determined Radiosodium, Radiosulphate and Radiopotassium Spaces in Human Subjects. J. Clin. Investigation 34, 924-925, June, 1955.

BIBLIOGRAPHY (Cont'd.)

JOSEPH F. ROSS, M.D.

PUBLISHED MATERIAL: (CONT'D.)

D. Abstracts: (Cont'd)

20. Freireich, E.J., Miller, A., Emerson, C.P. and Ross, J.F.: The Effect of Inflammation on the Utilization of Erythrocyte and Transferrin Iron for Hemoglobin Synthesis. J. Clin. Investigation, 34, 934, June 1955.

21. Pollycove, M., Elmlinger, P.J., Sarkes, L.A., Apt. L. and Ross, J.F.: Radioiron Determination of Human Erythrocyte Life-Span Distribution. Clin. Research Proceedings, 4, 79-80, April 1956.

APPENDIX 2

REPORTS OF HUMAN POISONINGS FROM LAETRILE

AND FROM CYANOGENIC FRUIT KERNELS

(Not a Complete Survey of the Literature)

I Laetrile tablets - 1 death

James Humbert - Report in press - JAMA Appendix 2A
Also A.P. report in Oakland Tribune 6/14/77

Ten month old infant ingested her father's Laetrile tablets and died with symptoms, laboratory, and autopsy findings of acute cyanide poisoning.

II Apricot Kernels - 18 cases of poisoning with 3 deaths

A. Gunders et al. J. Israel Medical Association 76:536 (1969)
One non-fatal illness; consumption of apricot kernels.

B. Ioanio and Bors. Ann. De. Med. Leg. 41:275 (1960)
15-year-old girl; death in 5 hours; consumption of wild apricot kernels. Inst. of Medico Legal Research, Bucharest, Rumania.

C. Sayre and Kay Makcalan. New England Journal Med. 270:1113 (1964) (Photocopy appended) B
Nine cases of cyanide intoxication during 1960, 1961, 1962 near Ankara Turkey; consumption of cultivated and wild apricot kernels - 2 deaths soon after admission to hospital; 7 illnesses 30 minutes to 2½ hours after ingestion of kernels. Symptoms: Vomiting, crying, lethargy, fainting, coma.

D. California morbidity, September 1, 1972 (photocopy appended) 2C
Two persons, non-fatal illness. Apricot kernels obtained in health food store, Los Angeles. 30 kernels, dried apricots and water pureed in blender, consumed by both persons. Symptoms after one hour: abdominal discomfort, tachycardia cns symptoms - hospitalization - recovered after 3 days.

E. California morbidity, November 14, 1975 (photocopy appended) 2D
34-year old man, non-fatal illness. Apricot kernels obtained in health food store, San Diego county. 48 kernels, milk and honey used to prepare two milk shakes. Wife consumed only small amount. Man drank nearly entire amount. He also consumed a few roasted kernels for total consumption of about 48 kernels. Kernels were home roasted at 300°/F for 10 minutes. Symptoms: 1 hour: vomiting, headache, flushing, perspiration, dizziness, fainting. Both husband and wife treated at hospital. Wife remained asymptomatic.

II Apricot Kernels, Cont'd

F. California morbidity, December 25, 1975 (photocopy appended) DE
56-year-old woman - non-fatal illness. Apricot kernels obtained in San Jose Nutrition Center. Handful apricot kernels consumed. Symptoms: 30 minutes: headache, tachycardia, lightheadedness, flushing, weakness - hospitalized.

G. Food and Drug Section Report, J. Waddell, December 10, 1976.
Woman, Long Beach, non-fatal illness. Apricot kernels obtained from nutrition center, Cerritos. Two handfuls or about 40 kernels consumed on empty stomach. Symptoms after 20 minutes: Dizziness, loss of equilibrium, vomiting, tachycardia. Not hospitalized. Saw physician next day.

H. Honolulu Sunday Star-Bulletin and Advertiser, Dec. 10, 1972
Young woman, non-fatal illness. Apricot kernels obtained from health food store. Half pound apricot kernels consumed. Symptoms: Violent illness, vomiting, fainting spells.

I. Med. Hyg. Geneva 16:306 (1958)
Child, non-fatal illness. 10 to 20 raw apricot kernels; Cns symptoms.

III Bitter Almonds - 5 cases of poisoning with 5 deaths

A. Ioanid and Bors. Ann. De. Med. Leg. 41:275 (1960)
63-year-old man.- death. Bitter almond consumption.

B. Blyth, A.W. and Blyth, M.D. Poisons 5th Ed. P. 215, 223 (1920)
31-year-old woman - death. Bitter almond consumption. Death 1½ hours; 90g almond pulp in stomach.

C. Jacobi. D.Z. Ges. Gerich. Med. 21:14-17 (1933)
20-year-old woman - death; bitter almond consumption. 175 almonds consumed. Lethal dose estimated at 50-60 almonds, since each contains about 1 mg. HCN.

D. Food, Cosmetic Toxicology 3:358 (1965)
One fatal case, bitter almond consumption.

E. Z. Rechtamedizin 70:53 (1972) (photocopy of abstract appended) DF
One fatal case, bitter almond consumption.

IV Peach Kernels - 4 cases of poisoning with 4 deaths

A. Jeannin et al - Lyon Med. 93:785-93 (1961)
4-year-old girl, France - ground peach kernel consumption. Rapidly became comatose, died.

B. Falck, I., cited by Schrady. Med. Rec. (N.Y.) 45:633.
3 deaths from consumption of peach kernels.

V Wild Choke Cherry Kernels - 5 cases of poisoning with 1 death

A. Pijoian, M. Am. J. Med. Sci. 204:550 (1942)
3-year old boy, death; 4 adults ill from consumption of

VI Sweet Cherry Kernels - 2 cases of poisoning with 1 death

A. Taylor, A.S. On Poisons, London, Churchill (1848)
5-year-old girl - death, 40 hours.
Boy, age unknown, recovered in one month. Consumption of sweet cherry kernels.

VII Prune Kernels - 2 cases of poisoning with 2 deaths

A. Ioanid and Bors. Ann. De Med. Leg. 41:275 (1960)
2 children consumed prune kernels in jam. Symptoms, 6 hours: cyanosis, intestinal pain, vomiting, death.

Summary of Cases of Poisoning

by Laetrile and Cyanogenic Fruit Kernels

Product	Cases of Poisonings	Death
Laetrile	1	1
Apricot Kernels	18	3
Bitter Almonds	5	5
Peach Kernels	4	4
Wild Choke Cherry Kernels	5	1
Sweet Cherry Kernels	2	1
Prune Kernels	2	2
Total	37	17

APPENDIX 2A

ROUTING AND TRANSMITTAL SLIP		
1 TO (Name, office symbol or location) R. Lawrence	INITIALS	CIRCULATE
	DATE	COORDINATION
2	INITIALS	FILE
	DATE	INFORMATION
3	INITIALS	NOTE AND RETURN
	DATE	PER CONVERSATION
4	INITIALS	SEE ME
	DATE	SIGNATURE

REMARKS

This letter to the Editor of JAMA has been accepted for publication within the next several weeks. There is no prohibition against making this letter available to interested parties prior to publication. Dr. Humbert (716-878-7349) is willing to speak with concerned physicians or the press on this matter.

Do NOT use this form as a RECORD of approvals, concurrences, disapprovals, clearances, and similar actions.

FROM (Name, office symbol or location)	DATE
	PHONE

OPTIONAL FORM 41
AUGUST 1967
GSA FPMR (41CFR) 100-11.206

GPO 843-16-81418-1 418-016 5041-101

FATAL CYANIDE POISONING FOLLOWING ACCIDENTAL INGESTION OF AMYGDALIN (LAETRILE)

To the Editor.- Amygdalin (Laetrile) tablets upon exposure to hydrolytic enzymes can release hydrocyanic acid. To our knowledge no fatality due to such poisoning has been reported to date. We wish to draw attention to the fact that when ingested accidentally by young children amygdalin tablets may constitute a potentially fatal hazard as exemplified by the following case.

The patient was an eleven-month old girl who accidentally ingested from one to five 500 mg. Laetrile tablets. The tablets belonged to the child's father who has a malignancy. They were thought to be harmless by the parents and were contained in a vial along with an assortment of vitamin tablets. The patient became listless within half an hour after ingestion and vomited. Emesis was induced again by the mother who rushed the child to the local hospital when her breathing became irregular and her state of consciousness became altered. An hour after ingestion she was found at that hospital in shock with irregular respirations and acidosis. She was intubated, lavaged, treated with IV fluids, sodium bicarbonate, and oxygen and then transferred to the Children's Hospital of Buffalo.

Shock, acidosis, superficial coma, and Kussmaul respirations were present on admission. Significant cyanide amounts (29 µg/dl) were detected in the blood. Shock and acidosis responded to bicarbonate and plasma expanders. Improvement of neurological signs and breathing pattern was noted and continued following treatment with sodium nitrite and sodium thiosulfate (administered 3½ hours after ingestion). Respiratory arrest occurred, however, 14 hours post-ingestion. The child was placed on the respirator and given two more treatments with nitrite and thiosulfate but slipped into an irreversible coma over the next 30 hours. No cyanide was detected in the blood drawn shortly before the respiratory arrest. Approximately 72 hours following ingestion the child expired.

Due to the increased interest and changing legislation amygdalin is becoming more available in this country. Its use is controversial, its potential toxicity is not well known, and many users consider it harmless ("Vitamin B17"). This tragic case emphasizes the potentially fatal effect of this drug in young children. Our purpose is to alert users of amygdalin and physicians who administer that drug to the danger of cyanide intoxication which attends its

use. Appropriate protective steps should include packaging the drug in childproof containers and knowledge of the emergency treatment of cyanide poisoning. Specifically, if children less than four years are present in the family of amygdalin users, a cyanide resuscitation kit marketed by Eli Lilly and Company should be available for immediate use either in the home or at the family physician's office should the need arise.

James R. Hurbert, M.D.
Associate Professor of Pediatrics,
State University of New York at Buffalo
Director, Pediatric Hematology,
The Children's Hospital of Buffalo
(Phone 716-878-7349)

Jonathan H. Tress, M.D.

Kathleen T. Braico, M.D.

APPENDIX 2B

[From the New England Medical Journal, Vol. 270, No. 21]

HAZARDS TO HEALTH

Cyanide Poisoning from Apricot Seeds among Children in Central Turkey

JAMES W. SAYRE, M.D.,* AND
SÜKRÜ KAYMAKCALAN, M.D.†

ANKARA, TURKEY

ACCIDENTAL poisoning in childhood is a world-wide occurrence. The toxic agents involved naturally vary to a great extent from one area to another, depending on the customs, social stru

*Consultant pediatrician, Hacettepe Medical Center.
†Professor of pharmacology, Ankara University Medical School.

TABLE 1. *Comparison of the Numbers of Cases of Several Types of Poisoning Seen at Hacettepe Children's Hospital from 1957 to 1962.*

YR.	SALICYLATES	BARBITURATES	KEROSENE	CYANIDE FROM SEEDS	TOTAL NO. OF PATIENTS SEEN AT HOSPITAL
	NO. OF PATIENTS	NO. OF PATIENTS	NO. OF PATIENTS	NO. OF PATIENTS	
1957	—	—	—	—	5,160
1958	—	3	5	—	20,097
1959	1	6	10	—	29,182
1960	3	10	17	2	39,167
1961	5	4	15	1	40,046
1962	2	1	25	6	59,934
Totals	11	24	72	9	193,586

ture, economy and other factors. Among the people of Anatolia, the central part of Turkey, it is a common custom to eat seeds of all kinds: hazel nuts; sweet almonds; pistachios; chickpeas; and sunflower, watermelon and squash seeds. Many people also like the usually sweet taste of the apricot seed. Whereas the former seeds are free from toxic effect, the apricot is known to contain a cyanogenetic glycoside, amygdalin, which is hydrolyzed in the process of digestion releasing hydrocyanic acid. Other amygdalin-containing seeds in fruit commonly consumed by human beings are the peach, cherry, pear and plum, and some that are less frequently or inadvertently consumed are jet beads, chokecherries, cassava beans and bitter almonds.

Reports of actual poisoning from seed sources among human beings are not frequent. Jeannin et al.[1] described a four-year-old girl who became comatose after consuming a ground-up mixture of peach seeds. Studies of 4 such cases were reported by Ioanid and Bors.[2] The fruits involved in these cases were prunes (2 children), wild apricots (a fifteen-year-old girl) and bitter almonds (a sixty-three-year-old man). These 4 were the only cases observed over a period of twenty-two years at the Institute of Medico-Legal Research in Bucharest, Rumania. Wild chokecherry pits were implicated by Pijean[3] in 4 cases of intoxication among the Indians of the western United States. The industrial hazards of cyanide released in the processing of apricot seeds during the manufacture of various oils has been investigated by Grabois,[4] who, although reporting no actual poisoning, points out the dangers of this chemical reaction.

In Anatolia (Turkey) there is a rather general awareness of the potential danger of such seed consumption, for many adults, while admitting their fondness for the seeds, warn against eating more than 8 or 10 at one time. That this caution is not always heeded by children is attested by the fact that since the opening of the Children's Hospital of Hacettepe Medical Center, Ankara, Turkey, in late 1957, 9 cases of cyanide intoxication due to the ingestion of apricot seeds have been recorded in our files (Table 1). For comparison cases of poisoning by 3 other agents seen over the same period are shown. The low rate of salicylate intoxication results from the lack of use of this agent here. Likewise, the low incidence of kerosene poisoning is undoubtedly due to its common use in small cooking stoves, particularly in villages.

The mechanism of hydrocyanic acid release is the utmost importance in the sequence of events leading to the appearance of symptoms in these cases. Amygdalin present in the seed kernel is harmless as such. However, when the seed is crushed and the pulp moistened an enzyme, emulsin, which is also present, catalyzes the following reaction:

$$\underset{\text{Amygdalin}}{C_{20}H_{27}NO_{11}} + 2H_2O \rightarrow 2\,\underset{\text{Glucose}}{C_6H_{12}O_6} + \underset{\text{Benzaldehyde}}{C_6H_5CHO} + \underset{\text{Cyanic}}{HCN}$$

This reaction takes place very slowly in the presence of an acid pH, but in an alkaline medium occurs quickly, hydrolysis being complete in ten minutes at 20°C.[5] This fact perhaps explains why symptoms of intoxication occur after some delay, the interval necessary for transit from the stomach to the alkaline medium of the duodenum.

Patients seen to date in this hospital ranged in age from two and a half to five years. The interval between ingestion and the onset of symptoms ranged from half an hour to two hours as related by the parents. Symptoms at onset occurred quickly, consisting of sudden vomiting and crying, followed by fainting, lethargy or coma. Examination sometimes disclosed a comatose state, but more usually a variable state of lethargy and hypotonia was seen.

many children nevertheless being quite able to recognize people. Two were moribund on admission, death following in ten to twenty minutes after arrival at the hospital. One of these children came from a village about an hour and a half distant — too far to benefit from treatment. In the other children vital signs and blood pressure were normal. Trismus was present in 2 cases. Gastric lavage sometimes revealed a characteristic odor and particles of seeds. Seven patients received treatment of sodium nitrite and sodium thiosulfate intravenously, and 1 received 1 per cent methylene blue.

Toxicologic studies on stomach contents and on autopsy material have not been performed to date, but we have studied the cyanide content of the types of amygdalin-containing seeds most commonly consumed here: the cultivated apricot (Latin, *Prunus armeniaca;* Turkish, "kayısı") and the wild apricot (Latin, *Pr. pseudoarmeniaca;* Turkish, "zerdali"). For purposes of comparison we have included the peach, which is capable of producing the same intoxication. The results of this analysis are presented in Table 2.

To date, in this hospital, there have been no cases due to peach seeds, but this may occur from time to time in Anatolia. The marked difference in content of cyanide between wild and cultivated apricots may be very important in the causation of these cases since the two types of fruit differ only slightly in size, the wild type being somewhat smaller. Its seed is also smaller and, owing to its high content of amygdalin, has a bitter taste. Bitterness of taste may be a fair warning to an adult, but this is not always forbidding to a child. Curiously enough, in all but 1 of these 9 cases the parents said that the child had eaten the seeds of the cultivated apricot (kayısı), and it is perhaps not unfair to guess that even the parents were unable to distinguish grossly between the two varieties of fruit.

TABLE 2. *Cyanide Content of the Seeds of Three Fruits.*

FRUIT	HYDROCYANIC ACID*
Peach	88 mg.
Cultivated apricot	8.9 mg.
Wild apricot	217.0 mg.

*Per 100-gm. moist seed (silver nitrate volumetric method of Gettler & Baker, as described by Gradwohl[5]).

The true magnitude of this problem in Turkey is difficult to assess accurately. Mountainous, rugged terrain, unavailability of rapid transportation and the paucity of adequate medical care in smaller towns and villages make it quite possible that a large majority of patients with cyanide poisoning go unattended and untreated. It is hoped that in the future it may be possible to make more detailed studies in these cases and a survey to learn more of the true incidence of this occurrence.

We are indebted to our chemist, Mrs. Esin Temelli, for performing the cyanide determinations in the seeds.

REFERENCES

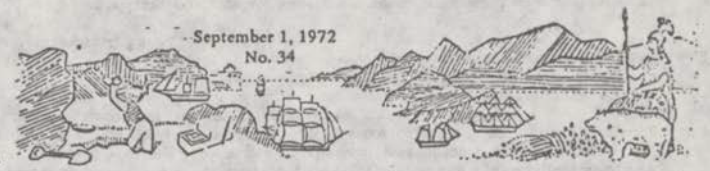
1. Jeanniti, J., Berrod, R., Lemaire et Bazin. Intoxication grave survenue chez une enfant après ingestion de noyaux de pêches. *Lyon méd.* 52 (15):763-793, 1901.
2. Ioanid, N., and Bors, G. Les empoisonnements par les glucosides cyanogénétiques et leur différenciation de ceux dus à l'acide cyanhydrique ou à ses sels. *Ann. de méd. lég.* 41:275-279, 1961.
3. Pipon, M. Cyanide poisoning from choke cherry seed. *Am. J. M. Sc.* 204:550-553, 1942.
4. Grabois, B. Exposure to hydrogen cyanide in processing of apricot kernels. *Monthly Rev. New York State Dept. of Labor* 23:53-56, 1954.
5. Gradwohl, R. B. H. *Clinical Laboratory Methods and Diagnosis.* Fifth edition. 2431 pp. London: Kimpton, 1956. P. 2264.

96-492 O - 77 - 8

California Morbidity

Weekly Report from the
Bureau of Communicable Disease Control
State Department of Public Health

September 1, 1972
No. 34



CYANIDE POISONING FROM THE INGESTION OF APRICOT KERNELS

An incident of possible cyanide poisoning in two health food faddists who consumed apricot kernels was recently reported from Los Angeles. A man and his wife purchased a two-pound bag of apricot kernels at a local health food store. They soaked some 30 kernels with dried apricots in distilled water overnight and the following day pureed the ingredients in a blender. The resulting concoction was bitter and took some effort to swallow. About an hour after drinking the mixture, the wife complained of abdominal discomfort, tachycardia and feeling strange. She drank some water and vomited. Within minutes of his wife's onset, the husband became symptomatic also and complained of headache, light-headedness, tachycardia, a generally strange sensation, and impaired vision . . . "as if looking through frosted glass." He felt impending doom.

They were rushed to the emergency room of a nearby hospital. Vomiting was successfully induced, and after several hours of observation, they were released. For the next three days the husband complained of insomnia and tinnitus. The wife had diarrhea which abated in one day. Both recovered fully.

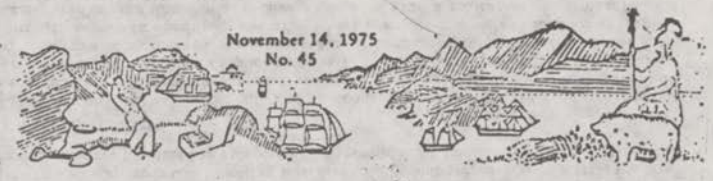
In apricot kernels, apple seeds, cherry and peach pits, as well as the pits and seeds of some other fruit, there is a cyanogenic glycoside called amygdalin. This substance may liberate hydrogen cyanide and produce the characteristic odor of bitter almonds. Symptoms may develop within an hour of ingestion, and include dyspnea, asphyxia, cyanosis, vomiting, lassitude, prostration, excitement, twitching, convulsions, stupor, paralysis, coma and in some cases death. Chronic cyanide intoxication has been hypothesized as a cause of some of the neuropathies seen in developing countries where cyanogenic seeds and nuts are consumed. Blood thiocyanate levels have been high in cases studied; the thiocyanate is thought to arise from detoxication of cyanide. Clinical improvement followed the reduction of cyanogenic foods in the diet.

The minimal number of apricot kernels necessary to cause symptoms or death in humans is not known. Since this and similar products are widely distributed in health food stores for reputed nutritional and medicinal value, the possibility of disease from a large number of kernels should be recognized.

California Morbidity

Weekly Report from the
Infectious Disease Section
State Department of Health

November 14, 1975
No. 45



CYANIDE POISONING FROM INGESTION OF APRICOT KERNELS*

On October 22, 1975, a 34-year-old man residing in San Diego County developed symptoms of cyanide poisoning after ingestion of apricot kernels. A one-pound package of raw, dried apricot kernels was purchased at a health food store and used in the preparation of milk shakes, following a recipe in the magazine, Prevention. The kernels were roasted at 300°F for 10 minutes, and 48 kernels were used, together with milk and honey, to prepare two milk shakes. The man's wife consumed only a small amount of her milk shake since she didn't like the taste, and the man drank all of his milk shake plus the remainder of his wife's. He had also eaten a few kernels separately, for a total consumption of approximately 48 seeds.

Around one hour later the husband developed forceful vomiting, headache, flushing, heavy perspiration, dizziness and faintness. The couple immediately went to a local emergency room where vomiting was induced in both by Ipecac and the husband's symptoms rapidly subsided. Fragments of kernels were observed in the vomitus of both. The wife was asymptomatic.

Apricot kernels, along with cherry and peach pits and apple seeds and other pits and seeds, contain a cyanogenic glycoside called amygdalin, which releases hydrogen cyanide upon reaction with digestive chemicals. Symptoms of cyanide poisoning may develop soon after ingestion, including dyspnea, cyanosis, vomiting, prostration, excitement, convulsions, stupor, paralysis and sometimes death, depending on dosage. (The minimum number of seeds needed to cause disease or death is not known.) Roasting of apricot kernels (especially when crushed) can remove the cyanide, but this requires up to ten hours.

Chronic cyanide intoxication has been postulated as a cause of neuropathies in some developing countries where cyanogenic nuts and seeds are consumed.[1] Laboraotry studies revealed high levels of breakdown products of cyanide. Symptoms diminished when the suspect foods were eliminated from the diet. Two previous cases of probable cyanide poisoning after ingestion of apricot kernels were reported in California Morbidity on September 1, 1972.

COMMENT: Apricot kernels and similar pits and seeds and related products are widely promoted as having disease preventive or curative properties and sold at health food stores. Physicians should be aware of the possibility of cyanide poisoning when large quantities of such products are consumed.

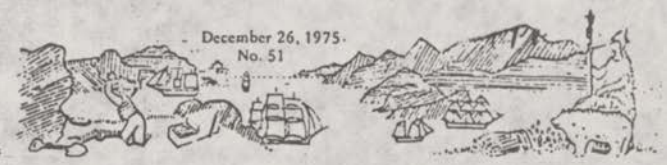
Reference: 1. Sayre, JW, NEJM 270:1113, 1964.

*Case reported by William A. Townsend, M.D., Chief, Division of Medical Services, San Diego County.

California Morbidity

Weekly Report from the
Infectious Disease Section
State Department of Health

December 26, 1975
No. 51



CYANIDE POISONING FROM APRICOT KERNELS*

Since issue #45 of November 14, 1975, another case of apparent cyanide poisoning from ingestion of apricot kernels has been reported.

A 56-year-old woman ate a "handful" of apricot kernels purchased at a "nutrition center" in Santa Clara County and within 30 minutes developed headache, tachycardia, light-headedness, flushing and generalized weakness. She was seen at the emergency room of a local hospital were ipecac was used to induce vomiting. The patient was admitted overnight for observation, and her symptoms had cleared, except for a mild headache, by morning.

A specimen of the patient's vomitus proved to have a cyanide content of 1.7 mcg/ml, while a serum specimen (drawn several hours after ingestion) was negative for cyanide.

*Case reported by Harold Johnson, M.D., and Gary Rich, M.D., Redwood City.

APPENDIX 2F

Food Cosm Toxic vol 11
1473

abstract of article

NATURAL PRODUCTS

2471. Bitter almond poisoning

Pack, W. K., Raudonat, H. W. u. Schmidt, K. (1972). Über eine tödliche Blausäurevergiftung nach dem Genuss bitterer Mandeln (Prunus Amygdalus). *Z. Rechtsmedizin* 70, 53.

A fatal case of cyanide poisoning following the ingestion of bitter almonds, which contain the cyanogenetic glycoside amygdalin, was reported once before (*Cited in. F.C.T.* 1965, 3, 358) and a comment on the surprisingly large number of such cases was made at that time. Since then a similar, but non-fatal, event has resulted from the consumption of apricot kernels (Gunders *et al. J. Israel Med. Ass.* 1969, 76, 536). The present short paper is worth attention, not only as a reminder of the danger of eating this culinary commodity in its uncooked state, but also because the results of the post-mortem examination of the victim provide the sceptic with convincing evidence that bitter almonds can indeed be the source of a lethal dose of cyanide.

The victim, a 40-yr-old man, was found dead by his bed, his mouth full of reddish foam. When analysis of blood and urine had demonstrated the absence of alcohol, the stomach contents were examined and the presence therein of about 150 ml of a semi-fluid white material smelling strongly of bitter almonds gave a clue to the source of the trouble. Analysis of various body tissues and fluids confirmed the presence of cyanide, and the blood level (312 μg/100 ml, calculated as the anion) was in accordance with values found in other cases of lethal cyanide poisoning. Measurable amounts were also detected in the stomach contents (4380 μg/100 ml), kidneys (69·3 μg/100 g), liver (7·4 μg/100 g), brain (24·7 μg/100 g), muscle (122·9 μg/100 g) and urine (11 μg/100 ml).

These findings, together with microscopic evidence of bitter almond husks in the stomach and the presence therein of benzaldehyde and benzoic acid (which, together with hydrocyanic acid and glucose, are breakdown products of amygdalin) left little doubt as to the cause of death and the source of the cyanide.

APPENDIX 3

CHRISTMAS
MEDIA REVIEW
THIS WOMAN
JUST FED CYANIDE
TO HER HUSBAND

MEDIA REVIEW

REVIEW
of
BOOKS
RECORDINGS
and
FILMS

AND SHE'LL DO IT AGAIN TOMORROW

BOOKS
pages 3-22

RECORDINGS
pages 23-29

FILMS
pages 29-30

In fact, she even wrote a book about it. You see, June de Spain is one of a growing number of nutritionists who are convinced that cyanide compounds, as found in trace amounts in certain foods, are nature's way of preventing cancer. Because of their unique molecular structure, these compounds release the cyanide only at the cancer site, thus destroying cancer cells while nourishing non-cancer tissue. Those populations in the world which eat these vitamin-rich foods simply do not get cancer—and they live to be much older than those who subsist on the the typical modern diet.

Mrs. de Spain is emminently qualified to compile this cookbook. She has been a toxicologist and a pharmecologist for the federal Food and Drug Administration. She was a histologist specializing in diet research at the University of Chicago. And she has conducted animal diet research at the University of Pennsylvania. She has taught at the John Robert Powers School of Modeling and Charm, and now teaches a series of her own courses in nutrition, creative organic cooking, and total care for self and family.

© 1975
American Media
P.O. Box 4646
Westlake Village
California 91359

The Little CYANIDE COOK BOOK

Delicious Recipes Rich in Vitamin B_{17}

By June de Spain

Sorry, ladies, this is NOT a manual on how to scuttle an over-insured husband! In fact, to the contrary, it's a helpful and delightful guide for keeping him around—and the rest of the family, too—for many years of health and vigor.

Nutritionist June de Spain has compiled 400 taste-tested recipes rich in natural sources of vitamin B_{17}, the cyanide-containing substance that many doctors and scientists now believe to be nature's control for cancer.

Contrary to popular belief, cyanide in minute quantities and in the proper food *forms*, instead of being deadly poisonous, actually is an essential component of normal body chemistry. Vitamin B_{12}, for instance, contains cyanide in the form of cyanocobalamin.

Vitamin B_{17} (also known as Laetrile, amygdalin, or nitriloside) gradually has been deleted from the menus of modern man in favor of foods which have been sweetened, processed, refined, and synthesized. It is significant that, during this same time span, the cancer rate has been climbing steadily upward. Here's the long-awaited book that shows what foods contain this vital nutritional factor and how to best prepare them for the whole family.

For the full story of the discovery and development of vitamin B_{17} in the control of cancer, see G. Edward Griffin's WORLD WITHOUT CANCER; THE STORY OF VITAMIN B_{17} elsewhere in this review.

Full size paperbound
200 pages (estimated)
$4.95 PRE-PUBLICATION PRICE ONLY.
$5.95 after publication: February 25, 1976
(Stock #APB12)

APPENDIX 4

[From the Lancet, August 4, 1973]

CHRONIC CASSAVA TOXICITY

ALTHOUGH tapioca is the sad archetype of many a revolt against school-dinners, it is one of the many ways of presenting the tuberous root of cassava, *Manihot esculenta*, a plant which flourishes in the tropics and subtropics. Enthusiastic agriculturalists are bent on making it flourish even more. Already world production is estimated at 90 million tons per annum, contributing 8–10% of global daily caloric needs. This represents the major caloric intake for 200–300 million people, and, if present trends continue, world production may have doubled by the end of the century. The reasons for its attraction as a root-crop are obvious: whereas the average global yield is 9·4 tons per hectare, even under ordinary conditions averages of 20 tons per hectare have been reported. Under experimental conditions yields of more than 70 tons per hectare are possible. As a carbohydrate food source, related to land use cassava ranks first, producing 250×10^3 calories per hectare per day, compared with 176×10^3 for rice, 110×10^3 for wheat, 200×10^3 for maize, and 114×10^3 for sorghum.[1] Whereas the genetic potential of grain crops has already been exploited to a considerable extent, cassava offers much scope for genetic improvement. Apart from the ease of cultivation, the crop is also economically attractive, and importation of cassava to Europe as animal feed-stuff and for non-edible purposes has steadily increased in the past decade.

The major drawback lies in the fact that cassava's cultivable superiority, and its resistance to pests, may depend on the highly toxic accumulation of the cyanogenetic glycoside linamarin, and linamarase (its corresponding hydrolytic enzyme), in the outer integument of the tubers and in leaves. Damage (such as handling, bruising, and exposure) activates linamarase, which quickly releases hydrogen cyanide from linamarin. Some of the resulting hazards to man were reviewed at an interdisciplinary workshop sponsored by the Canadian International Development Research Centre.[2] Although there are well-authenticated cases of acute cyanide poisoning in animals, evidence for chronic cyanide toxicity in domestic animals is lacking. Methionine supplementation in rats and pigs fed a cassava-based diet enhances growth-rates and increases the urinary excretion of thiocyanate, the main detoxication product of cyanide. By contrast, in man there is strong circumstantial evidence that among adult African populations who subsist mainly on cassava—for example, in the rain-forest belt of Nigeria, and in Tanzania—there is a relatively high incidence of a degenerative neurological disease, so-called tropical ataxic neuropathy. Elsewhere, both in Nigeria and in the Republic of Zaïre, there is evidence that the high incidence of endemic goitre is related to a goitrogenic effect of cassava. The data from Zaïre are of particular interest because on the island of Idjwi, where the population is uniformly iodine-deficient, the prevalence of goitre varies from 55% in the north to 5% in the south, and this difference corresponds to differences in cassava consumption, the population being homogeneous in other respects. In Nigeria, where tropical ataxic neuropathy has been most fully studied, cassava intake is unlikely to be the sole ætiological factor, because the populations at risk tend also to be protein and riboflavine deficient. Moreover, it is uncertain whether chronic toxic effects are due to absorption of cyanide as such, or to ingestion and metabolism of the glycoside. But, in either case, toxic exposure is substantial, and efficient detoxication of both cyanide and cyanogen depends on a freely available source of aminoacid sulphur to allow conversion to thiocyanate. Without protein enrichment, the attraction of cassava for people on a subsistence diet may be potentially harmful, even dangerous, despite culinary precautions aimed at reducing acute cyanide toxicity.

Interest in cyanide and cyanogen toxicity is timely. International agricultural agencies are poised to promote cultivation of cassava extensively in the natural hothouses of the world, and it is important that the right plant strains are encouraged, preferably combining high yields with low toxicity. Of course, it is to be hoped that this will not mean loss of resistance to disease and pests—otherwise back to D.D.T. There is, too, need for a careful appraisal of the role of cyanide as a ubiquitous (1500 p.p.m. in tobacco smoke) and potent metabolic inhibitor, during chronic environmental exposure—a role which has been largely ignored.

1. Coursey, D. G., Haynes, P. H. *Wld Crops*, 1970, July/August, p. 261.
2. Chronic Cassava Toxicity: proceedings of an interdisciplinary workshop. Edited by B. NESTEL and R. MACINTYRE. Monograph IDRC-010e, International Development Research Centre, Ottawa, Canada. 1973. $5.0 Can.

IDRC-010e

CHRONIC CASSAVA TOXICITY

Proceedings of an interdisciplinary workshop
London, England, 29–30 January 1973

Editors: BARRY NESTEL AND REGINALD MACINTYRE

Contents

Foreword	Barry Nestel	5–7
Workshop Participants		8–10
Current utilization and future potential for cassava	Barry Nestel	11–26
Cassava as food: toxicity and technology	D. G. Coursey	27–36
Cyanide toxicity in relation to the cassava research program of CIAT in Colombia	James H. Cock	37–40
Cyanide toxicity and cassava research at the International Institute of Tropical Agriculture, Ibadan, Nigeria	Sidki Sadik and Sang Ki Hahn	41–42
The cyanogenic character of cassava (*Manihot esculenta*)	G. H. de Bruijn	43–48
The genetics of cyanogenesis	Monica A. Hughes	49–54
Cyanogenic glycosides: their occurrence, biosynthesis, and function	Eric E. Conn	55–63
Physiological and genetic aspects of cyanogenesis in cassava and other plants	G. W. Butler, P. F. Reay, and B. A. Tapper	65–71
Biosynthesis of cyanogenic glucosides in cassava (*Manihot* spp.)	Frederick Nartey	73–87
Assay methods for hydrocyanic acid in plant tissues and their application in studies of cyanogenic glycosides in *Manihot esculenta*	A. Zitnak	89–96
The mode of cyanide detoxication	O. L. Oke	97–104
Chronic cyanide toxicity in domestic animals	D. C. Hill	105–111
Implications of cyanide toxicity in animal feeding studies using high cassava rations	Jerome H. Maner and Guillermo Gómez	113–120
Cyanide and human disease	J. Wilson	121–125
Ataxic neuropathy associated with high cassava diets in West Africa	B. O. Osuntokun	127–138
Endemic goitre and high cassava diets in eastern Nigeria	O. L. Ekpechi	139–145
Evidence of an antithyroid action of cassava in man and in animals	F. Delange, M. van der Velden, and A. M. Ermans	147–151
Mechanism of the goitrogenic action of cassava	A. M. Ermans, M. van der Velden, J. Kinthaert, and F. Delange	153–157
Summary of the General Discussion		159–162

Summary of the General Discussion

- Screening for acyanogenesis and low cyanide levels in the extensive collections of cultivated lines of cassava which are available and also of uncultivated "wild" material would be desirable. No acyanogenic strains of *M. esculenta* are known (although one was reported in Indo-China some years ago). The most promising material might be expected to be at the centre of origin of *M. esculenta* (now believed to be in North Colombia) and also at the periphery of its natural distribution. It is unlikely that an acyanogenic line, once developed, would revert to cyanogenesis (on the basis of experience over 20 years with acyanogenic white clover lines).

- The intermediates in the biosynthesis of linamarin and lotaustralin do not accumulate in the plant and do not represent a toxicological hazard. If acyanogenic cassava plants were discovered, it is likely, on the basis of experience with other species, that the metabolic block would be at the commencement of the pathway as a result of mutation of a regulatory gene which eliminates the entire pathway. The possibility of inhibition of the biosynthesis by the use on the cassava crop of an inhibitor selective for the cyanoglucoside pathway should be considered, although no suitable substances can be suggested at this stage.

- Knowledge of the physiology of the cassava plant insofar as it affects cyanoglucoside levels requires further investigation under conditions of controlled environment and controlled mineral nutrition. Such information may well be obtainable as an adjunct to experiments aimed at studying other parameters such as photosynthetic efficiency. It is particularly important to establish whether or not the primary site of cyanoglucoside synthesis is the leaves, followed by cyanoglucoside translocation to the roots. The extent to which the glucosides are synthesized in the roots can be tested by C^{14}-valine feeding experiments using cores of root tissue. The cyanoglucoside content of stem phloem sap should also be determined if possible.

- If the leaf proves to be the site of cyanogenesis it will be possible to screen for cyanogen content using leaf tissue in which case zero linamarin rather than zero linamarase should be sought. As the gene(s) controlling cyanogenesis may be recessive, it would be preferable for inbred lines to be used for the screening process.

- The techniques of radiation- or mutation-breeding merit attention; although frequently unsuccessful as a breeding tool, it should be borne in mind that, in the case of acyanogenesis in cassava, it is desired to eliminate a character rather than to develop a new one and hence the chances of success may well be greater than usual.

- The advantages of varieties with low- or zero-cyanide contents in the interior of the tuber, combined with high cyanide levels in the skin were discussed, from the viewpoint of possible pest resistance. In Thailand, cassava with high cyanide levels is grown with low cyanide varieties, but it seems likely that these mixed crops of bitter and sweet varieties are grown essentially to reduce pilfering by humans.

However, there is evidence that, under some circumstances, cyanoglucosides can have a protective role in plants and therefore it is possible that an acyanogenic variety of cassava could be more susceptible to pathogens and to pests than the existing cyanogenic form. Conflicting comments on the effects of breeding-out of alkaloids and of thioglucosides from other species only strengthened the view that no prediction could be made for cassava about possible susceptibility. Subjective observations on the occurrence of dead partridges and other animals near cassava crops were mentioned, while grasshoppers had also been seen eating some varieties of cassava, but not others. It was not known whether this differential eating was associated with the cyanogenic glucoside content of the leaves.

The difficulties encountered over the apparent retention of cyanide in prepared cassava were discussed. Cyanhydrins, as a class, have a wide range of dissociation constants with the equilibrium in tissues well over towards cyanhydrin. The concentration of hexose sugars is high (about 4%) in the tuberous roots of cassava and hence interaction between the HCN released and these sugars is highly likely. Thus the HCN could be trapped as cyanhydrin, being released when water or acid is added. It was stated that cassava which has been fried in cooking oils retains the capacity to release HCN whether or not linamarase is added later. A possible explanation is that the HCN produced before the β-glucosidase is destroyed by heat reacts with carbonyl groups in these oils.

Apart from the nutritional problems implied, retention of HCN in processed cassava negates any consistent method of estimating the cyanogenic glucoside content of tuberous roots by measuring the CN produced on hydrolysis. Clearly, this also casts doubt upon the validity of estimations of cyanogenic glucosides in other species. Indeed, when known quantities of substrate were added with linamarase to cyanogenic plant tissue, only 50% of the added part could be recovered. Although it was possible that an enzyme inhibitor was present, it was more likely that the HCN released was trapped by aldehydes and sugars.

Although the discussion concentrated on HCN, the possibility that cyanogenic glucosides themselves could be trapped was considered as a possibility. Reference was also made to the fact that about half of the total nitrogen of cassava is non-protein nitrogen and it was suggested that nitriles might possibly play a role in cassava toxicity.

Indeed, the possibility that substances other than cyanogenic glucosides might be responsible for the clinical conditions described in humans was discussed. However, experiments in New Zealand with rats and guinea pigs, using the cyanogenic or acyanogenic forms of white clover, produced thyroid changes in complete agreement with those recounted at the workshop by the Belgian team. The essential difference between the two experimental conditions was the control feed: acyanogenic white clover as opposed to a Remington diet. Thus other plant constituents are probably unimportant, because it is likely that cyanogenic and acyanogenic white clover plants of the same commercial variety differ only in the cyanogenic glucoside content.

Participants questioned whether linamarin itself is toxic and noted that both linamarin and lotaustralin are relatively stable compounds which are unchanged in 0.1 N acid over 39°C during 48 h, i.e. under the conditions of acidity encountered in the stomach, they are also unchanged by boiling in water at 100°C. It was suggested that while linamarin could be absorbed through the small intestine, it would otherwise be degraded in the large intestine particularly by enzymes produced by the gut flora. Certainly HCN is present in fresh faeces, while cyanogenesis in sewage can present a health hazard. It was concluded that little was known about the digestion of linamarin on the one hand, and the possible variation in gut flora, related to diet, on the other.

However, in feeding trials, it seems reasonable to distinguish between monogastric and polygastric mammals. The stomachs of ruminants were like fermentation tanks, in which breakdown of cyanogenic substances was probable. Ruminants have a higher tolerance to HCN than the other mammals tested. There is ample evidence to show that high levels of cassava can be fed to pigs and poultry with no ill effects, providing the diet is balanced and possibly enriched with methionine. Instances were cited of dried cassava being used at up to 69% in compounded feeds, and of fresh cassava as the sole carbohydrate source. Earlier reports of toxic effects in livestock were probably associated with unbalanced diets.

In some parts of Africa, two important human diseases, tropical ataxic neuropathy and endemic goitre, appear to be associated with a high cassava intake. Ataxic neuropathy is a disease of poor people who eat cassava, and little else, twice daily. Under such circumstances, the disease may have an incidence many times that of some well-known diseases of affluent society. In Nigeria, ataxic neuropathy is always associated with an unbalanced diet, especially one low in meat which may have some protective effect associated with its high content of sulfur-containing amino acids. However, in one area where both cassava and fish are consumed in large quantities, the incidence of neuropathy is high.

In Zaire, goitre rather than neuropathy has been reported, and this condition appears to be associated with the formation of thiocyanate (SCN) from cyanide detoxification. However, the evidence for this is purely circumstantial based on feeding experiments and requires verification before SCN can be definitely incriminated as the sole causative factor. In any event, a low iodine intake and nutritional status appear to be preconditions for disturbances in iodine metabolism associated with high cassava intakes. In some cassava-eating patients with goitre, the symptoms have disappeared following the injection of iodized oil.

Apart from its association with goitre, high cassava intake may also be associated with congenital cretinism of the newborn especially when the iodine and nutritional status of the mother in the last trimester of pregnancy are low. In discussing this, it was noted that cows eating cruciferous plants containing thioglucosides do not pass iodine on to their calves.

There appeared to be a considerable lack of organized information on traditional methods of detoxicating or otherwise preparing cassava for human food and it was suggested that there was a need to establish internationally acceptable standards for permissible levels of linamarin and of free or available cyanide, as has been done for other glycoside-containing foodstuffs. In view of the current concern with toxic factors in food and the good market potential that seems to exist for cassava products, this subject would seem to warrant further study.

It was recognized that the prospects for reducing toxicity by changing rural processing procedures were limited, due to the strength of traditional customs. Nevertheless cassava is a crop that has relatively recently been introduced to many countries suggesting that new technology and practices can be introduced if suitable new (and perhaps fortified) processed cassava products can be developed. The need for such products is apparent from the levels of cyanide in some widely used cassava products—e.g. purupuru in West Africa may be consumed in quantities which give a daily cyanide intake of 20–50 mg. In some purupuru-eating areas, ataxic neuropathy assumes endemic importance. Likewise in Idjwi Island where the level of goitre is high, the population eat both cassava flour which is low in cyanide and raw cassava which has a very high cyanide level.

- For further experimental work on toxicity, it may be desirable to use species other than rats and pigs. The major problem in this type of work concerns the comparability of the physiological age of the animals used and this makes it difficult and perhaps misleading to extrapolate to man. It also appears to be difficult to reproduce neurological diseases in animals. Rats seem to be very resistant to cyanide and show an astonishing capacity for renal clearance of orally administered cyanide. The need for primate work was stressed. However, it is important not to underestimate the difficulties of using primates.

- For further animal work on both toxicology and metabolism, a substantial amount of purified linamarin would be desirable. Smaller quantities of isotopically labelled linamarin are also needed for work on animal physiology and biochemistry. For such work, it should be possible to synthesize linamarin or to extract it from suitable plant material. It was suggested that this subject should be investigated from the standpoint of obtaining a large enough supply for a cooperative interdisciplinary research program on cassava toxicity.

Peripheral Neuropathy in Tropical (Nutritional) Ataxia in Nigeria

Light and Electron Microscopic Study

A. Olufemi Williams, M.A., M.D., M.R.C.P., M.R.C.Path., and Benjamin O. Osuntokun, M.B., M.R.C.P., Ibadan, Nigeria

THE TROPICAL or nutritional ataxic neuropathy as seen in Nigerian patients is characterized by bilateral optic atrophy, bilateral nerve deafness, and predominantly posterior column myelopathy with or without peripheral neuropathy. The clinical, biochemical, and electrophysiologic features of this syndrome have been described,[1] but there is no pathologic study of the disease in Nigeria. The natural history of the disease is one of slow progression, and there has been no fatal case among the patients studied. There is evidence that chronic cyanide intoxication from dietary sources may be an etiologic factor.[1,2] The effects of chronic cyanide intoxication on the nervous system in man and in experimental animals have been well documented; these include, among other things, diffuse demyelination. It is believed that the tropical ataxic neuropathy is a demyelinating disease. The evidence for this is scanty and, to date, has been based on the findings of segmental demyelination in single nerve fibers prepared according to the method of Vizoso and Young.[3] Similar findings have been noted by one of us (B.O.O.) (unpublished data). In order to confirm and characterize the type of demyelination, it was decided to study the pathologic changes in the peripheral nerves of patients with the syndrome, employing light and electron microscopy. Since abnormalities of motor nerve conduction are demonstrable in the lower-limb segments, and furthermore, the neuropathic changes are usually more marked in the lower limbs, the digital branches of the anterior tibial nerves were studied. The light microscopic features of peripheral nerves from 23 patients and electron microscopic features of peripheral nerves from four of these patients are described.

Submitted for publication Nov 18, 1968; accepted June 12, 1969.

From the Departments of Pathology (Dr. Williams) and Neurology (Dr. Osuntokun), University of Ibadan and University College Hospital, Ibadan, Nigeria.

Reprint requests to Department of Pathology, University College Hospital, Ibadan, Nigeria (Dr. Williams).

Materials and Methods

The peripheral nerves were obtained from 23 Nigerian patients with varying severity of peripheral neuropathy. All the patients had clinical and biochemical features of the ataxic syndrome. Peripheral nerves from two patients with amputation of the legs following trauma were also examined and served as control subjects. The majority lived in the coastal town of Ijebu in the western state of Nigeria. There were 12 men and 11 women. Their ages ranged from 14 years to 40 years. In patients with bilateral peripheral neuropathy, the biopsy was obtained from the more affected foot, while there was no preference for either foot in patients with symmetrical involvement. Of the 23 patients, ten had clinical evidence of peripheral neuropathy and abnormal nerve conduction, nine had no clinical evidence of peripheral neuropathy, but had abnormal nerve conduction, and two had no clinical evidence of neuropathy or abnormal nerve conduction time. All the nerves were fixed in 10% formaldehyde solution, embedded in paraffin, and stained routinely with hematoxylin and eosin. The following special stains were also carried out on fresh and paraffin-embedded sections: Picro-Mallory, Glees and Marchand, luxol fast blue, phosphotungstic acid-hematoxylin, Sudan IV, and Bielschowsky-Gross. Four nerves were fixed in 3% glutaraldehyde for one to two hours in the cold, post-osmicated for four to six hours in 2% osmium tetroxide, dehydrated in graded ethanols, and embedded in epoxy resin. Sections, 2μ thick, were cut with an ultramicrotome (Porter Blum) using glass knives, and after trimming, ultrathin sections of nerve tissues were cut on

an ultramicrotome (LKB) using a diamond knife. Tissues were mounted on copper grids, stained with uranyl acetate and lead citrate, and examined with an electron microscope (RCA EMU 3G).

Plasma thiocyanate was determined by the method of Aldridge,[4] and vitamin B_{12} levels were estimated as described by Matthews.[5]

In order to elucidate the possible role of cyanide in the pathogenesis of the disease, an experimental study was carried out on laboratory rodents. The sciatic nerves of six Sprague Dawley strain of rats were exposed aseptically, under chloral hydrate aided by ether anesthesia. The sciatic nerves of the right leg were injected with 0.5 cc of 1% sterile potassium cyanide, and 0.5 cc of sterile saline was injected into the sciatic nerves of the left leg. The muscle and skin layers were closed with catgut and metal clips, respectively, and the animals were observed for four weeks, during which time they developed progressive weakness of their right hind limbs compared with the left. The sciatic nerves were removed after cold 3% glutaraldehyde had been injected into the abdominal aorta, thereby fixing the nerves in situ (communication from P. Lampert in A.F.I.P. Washington DC). Sections of nerves examined by the light and electron microscopes were derived from the farthest possible area away from the injection sites. The nerves were fixed in 2% osmium tetroxide for six hours and processed in the usual fashion for electron microscopy.

The clinical features, biochemical, electrophysiologic, and histologic findings of the four patients whose peripheral nerves have been studied under the electron microscope are presented below in detail.

Report of Cases

CASE 1.—The patient (No. 86106) was a 33-year-old woman who presented with a four-year history of ataxic gait, and a burning sensation and numbness in the feet and which later appeared in the hands. The ataxic gait was so rapidly progressive that within a year of the onset of symptoms, she could only walk with the aid of supporting sticks. She also suffered from recurrent angular stomatitis and glossitis. Her symptoms showed some degree of intermittency, her condition being worse during the rainy season. Her diet over the years consisted mainly of cassava derivatives eaten twice daily, supplemented occasionally by plantain, beans, and rice. She had no splanchnic disturbances.

On examination, the tongue was normal but there were healed scars of angular stomatitis. She was mentally alert and cooperative with normal higher cerebral functions or mentation. Visual acuity was 6/60 in each eye (Snellen types) and funduscopy showed bilateral primary optic atrophy. She had mild bilateral perceptive deafness, which was confirmed on audiometric examination. Bilateral foot drop was present, and there was symmetrical wasting and weakness of the muscles of the lower limbs below the knee, the wasting being more marked distally. The muscles were hypotonic. There was grade 0 weakness (Medical Research Council of United Kingdom scale) of the extensor hallucis brevis, extensor hallucis longus, anterior tibialis, extensor hallucis longus, and the peronei muscles. There was a grade 1 weakness of the plantar flexors of the feet. There was mild weakness (grade 4) of the proximal musculature of the lower limbs. Coordination was severely impaired in the lower limbs. The upper limbs were normal. No fasciculations were seen, and there was no muscle tenderness. Light touch sensation (to cotton wool) was lost in a symmetrical fashion in the lower limbs below the waist. She could appreciate pin prick and temperature sensation. Vibration sense was lost in the lower limbs below the anterior superior iliac spines and so were joint position sense and appreciation of joint movement of the toes and ankles. Two point discrimination was impaired in the soles of the feet (3 cm between compass points). Apart from slight diminution of vibration sense in the fingers, the upper limbs were normal. The knee and ankle jerks were absent, but the tendon reflexes were present in the upper limbs. The plantar reflexes were flexor, and the abdominal reflexes were present. The stance was unsteady and wide-based. She exhibited a high steppage, wide-based gait, like a tabetic gait with her eyes fixed to the ground. Toeing a line was impossible to accomplish. Romberg's sign was present. The peripheral nerves were not palpably thickened. The cardiovascular and respiratory systems and the abdomen were normal. There were no skeletal abnormalities.

Investigations.—The hemoglobin concentration was 11.0 gm/100 ml; mean corpuscular hemoglobin concentration (MCHC), 33; hemoglobin electrophoretic fractionation, AS. Serum bilirubin level was 0.2 mg/100 ml; alkaline phosphatase, 3.7 King-Armstrong units/100 ml; thymol flocculation test was negative, and thymol turbidity test was 1+. Sulfobromophthalein retention in 45 minutes was 3% of the administered dose. Serum albumin level was 2.8 gm/100 ml and serum globulin was 3.8 gm/100 ml with

...mal pattern on electrophoretic fractiona... Total serum cholesterol level was 167 .../100 ml. Serum urea and electrolytes ...e normal. Serological test (Kahn) for ...philis was negative. Results of a standard ...ose tolerance test and (prednisolone) ...roid-stressed glucose tolerance tests[6] were ...rmal. Serum calcium level was 9.4 ...g/100 ml, and inorganic phosphate level, ...5 mg/100 ml. Fecal fat was 3 gm/24 hr. Serum vitamin B_{12} level (*Lactobacillus leichmannii*) was 850$\mu\mu$g/ml (in presence of cyanide) and 650$\mu\mu$g/ml in the absence of cyanide to the assaying medium (normal values $> 150\mu\mu$g/ml). Total serum folate value was 14 mμg/ml (*L casei*) (normal values > 5 mμg/ml). Plasma thiocyanate level on admission was 7.5μmol/100 ml (normal values $< 5.0\mu$mol/100 ml). Electrocardiography showed no abnormality, and chest radiographs of chest, spine, sacro-iliac joints, and pelvis also showed no abnormality.

Electromyography confirmed neurogenic weakness in the muscle of the lower limbs, with markedly reduced interference pattern and occasional fibrillation and fasciculation potentials. Motor nerve conduction velocities in the right lateral and posterior popliteal nerves were 24.2 and 26.8 meters per second respectively (normal values for our laboratory range between 40 and 68 meters per second). Conduction velocities for ulnar and motor nerves were normal: 65.5 and 62.2 meters per second for the upper arm and forearm segments of the right median nerves, respectively, and 65.0 and 78.5 meters per second for the corresponding segments of the right ulnar nerve. Audiometry showed severe loss in the low and high frequencies.

Liver biopsy showed no histologic changes. Anterior tibial nerve biopsy was carried out aseptically under local anesthesia.

CASE 2.—The patient (No. 167970) was an 18-year-old male plumber who gave a one-year history of unsteady gait which was worse at night; sensation of pins and needles in feet; and heaviness of lower limbs, which was most marked after exertion. The ground felt to him as if he walked on cotton wool. Three months after the gradual onset of symptoms, he developed tinnitus in both ears, and by the time he reported into the hospital, he had noticed his hearing was considerably impaired. Although his gait was very unsteady, he could walk without the aid of any support. For many years, his diet consisted mainly of cassava derivatives, eaten at least twice, and sometimes three times daily. There was no history of intermittency in the symptoms and no sphincteric disturbances.

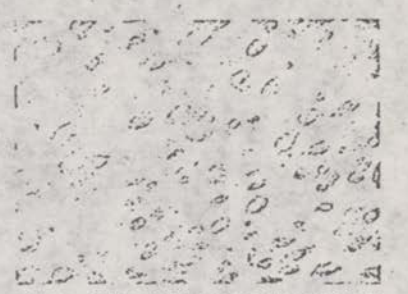


Fig 1.—Plastic embedded section of peripheral nerve showing patchy demyelination (osmium, × 600).

On examination he had glossitis, with hyperemic and hypertrophic papillae and a reddish tongue, but no signs of healed or fresh angular stomatitis. Mentation and sensorium were normal. Visual acuity was normal, but funduscopy showed bilateral temporal pallor. The visual fields appeared full on confrontation, but bilateral paracentral scotomata were demonstrable with the aid of the Bjerrum screen. There was bilateral perceptive deafness. There was mild weakness of the proximal musculature of the lower limbs, but no wasting was seen. There was a patchy loss of light touch sensation over the dorsum of the feet, but pain and temperature sensations were normal. Vibration sense was absent from the anterior superior iliac spines downwards. Joint position sense and appreciation of passive movement of the joints were absent in the toes and ankles. Two point discrimination was severely impaired in the lower limbs (5 cm between compass points in soles of feet). The upper limbs were normal in every respect. The ankle jerks were absent in the lower limbs, and the knee jerks were depressed. The plantar and abdominal reflexes were present and normal. The stance was wide-based and unsteady. Romberg's sign was elicited. The gait was staggering and ataxic in type with the patient carefully watching the ground. He could not walk along a straight line. The peripheral nerves were not palpably thickened. The cardiovascular system, the chest, and the abdomen showed no abnormalities. There were no cerebral abnormalities.

Investigations.—Hematological indices

Fig 2.—Transverse section of peripheral nerve showing large numbers of unmyelinated fibers compared to myelinated fibers. Note abundance of collagen (C) surrounding unmyelinated fibers. Ax indicates axon; N, nucleus (uranyl and lead, reduced slightly from × 12,000).

Fig 3.—Unmyelinated fibers surrounded by abnormally increased amount of collagen (C). Note electron dense body (arrow) with outer ring and inner solid core. SM indicates surface membrane; My, myelin (× 21,000).

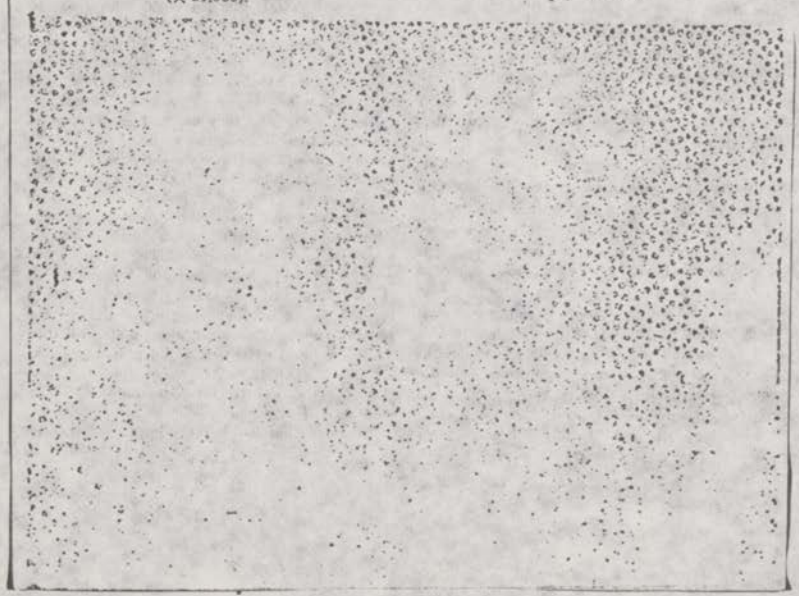
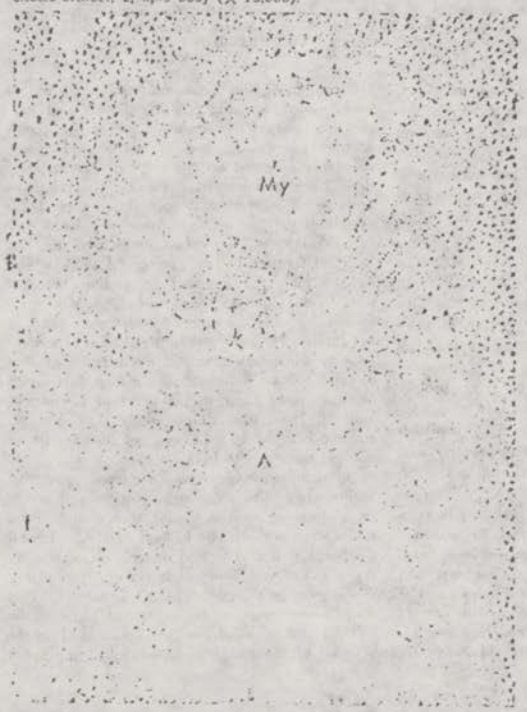


Fig 4.—Multilobulated body in axoplasm (Ax) of demyelinated fiber. One loculus is evidently filled with lipid material (Li) while others are vacuolated due to extraction. C indicates collagen (× 47,000).

Fig 5.—Demyelinated fiber, with ghost outline (My) of osmiophilic layered structure. Several osmiophilic bodies are present. Note mitochondria (Mi) with obscured cristae and increased surrounding collagen (C). A indicates artifact; L, lipid body (× 15,000).



were as follows: hemoglobin 15.2 gm/100 ml; packed cell volume (PCV), 47%; MCHC, 32%; white blood cell count (WBC), 5,400/cu mm; hemoglobin electrophoretic fractionation, AC; and the blood film showed normal morphology of the cellular components. Serum bilirubin level was 0.8 mg/100 ml; alkaline phosphatase, 17 King-Armstrong units/100 ml; thymol flocculation and turbidity tests were negative; serum glutamic oxaloacetic transaminase (SGOT) was 14 Cabaud units/ml. Total serum protein level was 7.6 gm/100 ml with a serum albumin level of 3.6 gm/100 ml and normal globulin fractions on cellulose acetate electrophoresis. Serum electrolytes and urea levels were normal. Cerebrospinal fluid (CSF) examination showed no abnormality with a glucose content of 71 mg/100 ml; protein concentration of 15 mg/100 ml; and 3 WBC/cu mm. Free acid was present in early morning gastric aspirates. Results of a standard glucose tolerance test were normal. Results of a steroid-stressed glucose tolerance test were slightly abnormal with values of 95, 168, 176, 165, and 144 mg per 100 ml at half hour intervals. Serum calcium level was 8.9 mg/100 ml and serum phosphate level was 3.8 mg/100 ml. Fecal fat was 5 gm/24 hr. Plasma thiocyanate level on admission was 11.0 μmol/100 ml, and serum vitamin B_{12} level was 1,001 $\mu\mu$g/ml (with cyanide extraction) and 829 $\mu\mu$g/ml without added cyanide to the assaying medium. Serum folic acid level

Fig 6.—Longitudinal section of myelinated and demyelinated fiber. Note slight increase of neurofilaments (Nf) in demyelinated fiber. C indicates collagen; A, artifact; My, myelin; N, nucleus (reduced slightly from × 15,000).

was 17 mμg/ml. Plain radiographs of skull, chest, spine, and sacro-iliac joints were normal. Electrocardiographic examination showed no abnormality.

Electromyography showed no abnormality. The following represent motor nerve conduction velocities in meters per second: lateral popliteal nerve (knee-ankle segment), 33.7; median nerve, 50.4 in the forearm segment, 54.0 in the upper arm segment; and ulnar nerve, 64.0 and 61.2 for forearm and upper arm segments, respectively. Audiometry showed severe loss of hearing in the high and low frequencies.

Histological examination of liver biopsy revealed nonspecific slight lymphocytic infiltration of portal tracts only. Anterior tibial nerve biopsy was obtained aseptically and under anesthesia for histopathologic examination.

Case 3.—The patient (No. 179300) was a 17-year-old male secondary school day-student. (A day-student is a student who lives with parents and goes to school daily in contrast to a student boarder who lives in the school.) The patient presented with a one-year history of ataxic gait, tinnitus, impaired hearing, and severe dysesthesia confined to the lower limbs. He complained of heaviness and weakness of lower limbs, burning sensation, pins and needles, a persistent sensation of tight bands around the calves, and of some cold messy substance smeared on the sides of his feet. He denied any impairment of vision. His symptoms have been intermittent; sometimes they bothered him very little, sometimes they were very "troublesome." The patient admitted he had suffered frequently from recurrent angular stomatitis and glositis, and these had made it difficult for him to tolerate the usually spicy sauces normally consumed by other members of his family. He gave a dietetic history of monotonous farinaceous meals derived from cassava derivatives, eaten three times a day. His mother, four years prior to the onset of his illness, suffered from a similar malady, but had recovered completely (she was not seen by us, as we had no access to her).

On examination, he was a rather emaciated looking boy with angular stomatitis and severe magenta-red glositis. Visual acuity and visual fields were normal, but he had marked bilateral temporal pallor. He had severe bilateral perceptive deafness. This made neurological examination rather difficult. There was bilateral foot drop, more severe on the right foot than on the left. There was atonic weakness and slight wasting of the distal musculature of the lower

Fig 7.—Demyelinated fibers in vicinity of Schmidt-Lantermann cleft (arrows). A indicates artifact, C, collagen; Ax, axon (× 11,000).

limbs below the knees. Coordination was severely impaired. No fasciculations were seen. Vibration sense was absent in the anterior superior iliac spines and below; joint position sense and appreciation of passive movement were absent in the joints of the toes. Two point discrimination was also impaired in the soles of feet (4 cm between compass points). Sensation to light touch, temperature, and pain was normal in the lower limbs. The ankle and knee jerks were absent in the lower limbs, but the tendon reflexes were normal in the upper limbs. The plantar and abdominal reflexes were normal. The stance was wide-based and unsteady. Romberg's sign was present. He showed a high steppage talctic gait. He could not toe a line. The upper limbs were normal. The chest, abdomen, and cardiovascular systems were normal. There were no skeletal abnormalities. Palpation of peripheral nerves revealed no thickening.

Investigations.—Hemoglobin concentration was 14.0 gm/100 ml; PCV, 40%; WBC, 6,400/cu mm. A blood film showed normal morphology of the cellular components. Hemoglobin electrophoretic fractionation was AA. Serologic test for syphilis (Kahn) was negative in blood and in CSF. Free acid was present in an overnight fasting gastric aspirate. Serum bilirubin level was 0.4 mg/100 ml; alkaline phosphatase, 3 King-Armstrong units/100 ml; thymol turbidity and flocculation tests were negative. Levels of SGOT and serum glutamic pyruvic transaminase (SGPT) were 26 and 14 Cubaud units per ml, respectively. Sulfobromophthalein retention test was normal at 14% in 45 minutes. Total serum cholesterol level was 147 mg/100 ml; total serum protein level was 7.5 gm/100 ml, with a serum albumin level of 3.2 gm/100 ml, and serum globulin level of 4.3 gm/100 ml, but with normal globulin fractions on cellulose acetate electrophoresis. A CSF examination was normal in dynamics, protein content (35 mg/100 ml), glucose content (54 mg/100 ml); and there was no excess of cells.

Serum calcium level was 9.9 mg/100 ml, and serum inorganic phosphate level, 4.6 mg/100 ml. Fecal fat was 4.5 gm/24 hr. Results of a standard glucose tolerance test were normal. Plasma thiocyanate level on admission was 11.2 μmol/100 ml. Serum vitamin B_{12} levels were 700 $\mu\mu$g/ml (with cyanide extraction) and 375 $\mu\mu$g/ml (without cyanide added to the assay medium). Plain radiographs of chest, spine, and sacro-iliac joints were normal. Electrocardiographic studies were normal. Electromyography showed neurogenic weakness in the distal

Fig 8.—Relatively normal myelinated and unmyelinated fibers with minimal changes. Note normal quantity of collagen (C). Note vacuoles (arrows and v) in axoplasm (Ax) and within compact myelin (My) near node of Ranvier. Some of these contain membrane profiles. A indicates artifact; N, nucleus, SM, surface membrane (× 7,000).

musculature of the lower limbs, which showed markedly reduced interference pattern on maximal volitional contraction. There was, however, no spontaneous activity at rest. There were no giant polyphasics suggestive of reinnervation. The H-reflex latency recording from the triceps-suae was 41 msec (normal value in our laboratory, < 37 msec). Motor nerve conduction velocities in the lateral popliteal nerve were grossly slowed at 32.5 meters/sec, and normal in the upper limbs: 41.6 and 58.3 meters per second for forearm and upper arm segments of median nerve, and 47.2 and 49.0 meters per second for corresponding segments of ulnar nerve.

Audiometry showed loss of hearing in the high and low frequencies. Percutaneous liver biopsy showed normal histologic appearance. Peripheral nerve biopsy was obtained for pathologic examination.

Case 4.—The patient (No. 179543) was a 14-year-old girl who gave an 18-month history of girdle pain about the waist level radiating down the legs, heaviness, weakness, numbness, pins and needles, and burning sensation in lower limbs. She volunteered that the ground felt as if she were walking on cotton wool and sometimes, her legs felt as if they did not belong to her. She had had tinnitus intermittently and, in recent months, she was convinced her hearing had deteriorated. She admitted precipitancy of micturition in the last six

months before admission to hospital. She said she had no disturbance of her vision. The patient's diet for several years consisted of cassava derivatives eaten at least twice a day. She had suffered frequently from stomatoglossitis.

Physical examination revealed an emaciated young girl with healed angular scars, hypertrophy of papillae of the tongue, and nonhemorrhagic follicular hyperkeratosis on the extensor surfaces of both upper and lower limbs. Her sensorium was normal, but she was of rather low intelligence. Her reasoning and interpretation of abstract ideas were impaired. Visual acuity on the right was 6/12, and 6/18 on the left (Snellen's type). Funduscopy showed bilateral temporal pallor. She had bilateral perceptive deafness. There was hypertonia of the lower limbs. There was a grade 3-4 (MRC scale) weakness of the proximal musculature of the lower limbs without any convincing wasting. Coordination was grossly impaired in the lower limbs. No fasciculations were seen. Sensation to cotton wool and vibration sense were lost below the anterior superior iliac spines. Joint position sense and appreciation of passive movement were lost in the joints of the toes and ankles. Pain and temperature sensations were normal. The upper limbs were normal with regards to muscle power, tone, coordination, and sensations. The tendons reflexes in both upper and lower limbs were exaggerated with sustained ankle and patella clonus in both lower limbs. The plantar and abdominal reflexes were normal. There was no abnormality detected in the skull and spine, but she had marked bilateral pes cavus. The stance was wide-based and unsteady. Romberg's sign was present. Her gait was ataxic, and she could not walk along a straight line. The chest and abdomen were normal. Apart from a pulse rate of 100 beats per minute, which did not slow during sleep or with basal sedation, the cardiovascular system was normal. There was no thickening of peripheral nerves on palpation.

Investigations.—Hematologic studies disclosed the following values: hemoglobin concentration, 12.0 gm/100 ml; PCV, 34%; WBC, 5,500/cu mm. The patient showed no abnormalities. Hemoglobin electrophoretic fractionation was AA. Serum urea level and electrolytes were normal. Serum calcium level was 9.9 mg/100 ml, and serum inorganic phosphate level was 3.4 mg/100 ml. Fecal fat was 5.5 gm/24 hr. Serological tests for syphilis in blood and CSF were negative. Serum bilirubin level was 0.1 mg/100 ml; alkaline phosphatase, 17 King-Armstrong units; and thymol turbidity and flocculation

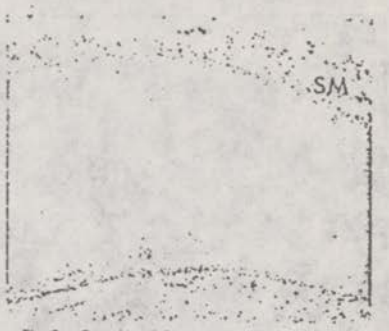


Fig 9.—Granular disintegration of compact myelin. Note relatively normal surface membrane (SM). (× 20,000).

tests were negative. The SGOT and SGPT were 22 and 5 Cabaud units per milliliter, respectively. Serum cholesterol level was 118 mg/100 ml. Serum total protein level was 7.6 gm/100 ml, with a serum albumin level of 3.9 gm/100 ml, and normal globulin fractions on electrophoresis. Sulfobromophthalein retention test was 3% in 45 minutes. A CSF examination showed no abnormality with a glucose content of 72 mg/100 ml, protein content of 25 mg/100 ml, and no leukocytosis on microscopic examination. No free acid was present in overnight fasting gastric aspirate, but the Kay's augmented histamine test meal showed 48 mEq of free acid in the 30 minute aspirate. Results of a standard glucose tolerance test and the prednisolone-stressed glucose tolerance test were normal. Plasma thiocyanate level on admission was 9.5 μmol/100 ml. Serum vitamin B_{12} levels were 500 $\mu\mu$g/ml and 425 $\mu\mu$g/ml, with and without cyanide extraction, respectively. Serum folate activity was 9.0 mμg/ml. Plain radiographs of the chest, spine, and sacro-iliac joints were normal. Electrocardiographic examination showed sinus tachycardia.

Electromyography showed neurogenic weakness in the distal musculature of the lower limbs. There was no spontaneous electrical activity at rest. The following were motor nerve conduction velocities in meters per second: lateral popliteal nerve, 37.5 on the right, and 50.1 on the left (knee-angle segment); 42.0 and 42.7 in the forearm and upper arm segments of the median nerve; 42.8 and 42.8 in the corresponding segments

Fig 10.—Variation in size, shape, and thickness of myelin figures. Some are oval and some are folded. Note Schmidt-Lantermann cleft (arrow) (reduced slightly from × 7,500).

Fig 11.—Folded myelin (My) with loss of axoplasm. Note neurotubular structures (arrows) in Schwann cell cytoplasm (reduced slightly from × 15,500).

of the ulnar nerve. The H-reflex latency measured in the triceps surae in the lower limbs was 37 msec. Myelography demonstrated no abnormality. Audiometry showed loss of hearing in the low frequencies only. Percutaneous liver biopsy showed no abnormal histologic features. Biopsy of the more affected peripheral nerve was obtained for pathologic examination.

Results

Gross.—There were no macroscopic changes in the peripheral nerves from the 23 patients and experimental animals.

Light Microscopy of Peripheral Nerves.—Histologic changes in various stages of evolution were observed in all the 23 human peripheral nerves examined. The lesions were multifocal, segmental, and scattered at varying intervals along the nerves. Some changes could be considered early or of a minor degree, while others were late and chronic in type. In frozen sections of eight peripheral nerves, sudanophilic granules were seen either lying free in the perineurium or endoneurium or in myelinophagic cells. In more severely affected nerve segments, there was considerable distortion of myelin sheaths, and phagocytosis of degenerate myelin was evident. Wallerian ovoids were only seen in two cases, but free degenerating macrophages were more frequent in the severely damaged fibers. The blood capillaries were usually congested and there was moderate proliferation of the endothelial cells. In some areas infiltration of lymphocytes, plasma cells, and mononuclears around the small blood vessels of the nerves were prominent. The perineural connective tissue was thickened by dense fibrous

some in some nerves, and hyalinized collagen was seen in a few. The nerve fibers were widely separated in areas presumably by edema fluid. There was reduction in the number of myelin sheaths in about one third of the cases. In a few cases, eosinophils and plasma cells were seen around the endoneural septal fibers. Axonal changes were infrequent, but in some cases there were striking irregularities in the caliber of the axons, giving rise to globules or an appearance which could be referred to as "axonic bubbles." The axonal lesions were not as striking and extensive as the myelin changes. Schwann cell and neurilemmal cells were not increased in numbers, although pyknotic Schwann cells appeared rather prominent in places. In osmium fixed material, demyelination was very well demonstrated (Fig 1). Although demyelination was of long standing in most cases, acute demyelination with accompanying cellular reaction was occasionally observed.

Electron Microscopy.—Out of the 23 peripheral nerves studied by light microscopy, four peripheral nerves were studied under the electron microscope, and the changes observed will be described together. The detailed clinical features of the four unselected patients are presented above (cases 1 to 4). Although there was variation in the severity and extent of the disease, similar variations in the morphologic evolution of the changes were also observed on electron microscopy. However, there were features common to all which probably reflected a common etiologic factor.

Transverse sections of the peripheral nerves viewed at low magnification revealed an abundance of unmyelinated fibers compared with myelinated fibers. In some cases, the ratio of unmyelinated to myelinated fibers was about 10:1 (Fig 2). It is tempting to suggest that these were demyelinated fibers in view of the marked increase of endoneural collagen fibers (Fig 3). In a few unmyelinated fibers, electron dense bodies with outer sense layers and inner cylindrical solid bodies were present (Fig 3). The surface membranes of the unmyelinated fibers were usually intact, except in a few areas where there was fragmentation. The neuraxon of the unmyelinated fibers were also intact except in a few fibers which were considered to be demyelinated. The axon membrane showed no lesion and the Schwann cell nuclei were unremarkable. Lipid bodies were seen in the axoplasms of demyelinated fibers (Fig 4 and 5) and these appeared sometimes vacuolated during technical processing (Fig 4). These vacuoles, however, were distinguishable from artifacts of preparation which were not uncommon in all the materials examined. The mitochondria of some unmyelinated fibers were osmiophilic and their membranes and cristae may be obscured. The axoplasm of the myelinated fibers were relatively normal, except for a slight increase of neurofilaments and neurotubules (Fig 6).

Fig 12.—Fragmentation of myelin (My) with vesicular membrane formation. Note areas of interrupted myelin (arrows) (× 36,000).

The changes in compact myelin which varied from one nerve to another showed the various stages of evolution. There were several nerve fibers with no changes in the myelin sheath or in the axoplasm. Demyelination was frequently seen in the vicinity of the node of Ranvier or the Schmidt-Lanter-

Fig 13.—Dissolution of myelin (*My*) with ghost outlines of wrinkled layered structure. Note presence of normal Schwann cell nuclei (N) (× 7,500).

mann clefts (Fig 7). Minimal lesions of compact myelin, observed in longitudinal sections, included vacuoles containing membrane profiles (Fig 8). Similar vacuoles were also seen in the axoplasm. These vacuoles were sometimes prominent in the vicinity of the node of Ranvier, but bore no relationship to the Schmidt-Lanterman clefts. Focal areas of granular disintegration in myelin were seen in places (Fig 9), with or without loss of lamellar pattern of myelin. Variation in the size and thickness of the smaller nerve fibers was not uncommon. Some of the myelin sheaths were folded and collapsed with absence or diminution of axoplasm (Fig 10 and 11). Fragmentation of myelin sheaths with membrane formation was striking in some cases (Fig 12), while total dissolution of myelin with ghost outlines of the layered structure may also be seen (Fig 13). Partial interruption of myelin was seen in places, and a peculiar unravelling of myelin interspersed by membrane bound vacuoles was observed (Fig 14). The

Fig 14.—Arrow points to area of split and abrupt interruption of thickness of compact myelin (*My*). Note peculiar unravelling of myelin interspersed by membrane bound vacuoles (*v*). Mi indicates mitochondria; N, nucleus (× 21,500).

Fig 15.—Relatively healthy compact myelin with normal surface membrane (SM) and mesaxon. Note increased density of mitochondria (Mi), retracted axoplasm, and membrane profiles. Increase of surrounding collagen (C) is also evident. Arrows indicate Schmidt-Lantermann clefts (× 45,500).

axoplasms of the myelinated fibers were relatively intact except for a slight increase of neurofilaments and, in some large fibers, retraction of axoplasm and membrane bound profiles was occasionally encountered (Fig 15). Digestion of myelin by macrophages was seen only after diligent searching and did not appear to be a common feature in all the cases (Fig 16 and 17). In two of the cases where the disease had been of long duration, several fibers showed complete disintegration and disorganization of the lamellar pattern of myelin (Fig 18). Inflammatory cells were not conspicuous, and blood vessels showed no significant abnormalities. The changes described in the peripheral nerves of these patients were not seen in the peripheral nerves of the control subject. Liver biopsies examined from all the patients revealed no significant changes.

The striking and significant changes in the sciatic nerves of rats injected with potassium cyanide were patchy areas of demyelination on light microscopy. On electron microscopic examination, dilatation of the Golgi apparatus and varying stages of myelin digestion (Fig 19 and 20) were observed in the nerves injected with cyanide, but not seen in the nerves injected with saline.

Comment

The syndrome of tropical nutritional ataxia is endemic in certain parts of Nigeria, particularly in the western state. The possible etiologic factors have been investigated, and there is some evidence that the neurologic changes are probably due to chronic dietary cyanide conditioned by vitamin deficiency.[1]

All the patients in this study ate cassava derivatives at least two times a day, had mucocutaneous manifestations, and estimations of serum vitamin B_{12} and plasma thiocyanate were found to be elevated. The frequent ingestion of cassava meals, which is a potent source of cyanide, may be of etiologic significance in these cases. Although there are several experimental studies on the effects of cyanide on the central nervous sys-

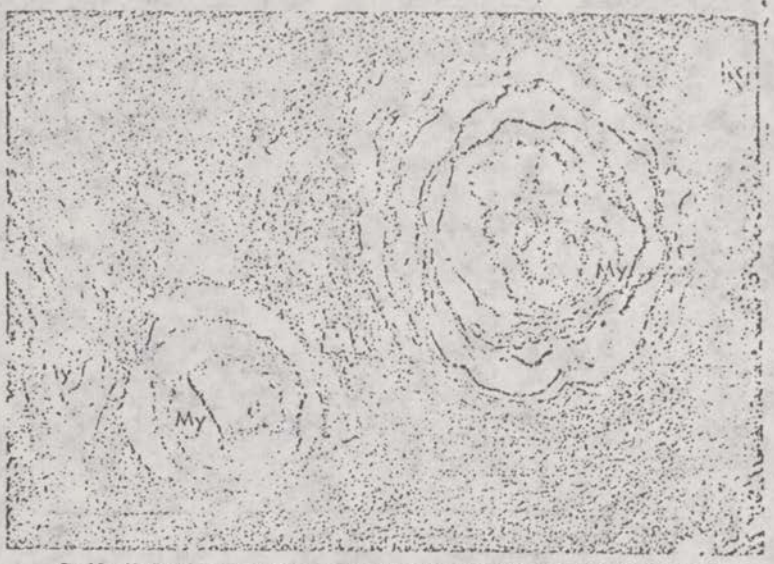


Fig 16.—Myelin (My) digestion showing variation in electron density and size of layered structures. Note wrinkled morphology of digested myelin. MI indicates mitochondria; N, nucleus (× 18,000).

tem, there is a lack of information on its effect on the peripheral nervous system.

Peripheral nerves from 23 patients who had the clinical, biochemical, and electrophysiologic features of the syndrome were studied by light microscopy in order to obtain additional information on the pathologic process which underlies some of the clinical manifestations. Peripheral nerves from four unselected patients, two male subjects and two female subjects, aged 14, 17, 18, and 33 years, respectively, were studied by electron microscopy. Three of the patients showed some unusual clinical manifestations which, however, did not affect diagnosis of the ataxic syndrome. One pa-

Fig 17.—Ovoid bodies with layered structure inside macrophage from human case. N indicates nucleus (× 15,500).

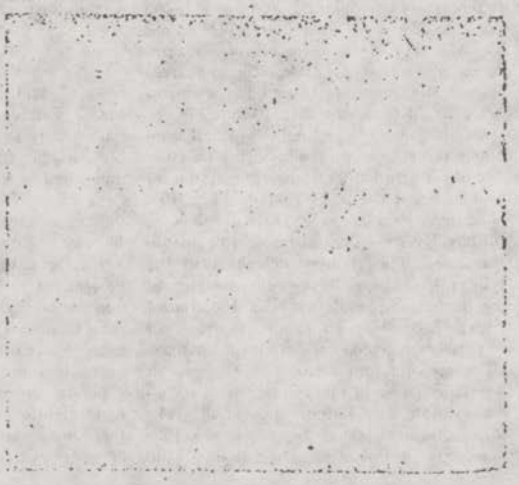


Fig 18.—Total disorganization and destruction of nerve fiber in severe case. Lamellar structure (arrow) is barely visible as osmiophilic concentric linear structures (× 15,000).

Fig 19.—Ovoid bodies (arrows) with layered structure inside macrophage two weeks after injection of potassium cyanide into rat sciatic nerve. M, indicates mitochondria; N, nucleus (× 16,500).

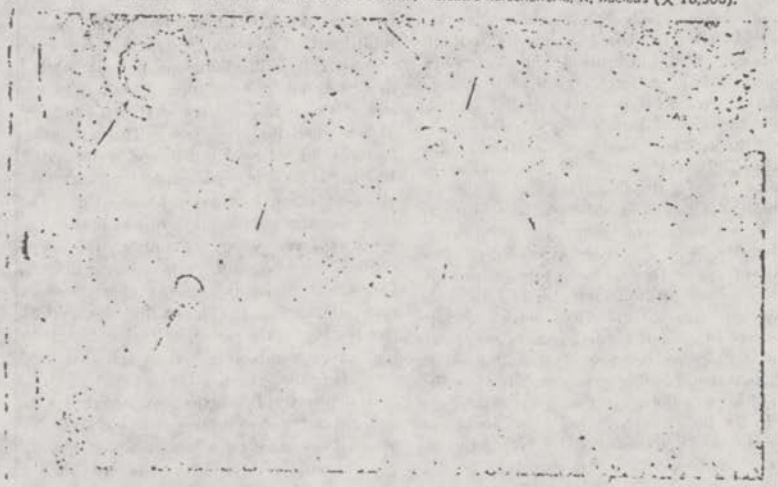


Fig 20.—Dilatation of Golgi apparatus (G) and smooth endoplasmic reticulum (SER) in Schwann cell cytoplasm. Note granular endoplasmic reticulum (arrow). Polyribosomes appear numerous. C indicates collagen; My, myelin; L, lipid bodies (X 14,500).

tient (case 2) had a slightly abnormal steroid stressed glucose tolerance test, but otherwise, clinical, biochemical, and electrophysiological findings were typical of the ataxic neuropathy. Two patients (case 3 and 4) gave histories of intermittency but were not seen during "remissions." On clinical examination, these patients did not appear to suffer from multiple sclerosis, a disease in which tinnitus and deafness are virtually unknown or extremely rare, but polyneuropathy has been observed occasionally.[7] One patient (case 4) gave a history of precipitancy of micturition and also had bilateral pes cavus; myelography was normal. Symptoms of bladder dysfunction associated with girdle pain are occasionally encountered in tropical neuropathic syndrome, but myelographic examination is usually normal.[1]

In the present study, breakdown or loss of myelin was demonstrated by fat or myelin stains in the peripheral nerves, but the distribution of demyelination was patchy or multifocal. Perivascular lymphocytic and plasma cell infiltration was present in the more severely affected nerves, and thickening of the perineural connective tissue was also marked in severe cases. The histological features did not clearly distinguish the nerve lesions of ataxic syndrome from several other nutritional or toxic neuropathies. In fact, the microscopic appearances of the lesions observed were not unlike those described in segmental periaxial neuritis of Gombault[8] and other causes of segmental demyelination. It is evident that the myelin sheaths were the more severely damaged part of the conducting system and that this was where the system was primarily affected and deprived of function. Although some axis cylinders were destroyed in the severely affected nerve fibers, a feature which probably accounts for the irreversible nature of

... disease, the relative sparing of axons ... striking and is consistent with segmental demyelination.[9] This is in contrast to ... taneous breakdown of myelin and axis ...linders usually observed in the wallerian ...pe of degeneration.

Demyelination is demonstrable in some of ...e patients who have no symptoms of peripheral neuropathy, although in such patients motor nerve conduction velocity is ...ow. The impaired nerve conduction is secondary to demyelination because it is well recognized that abnormalities of nerve conduction are not uncommon in peripheral neuropathy associated with segmental demyelination. Nerve conduction is impaired in a proportion of patients with diabetes mellitus at a stage when there are no symptoms of peripheral neuropathy. Dayan and Williams[10] demonstrated segmental demyelination in peripheral nerves of patients with cirrhosis of the liver, but who have no clinical symptoms of peripheral neuropathy. It is, therefore, not surprising that histologic changes do not correlate with symptomatology of peripheral neuropathy in the present study. Comparison with some other causes of segmental demyelination may reveal more useful information.

Although segmental demyelination is a cardinal feature of diabetic neuropathy,[9] allergic encephalomyelitis,[11] acute infectious polyneuropathy of Guillain-Barré,[12,13] and diphtheritic neuritis,[14,15] there is no evidence to suggest that tropical nutritional ataxia belongs to any of this group. It is noteworthy that segmental demyelinative neuropathy has been described in nutritional neuropathies, such as thiamine deficiency,[16] vitamin B_{12} deficiency, and alcoholic peripheral neuropathy, but these were excluded as possible etiologic factors in these patients.

For electron microscopic studies, one of the technical difficulties which facilitates degenerative artifacts is fixation of the peripheral nerves. The technique of fixing peripheral nerves in situ with osmium tetroxide is feasible in experimental animals, but was not applied to our patients for ethical reasons. The peripheral nerves were removed aseptically under local anesthesia, fixed in glutaraldehyde, and then postosmicated. This was followed by cutting the biopsied nerve segment into 1 cu mm and then processing in the usual fashion for electron microscopy. It was not surprising to observe variations in myelin sheath contours, and vacuoles were also not infrequent. Interpretation of electron micrographs has taken cognizance of the possible artifacts of preparation, and only changes which are thought to be of significance were considered. The severity and frequency of artifacts in the experimental animals was reduced by fixing the peripheral nerves in situ by the intra-aortic route.

Two different types of demyelinating processes were recognized on electron microscopy in the human material. The first and most striking process consisted of a vesicular disintegration and lysis of myelin lamellae similar to what has been described in diphtheritic neuritis[14] and allergic encephalomyelitis.[11] This type of demyelination has a patchy distribution, and in most cases the axons are intact. The second type of demyelination was characterized by the presence of ovoid or myelin bodies inside macrophages. This is consistent with digestion of myelin. The relative sparing of axons in most fibers supported light microscopic changes and is indicative of segmental demyelination.

In the sciatic nerves of the laboratory rodents, damage to myelin was observed, but not to the same degree as in the human material. The most striking change in the rats was myelin digestion, not unlike that which was observed in the peripheral nerves of the patients (Fig 19). The relative infrequency of myelin breakdown in rodents may be accounted for by the relatively short duration of the experiment. It is conceivable that if the animals were kept for much longer periods, a greater degree of myelin damage would have taken place. This aspect is being studied and will be the subject of another communication. Of relevance is the fact that laboratory animals are being fed the pulverized form of the cassava diet, which is consumed in large quantities by the patients with the syndrome. This experiment is still in progress and will be reported later.

The inability to identify any infective agent does not preclude this possible etiologic factor, but it is remarkable that no ultra-

structural changes were observed in the blood vessels to the nerves. The present study demonstrates that peripheral neuropathy in the ataxic syndrome has an underlying pathologic process consistent with segmental demyelination. Although no infective agent has been found, the changes in the peripheral nerve can be due either to nutritional deficiency or chronic cyanide intoxication or a combination of both. There is evidence that the patients studied were exposed to increased cyanide intake from their food and have clinical and biochemical manifestations of nutritional deficiency. Acute cyanide toxicity of rat sciatic nerve reveals myelin digestion, which provides support for the possible toxic effect of cyanide on peripheral nerves.

Summary

The tropical nutritional ataxic syndrome in Nigeria may be due to a dietary deficiency or an increased dietary cyanide, derived from cassava meals prepared in a particular way and consumed frequently by some patients. The clinical, electrophysiologic, and biochemical features of four of these patients are presented in detail. The pathologic changes, as demonstrated by light microscopy in the anterior tibial nerves of 23 Nigerian patients, have been studied and described, and peripheral nerves from four of these patients, whose clinical features are described in detail, have been studied by light and electron microscopy. The observed changes on light microscopy are consistent with segmental demyelination. These are confirmed in the cases studied by electron microscopy and are characterized by disintegration and lysis of myelin lamellae and/or myelin digestion in a patchy fashion. These changes are not specific and simulate, in many respects, other segmental demyelinative neuropathies. The role of cyanide in causing peripheral neuropathy was investigated by studying the ultrastructural changes in cyanide treated sciatic nerves of rats. Myelin digestion which is evidence of demyelination, was observed a few weeks after injection of a single dose of potassium cyanide. From epidemiologic and experimental evidence, it can be inferred that cyanides damage the peripheral nerves and may play a significant role in the pathogenesis of ataxic neuropathy in Nigerians.

Dr. Williams was a visiting scientist to the National Institutes of Health, Bethesda, Md., where part of this work was carried out.

Peter Lampert, MD, gave criticisms on the interpretation of electron micrographs. Ben Elbert and Mrs. Mowry gave technical assistance.

References

1. Osuntokun, B.O.: An Ataxic Neuropathy in Nigeria: A Clinical, Biochemical and Electrophysiological Study, *Brain* 91:215-248 (June) 1968.

2. Monekosso, G.L., and Wilson, J.: Plasma Thiocyanate and Vitamin B_{12} in Nigerian Patients With Degenerative Neurological Disease, *Lancet* 1:16-19 (May) 1966.

3. Vizoso, A.D., and Young, J.Z.: Internodal Length and Fibre Diameter in Developing and Regenerating Nerves, *J Anat* 82:110-134 (April) 1948.

4. Aldridge, W.N.: A New Method for the Estimation of Micro Quantities of Cyanide and Thiocyanate, *Analyst* 69:262-265 (Sept) 1944.

5. Matthews, D.M.: Observations on the Estimation of Serum Vitamin B_{12} Using *Lactobacillus Leichmannii*, *Clin Sci* 22:101-111 (Feb) 1962.

6. Jackson, W.P.U.: The Cortisone-Glucose Tolerance Test With Special References to the Prediction of Diabetes: Diagnosis of Prediabetes, *Diabetes* 10:33-40 (Jan-Feb) 1961.

7. Hasson, J.; Terry, R.D.; and Zimmerman H.M.: Peripheral Neuropathy in Multiple Sclerosis, *Neurology* 8:503-510 (July) 1958.

8. Gombault, cited by Greenfield, J.G., et al: *Neuropathology*, London: Edward Arnold (Publishers) Ltd., 1958, pp 586-590.

9. Thomas, P.K., and Lascelles, R.G.: Schwann cell Abnormalities in Diabetic Neuropathy, *Lancet* 1:1355-1357 (June) 1965.

10. Dayan, A.D., and Williams, R.: Demyelinating Peripheral Neuropathy and Liver Disease, *Lancet* 2:133-134 (July) 1967.

11. Lampert, P.W.: Demyelination and Remyelination in Experimental Allergic Encephalomyelitis, *J Neuropath Exp Neurol* 24:371-385 (July) 1965.

12. Miller, H.M.: Polyneuritis, *Brit Med J* 2:1219-1225 (Nov) 1956.

13. Haymaker, W., and Kernohan, J.W.: The Landry Guillain-Barré Syndrome: A Clinico Pathologic Report of 50 Fatal Cases and a Critique of the Literature, *Medicine* 28:59-141 (Feb) 1949.

14. Webster, H.D., et al: Phase and Electron Microscopic Studies of Experimental Demyelination: II. Schwann Cell Changes in Guinea Pig Sciatic Nerves During Experimental Diphtheritic Neuritis, *J Neuropath Exp Neurol* 20:5-41 (Jan) 1961.

15. McDonald, W.I.: The Effects of Experimental Demyelination on Conduction in Peripheral Nerve: A Histological and Electrophysiological Study: I Clinical and Histological Observations, *Brain* 86:481-500, 1963.

16. Adams, R.D., and Kubik, C.S.: The Morbid Anatomy of the Demyelinative Disease, *Amer J Med* 12:510-546 (May) 1952.

17. Fisher, C.M., and Adams, R.D.: Diphtheritic Polyneuritis: A Pathological Study, *J Neuropath Exp Neurol* 15:214-268 (July) 1956.

18. Greenfield, J.G., et al: *Neuropathology*, London: Edward Arnold (Publishers) Ltd., 1958, pp 584-589.

APPENDIX 5 Appendix

ADVERSE EFFECTS OF LAETRILE THERAPY IN PATIENTS WITH CANCER WHO WERE OBSERVED AT THE UCLA HOSPITAL

Epitome of 5 Representative Cases

Patients Who Took Laetrile Instead of Conventional Treatment

CASE E,S. A 57-year-old Caucasian female seen April 1973 at the Scripps Clinic with a lump in the right breast. Biopsy diagnosis of carcinoma of the right breast was established. Operation, radiation, and chemotherapy were advised but rejected by the patient who, on the advice of "friends" undertook Laetrile therapy for the next 5 months. She received the material by vein and also by mouth. The mass in the breast continued to enlarge and on 10-13-73, she was admitted to the UCLA hospital with a huge, foul, fungating, infected mass replacing the entire right breast. There was extension of the tumor to the left breast and through the chest wall.

Palliative treatment with radiation was instituted with some subjective relief and slight shrinkage of the tumor, but she expired on February 3, 1974.

Summary: This woman would have had a much pleasanter and longer period of survival if she had accepted the recommended therapy. The 5 months during which she took Laetrile therapy and during which no specific conventional anti-cancer therapy was given allowed the tumor to progress rapidly and to a deplorable degree, and her last days were miserable and tragic.

CASE R,L. A 76-year-old Colombian male developed a mass on his back and on October 2, 1974 a biopsy revealed reticulum cell sarcoma. Orthodox chemotherapy and radiation therapy were recommended but the patient refused this therapy and took Laetrile for the next 4 months, during which time there was steadily progressing symptomatology with increasing weakness of the legs, weight loss, and anorexia.

On February 18, 1975, he returned to the UCLA Hospital by ambulance with complete paralysis of his lower extremities, extreme emaciation, nausea and vomiting. On February 21, a laminectomy operation was performed to relieve the pressure on his spinal cord and much tumor tissue was removed. On March 3, 1975, he started radiation therapy with some symptomatic improvement. On April 7, 1975 he was discharged to a custodial care facility where he expired on May 2, 1975.

Summary: Had this patient accepted orthodox treatment, he would have been expected to have enjoyed several years of useful life. However, with Laetrile therapy, his disease progressed to the extent that he became completely paralyzed and immodilized. The institution of conventional therapy following this deplorable deterioration was not effective and the patient expired.

96-492 O - 77 - 10

Patients Who Interspersed or Used Complementary Laetrile Treatment:

CASE S.C. A 52-year-old Caucasian male in June of 1970 was diagnosed by biopsy as having a malignant melanoma of the right calf. In September of 1970 the right groin was dissected with removal of lymph nodes which were not involved with tumor. In June of 1971, metastases of the right lower leg appeared and he was given Cytoxan therapy with some relief. However, from June of 1971 until December of 1972, he was treated with Laetrile and Hoxy therapy and there was continual progression of the skin metastases. In December of 1972 he went to Germany and was treated with "immune stimulation therapy" without benefit. He also continued to receive Laetrile. On February 13, 1974, he was admitted to UCLA. There was total diffuse melanomatous involvement of the entire right leg to the gluteal fold. A hip disarticulation was performed and he was treated with BCG. On March 3, 1974 he died and autopsy revealed his body to be literally riddled with melanoma.

Summary: Because of the nature of his tumor, this man had an extremely unfavorable prognosis; however, immediate institution of conventional therapy and the administration of immunotherapy with BCG probably would have extended his life in a useful fashion for perhaps a year longer than he lived. The attempts at Laetrile therapy and other unorthodox forms of treatment were without benefit and allowed the disease to progress more rapidly than it otherwise would have done.

CASE N.P. A 31-year-old white male with malignant melanoma of the skin in back of the right ear. In 1971 wide surgical excision of the tumor was made. In 1973 there was recurrent tumor and evidence of malignant melanoma in the brain, lungs, and skin. He was referred to the UCLA Hospital and from 10-29-73 until 2-20-74 he was treated with multi-agent oncolytic chemotherapy. At the end of that time, he determined that he would receive no more of this treatment and he began receiving Laetrile treatment outside of the hospital. However, his illness progressed and in May 1974 he developed symptoms of a brain metastasis and was admitted to the UCLA Hospital and an attempt was made to improve his disease with multi-agent chemotherapy, without benefit and he died on July 12, 1974 with widespread metastatic malignant melanoma.

Summary: This patient received Laetrile therapy for a period of 7 months during which period he also was receiving conventional therapy. There was progression of his disease and no obvious improvement as a consequence of the Laetrile therapy or the conventional therapy.

CASE D.L. A 26-year-old Caucasian female who in 1971 had a biopsy diagnosis of malignant melanoma of the back established at the University of California, San Francisco Hospital. At that time there was no evidence of extension. In February 1973 there was evidence of tumor in the right axilla and an axillary dissection was performed and in April 1973 BCG therapy was instituted. On 10-24-73, the patient refused any more conventional treatment, went to San Diego where she received treatment with Laetrile, without benefit.

She expired on April 14, 1944 with widespread melanomatous disease.

Summary: There was no evidence that the Laetrile therapy alleviated her condition or delayed the progression of her disease.

These five cases are fairly typical of the 25 to 40 cases of cancer seen at UCLA each year who have been treated with Laetrile or who elect to take Laetrile rather than conventional treatment. There is no evidence that Laetrile has alleviated their symptomatology, delayed the progression of their disease, or been beneficial to these patients. In contrast, the delay in the implementation of proper conventional therapy in two instances resulted in the advance of their disease process to the extent that conventional therapy was of little benefit.

APPENDIX 6

EVALUATION OF CASE REPORTS SUBMITTED TO THE CALIFORNIA STATE DEPARTMENT OF HEALTH BY THE MCNAUGHTON FOUNDATION AS EVIDENCE OF THE EFFICACY OF LAETRILE IN THE TREATMENT OF CANCER*

The McNaughton Foundation and the North End Medical Center, both in Montreal, in January 1963 submitted a total of 14 clinical records on patients treated with Laetrile. These were not complete records but were abstracts furnished by the various hospitals in Canada to the McNaughton Foundation. The Cancer Advisory Council decided to examine these records and for this purpose a committee of three physicians highly qualified and actively engaged in the treatment of cancer were appointed from the membership of the Council to review and evaluate these records and to report on them. Each Committee member conducted an independent evaluation following which their reports were combined as Section I of a Supplementary Report on Laetrile. Members of this committee were as follows:

Dr. Joseph F. Ross, Professor of Medicine, UCLA School of Medicine

Dr. Thomas S. Nelsen, Professor of Surgery, Stanford University School of Medicine

Dr. Jesse L. Steinfeld, Professor of Medicine, USC School of Medicine
Subsequently, Assistant Secretary for Health, U.S. Dept. of Health, Education, and Welfare; and Surgeon General, U.S. Public Health Service

*Excerpted from: Supplementary Report by the Cancer Advisory Council on The Treatment of Cancer with Beta-Cyanogenetic Glucosides ("Laetriles"); Cancer Advisory Council, State of California Department of Public Health, 1965

Section I.

Review of Records

Case No. 1, Mrs. A.B., age 51, #62S066

Summary:

The abstract of a clinical record shows that a diagnosis of "generalized abdominal carcinomatosis by a basal cell adenoepithelioma," primary site not stated, was made on a biopsy specimen taken during laparotomy, although no pathologic report was included. One gram of Laetrile per day for a total of 36 grams was administered between October 25 and November 29, 1962, the date of the final summary and last examination. Blood counts on the same days showed a mild anemia but were otherwise within normal limits. Urinalysis which was normal before treatment was started showed a trace of albumin on November 29.

Results:

There is no follow-up information later than 1 month after treatment was started. There was no change in the blood picture and no information on weight gain. Without objective confirmation, it was stated that previously palpable abdominal masses were smaller and that the patient was "improved."

Impressions:

Reviewer No. 1 - Information inadequate to indicate effect of therapy. Follow-up time inadequate. No objective evidence to support claim of "improvement."

Reviewer No. 2 - This record requires an operative report, pathology report and follow-up information before the evaluation can be made.

Reviewer No. 3 - This is a record only of data in the files of the McNaughton Foundation with none of the original hospital records, and a statement that the patient has palpable abdominal masses which diminished very much in size. A totally inadequate record.

Case No. 2, Mr. H.G., age 58, #62-4693

Summary:

This record shows that a right colectomy and omentectomy performed on September 14, 1962 resulted in a diagnosis of adenocarcinoma of the ascending colon although no pathologic corroboration is included. One gram of Laetrile per day for a total of 38 grams was given pre and postoperatively up to the time of the clinical summary. Blood study before treatment with Laetrile showed a hemoglobin of 8.3 grams, hematocrit of 28.5%, and marked hypochromia and anisocytosis. Fifteen days postoperatively the hemoglobin was 12.2 grams and the hematocrit 40% with no comments regarding red blood cell morphology and on November 27 the hemoglobin and hematocrit were 12.4 grams and 41% respectively. Urinalysis pre and postoperatively were normal.

Results:

There was improvement in the blood picture postoperatively but the physician who last saw the patient on November 29 and who summarized the findings stated that not enough time had elapsed to permit an evaluation of Laetrile effect.

Impressions:

Reviewer No. 1 - Evidence presented totally inadequate to evaluate therapeutic effect, after 2½ months follow-up presumably.

Reviewer No. 2 - No evaluation is possible from the record. Perhaps a letter could provide sufficient information for evaluation.

Reviewer No. 3 - In this case the doctor says he is unable to evaluate Laetrile effects in a patient who has adenocarcinoma of the ascending colon. Once again there are no data and even here no beneficial effect is claimed.

Case No. 3, Sister M.E., age 71, #1936

Summary:

This record shows that in February, 1959, the patient underwent a surgical procedure which led to a pathologic diagnosis of mucous epithelioma of the breast and was followed by a left mastectomy. The pathologic report is included in the record. On October 9, 1963, the patient reported a weight loss of 25 pounds and subsequently hemorrhaging until November 30, 1962, from site unspecified. A chest X-ray on October 10, 1962 revealed numerous pulmonary condensations compatible with metastatic neoplasm. The hemoglobin at this time was 11 grams and red blood cells 3.6 million and an urinalysis was reported normal. On October 24 one gram of Laetrile three times weekly was started but was increased to one gram per day on November 20th. The latter dosage continued to the date of the clinical summary, December 20, for a total dosage of 51 grams over a two months' period.

Results:

After two months' observation it is stated that the results are satisfactory after Laetrile therapy, that the patient sleeps well and has a good appetite but no objective evidence of benefit is included.

Impressions:

Reviewer No. 1 - Record totally inadequate to permit evaluation of effect.

Reviewer No. 2 - No evaluation possible from this record.

Reviewer No. 3 - This is a patient with stated cancer of the left breast although the pathologic diagnosis report we have

is mucous epithelioma of the breast. It is undetermined here whether this patient has had radiotherapy to the breast or any hormonal therapy so that she has not received standard forms of therapy and the only benefit claimed is cessation of hemorrhaging, but we have no details as to where the hemorrhages were from, nor any data on what happened to the presumed pulmonary metastases, nor do we really have an adequate histologic diagnosis. From the description a totally unsatisfactory case.

Case No. 4, Mr. R.K., age 45. #8163

Summary:

The record shows that the patient was hospitalized on October 27, 1962 because of a painless, firm, freely movable 2.5 cm mass in the left supraclavicular area and a weight loss of 15 pounds during the past four to five weeks. On August 30 cervical lymph nodes were excised and a pathologic diagnosis of reticulum cell lymphosarcoma was made. The actual pathologic report is not shown. Between September 14 and October 17, 1962 the patient received 3,000 r to the left supraclavicular region. Chest X-ray was normal. Blood study on November 12, 1962 showed a hemoglobin of 14.8 grams, white cells 7,050 and on December 19 a hemoglobin of 14.5 and white cell count of 8,550. Urinalysis on November 12 showed a trace of albumin. Between November 14 and December 28, the date of the summary, the patient received three grams of Laetrile per week for a total of approximately 18 grams.

Results:

The blood picture showed no change over a period of about six weeks and the record shows that the patient's general health improved, that his appetite became better, he slept well and had more strength, but no objective evidence of benefit is shown.

Impressions:

Reviewer No. 1 - Record totally inadequate to permit evaluation of any effect of therapy.

Reviewer No. 2 - This patient underwent surgery (diagnostic and/or therapeutic ?) and radiation therapy in the amount of 3000r and was asymptomatic at the time of Laetrile administration approximately three months after his X-ray treatment. It is therefore difficult or impossible to evaluate the effect of Laetrile.

Reviewer No. 3 - This patient has lymphosarcoma presumably diagnosed on a biopsy in August 30, 1962 followed by radiotherapy 3000 r to the involved region from September 14 to

October 17, 1962 and started on Laetrile November 4, 1962 at which time he had no pain or no adenopathy, so that, in the absence of any evident disease it is impossible to evaluate a presumed therapeutic agent. This is no test whatsoever.

Case No. 5, Mrs. J.L., age 67, #49782

Summary:

The record shows that a left radical mastectomy was performed on April 21, 1961, resulting in a pathologic report (unsigned) of anaplastic epithelioma (Grade 3) of the breast. There is no indication of any further treatment or observation until October, 1962, when the patient returned because of pains in the lumbar vertebrae and a "very poor state of health." She received 15 grams of Laetrile during a 15-day stay in the hospital. Blood study before the Laetrile treatment revealed a hemoglobin of 11.3 grams, hematocrit of 35% and white cell count of 4,000. After treatment the hematocrit was still at 35% but no other values were given. Urinalyses were normal before and after treatment.

Results:

The record indicates that the patient gained eight pounds, that the lumbar pain disappeared after one week and that the patient left the hospital because, in her words -- "I am well and I feel well." No change in blood picture was shown.

Impressions:

Reviewer No. 1 - Record totally inadequate to evaluate therapy.

Reviewer No. 2 - This abstract is completely inadequate; apparently no X-rays were taken. The diagnosis of carcinoma is in question.

Reviewer No. 3 - Patient with a diagnosis of anaplastic epithelioma, Grade 3, of the breast who came in with pain in the lumbar spine and received 15 days treatment with Laetrile at one vial per day and went home saying she is well. Totally inadequate. No documentation of disease when drug therapy initiated.

Case No. 6, Mrs. W.M., age 49, #4012

Summary:

According to the record, biopsy specimens of an ulcerating and bleeding rectal mass were taken in April, 1962. The pathologic diagnosis was squamous cell carcinoma Grade 1

of perianal gland. There is no indication of further treatment until October 24, 1962 when daily doses of two grams of Laetrile were begun, 1500 mgs. being given intramuscularly and 250 mgs. applied locally twice a day. This dosage continued until November 12, 1962 when it was reduced to 500 mgs. per day until December 10 the date of last examination and of the clinical summary. The total dosage up to December 10 was approximately 62 grams.

On October 29, 1962 a chest X-ray showed no metastases and a cystic area in the skull was thought to be either a diploic blood lake or a metastasis. The final summary indicates that further surgery with resection of 33 cms. of rectosigmoid was performed on November 29, 1962 but the pathologic report indicates a date of November 23, 1962. The pathologic diagnosis on this specimen was mucoepidermoid epithelioma. During hospitalization the patient received several transfusions. Blood studies on admission showed 6.5 grams of hemoglobin, 2 million red cells and 3,300 white cells. The hematocrit was 17% and the sedimentation rate 58 mm. On December 10 the hemoglobin was 13 grams, red cells 4.1 million, white cells 13,200, the hematocrit was 39% and the sedimentation rate 27 mm. Urinalyses showed many white cells both on admission and on December 10.

Results:

The blood elements had returned to approximately normal levels but several transfusions had been given. X-ray films of the abdomen on November 20 showed less gaseous distension and a liver reduced in size from the observation on October 25; pains in the pelvic and hepatic areas were gone and therapeutic results were reported as "very satisfactory." There were no objective findings to indicate a beneficial effect by Laetrile.

Impressions:

Reviewer No. 1 - No objective evidence of beneficial effect.

Reviewer No. 2 - This patient underwent surgical resection of the carcinoma of the anus and the Laetrile was administered for non-specific symptomatology approximately one month before operation. At best the history and findings are most confusing.

Reviewer No. 3 - This patient has a rectal squamous cell carcinoma, Grade 1, diagnosis made on a biopsy when three pieces of tissue were removed, the largest of which measured 6 millimeters at its greatest diameter. On November 23, 1962 the patient had a large amount of colon removed, measuring 33 cm in length including the recto-sigmoid tumor. Lymph

nodes were not involved by tumor which was called an epidermoid epithelioma on November 23, 1962. There were no pulmonary metastases and this patient was started on Laetrile prior to operation. The claimed effects were a reduction in pain, a very good effect on fetor, and a decrease in tumor from 9 x 6 cm to 6 x 4 cm at the time of surgery one month later. In addition, the patient did receive supportive therapy and blood transfusions so once again there is no clear evidence of effect on tumor. It is impossible to distinguish what is happening here.

Case No. 7, Miss L.P., age 15, #62-4968

Summary:

A diagnosis of renal adenocarcinoma and a surgical procedure on September 24, 1962 were mentioned in the record but there were no pathologic or operative reports. The patient was given one gram of Laetrile daily for eight days pre and postoperatively and then presumably discontinued until October 24 when its administration was resumed. An additional 35 grams may have been given from this date until November 29 when the patient was last seen.

Preoperative blood studies showed a hemoglobin of 10.3 grams, white cells 6,100, hematocrit 30.7% and a sedimentation rate of 20 mm. On October 3 hemoglobin was 12.2 grams, white cells 9,700, and hematocrit 37.5%. On November 27 the hemoglobin was 12.7 grams, white cells 5,500, and hematocrit 38.5%. Urinalysis on one of three occasions showed a trace of albumin. A chest X-ray on November 27 was normal.

Results:

The blood picture was improved after surgery but there is no indication as to whether or not this was due to transfusions or other incidental therapy. The physician seeing the patient on November 29 stated that it was too early to make an evaluation of Laetrile effect.

Impressions:

Reviewer No. 1 - Record totally inadequate to evaluate effectiveness of Laetrile.

Reviewer No. 2 - The records are inadequate for evaluation.

Reviewer No. 3 - It is too early to evaluate effects of therapy.

Case No. 8, Mrs. C.P., age 50, #120-593

Summary:

The record shows that on May 17, 1960 the patient had a radical mastectomy which revealed an anaplastic epithelioma of right breast with axillary metastasis to one of six lymph nodes. Following local recurrence, she was reoperated on November 8, 1960. The pathology reports confirm the clinical diagnoses in both instances and both reports are included. Again in December, 1962, an inoperable, ulcerated, local recurrence was present.

Before beginning Laetrile therapy on October 10, 1962, a blood study revealed a hemoglobin of 12 grams and a white cell count of 5,700. On December 17, 1962, the hemoglobin was still 12 grams, red cells 4.02 million, and white cells 6,850. Urinalyses on October 10 and December 17, 1962 were normal. Chest X-rays on May 3, June 8 and December 18, 1962 were normal and no metastases were evident in X-ray films of the cervical and dorsal spine on December 18.

Laetrile, one gram three times a week, was given between October 10 and December 7, 1962 and thereafter one gram daily. The final summary is undated but presumably the patient was last seen on or about December 18, the date of last X-ray examination and she therefore probably received a total of 36 grams of Laetrile.

Results:

There was no essential change in the results of blood studies. Urinalyses remained normal and no objective evidence of benefit was presented.

Impressions:

Reviewer No. 1 - No objective evidence of therapeutic effect of agent.

Reviewer No. 2 - This is a patient with breast cancer who underwent a conventional mastectomy as therapy followed by a local recurrence in the operative wound. Because of multiple therapy, no evaluation of the Laetrile is possible.

Reviewer No. 3 - This is a patient with carcinoma of the breast who presumably has a relapse with ulceration of the mastectomy scar, but we have no measurements, no pictures, no data, no evidence for disease being treated with the drug. A totally inadequate record and no evidence that patient had previously received standard therapy.

Case No. 9, Mr. A.P., age 47, #550-831

Summary:

The record shows that on September 1, 1961, the patient underwent a laparotomy which resulted in a finding of generalized carcinomatosis with involvement and pelvic fixation of the sigmoid and ileum. There was additional tumor involvement of liver, stomach, mesentery and aortic nodes. A specimen of the tumor was taken for biopsy and an anterior enterostomy performed. A pathologic diagnosis of "polymorphous reticulocarcinoma" is included in the record.

Blood studies before treatment with Laetrile showed 9.5 grams of hemoglobin and a red cell count of 3 million. One gram of Laetrile per day was given for 30 days and thereafter two times per week for an additional month. The total drug administered was approximately 35 grams.

Results:

It was stated that the patient had gained 20 pounds, was eating and sleeping well and that he "has a very good spirit now." There was no objective evidence indicating benefit from Laetrile.

Impressions:

Reviewer No. 1 - Record inadequate for objective evaluation of effect.

Reviewer No. 2 - This record is insufficient for evaluation, an operative report is needed as well as a statement concerning conventional therapy.

Reviewer No. 3 - Patient who has abdominal carcinoma and was given one vial of Laetrile daily for 30 vials, then Laetrile twice a week for a total of two months. "The patient is eating and sleeping normally and has gained twenty pounds. Very good effect on pain." This is all we know. We have no data on tumor mass or tumor size. Tumor is called a polymorphous reticulosarcoma. No evidence that the patient received conventional therapy or if this is reticulum cell or Hodgkin's Disease (sarcoma). Inadequate record.

Case No. 10, Mr. E.R., age 47, #2143

Summary:

Early in 1962 the patient began to vomit and to have "heavy" pains in the stomach. On April 14 a biopsy specimen of the stomach was taken and on April 25, 1962, one of liver. In both instances neoplastic tissue was demonstrated but a

specific pathologic diagnosis was not made. Laetrile was started and after 15 days, pain and vomiting ceased and the patient could eat and sleep normally. The dosage was one gram of Laetrile per day for 30 days, then one gram each three days for a total of approximately 65 grams.

Before beginning the Laetrile therapy a blood study showed 13.6 grams of hemoglobin, a hematocrit of 42% and a white count of 10,500. In August, after a recurrence of symptoms, the blood study revealed almost identical levels. Urinalyse before treatment with Laetrile and four and one-half months later were reported as normal.

Results:

There was no change in the blood picture. Subjective relief was reported but no objective proof of benefit was found in the record.

Impressions:

Reviewer No. 1 - Record inadequate to support claim of "extended life 4½ months."

Reviewer No. 2 - No evidence is presented to justify the conclusion that 4½ months of life was saved in this particular patient.

Reviewer No. 3 - Has stomach cancer and hepatic metastases. Here the doctors say the patient received 1 vial of Laetrile daily for thirty days and then 1 every three days intravenously for 4½ months and the statement is: "After 15 days of Laetrile the patient could eat normally, sleep good, no pain nor vomiting. Symptoms recurred August, 1962. I should say Laetrile gave this man at least 4½ months of life. Good effect on pain." Once again this is a totally inadequate record. Doesn't tell us anything objective according to standard CCNSC criteria. Doesn't even tell us how the diagnosis of stomach cancer with hepatic metastases were made. Only data is that from McNaughton Research Foundation.

Case No. 11, Mr. I.R., age 48, #2452

Summary:

There is no date of admission nor copies of pathologic reports in the record. Nevertheless it was stated that the patient had an acute anemia due to recent hemorrhage which required four transfusions; that he had a gastric carcinoma; and that he received one gram of Laetrile per day for six weeks for a total of about 45 grams.

Results:

It was stated that the patient gained seven pounds, that his reported pain abated, and that he was eating and sleeping well.

Impressions:

Reviewer No. 1 - Record totally inadequate to provide objective evidence of improvement from Laetrile.

Reviewer No. 2 - This probably is the same patient that is abstracted as E.R. (No. 10). The records are not adequate to be sure these are different patients. A letter would clarify this matter.

Reviewer No. 3 - Had a gastric epithelioma. Only record is that of McNaughton Foundation. "Patient receiving 1 gram daily I V for 6 weeks and drug to be continued. Therapeutic results: the patient was almost dying. He gained from 140 to 147 pounds with no pain as he had on October 12, 1962. Had transfusions twice a week. He had abatement effect on pain." Received 4 transfusions without results of improvement. Patient is still on Laetrile, October 24, 1962. Given twice a week. He is in the hospital walking around, eating and sleeping well. Considered a terminal hopeless case. "This man should be dead; Laetrile did help him." Once again, a subjective evaluation only in the McNaughton files.

Case No. 12, Mrs. O.S., age 63 (no number)

Summary:

In 1959 this patient was hospitalized because of right-sided abdominal pain and a weight loss of about 16 pounds. Barium enema revealed a mass at the hepatic flexure of colon. On December 11, 1959 a laparotomy was performed which revealed an annular, constricting lesion of the hepatic flexure attached to stomach, duodenum and pancreas and infiltrating the pericolic fat but without evidence of lymph node invasion. A right hemicolectomy was performed which revealed a well-differentiated adenocarcinoma of colon.

In February, 1962, X-rays revealed a large ulcer of the stomach and on March 2 a malignant, unresectable ulcer of the stomach which had perforated into the third portion of the duodenum was seen at surgery. Only palliative surgery was performed. The pathologic examination revealed adenocarcinoma of gastric wall, probably metastatic.

In July, 1962 "due to weight loss, anemia and apparent progress of disease," Laetrile was started in a dosage of one gram three times per week and at the time of last entry into the record on October 19, 1962, approximately 40 grams had been given.

Blood study before Laetrile was started revealed a hemoglobin of 12.2 grams, red cells numbering 2.97 million, white cells 8,900, and after an undetermined amount of Laetrile therapy had been given, a hemoglobin of 11.4 grams, red cells numbering 3.9 million and white cells 8,500 were noted. Urinalyses before Laetrile was started and later were normal.

Results:

Blood study after Laetrile had been started revealed an increase of one million red cells with a coincident decrease of approximately one gram of hemoglobin. A note in the record on September 14, 1962 indicates a continuing weight loss and an episode of bloody diarrhea on August 18, 1962. There is no objective evidence of benefit from Laetrile.

Impressions:

Reviewer No. 1 - No objective evidence of therapeutic benefit.

Reviewer No. 2 - This patient had a slow growing but widespread tumor. If one takes the record at face value, the statement of improvement must be recognized, although further evaluation is certainly in order.

Reviewer No. 3 - December 11, 1959, this patient had a right hemicolectomy and an end-to-end anastamosis for an ulcerating, well differentiated adenocarcinoma of the hepatic flexure with infiltration into pericolic fat but without evidence of lymph node invasion. On April 14, 1962 the patient was operated and found to have carcinoma of the stomach with involvement of the pancreas and a sinus tract from the prepyloric area into the third portion of the duodenum. Following this operation she developed a gastric fistula which cleared up within three weeks and the patient returned home April 14, 1962 after having had the operation on March 2, 1962.

On July 12, 1962 she was started on Laetrile receiving 1 gram three times a week plus Vitamin B-15. It is stated that the medication seems to have had some beneficial effect, slowing down the progress of her illness, and in a report of September 14 he says there seems to be some arrest of her disease but she is still losing weight. No measurements! Nothing objective to follow. Again an inadequate chart.

Case No. 13, Mrs. C.T., age 33 (no number)

Summary:

This patient gave a history of tumefaction of left breast for two years. On physical examination at time of hospitalization there was fixation to muscle and a palpable axillary lymph node. X-rays of the 12th thoracic and the 1st and 2nd lumbar vertebrae were suggestive of possible metastases. On May 15, 1962 a bilateral oophorectomy and a breast biopsy were performed. The pathologic report revealed carcinoma simplex of breast. At an unstated time Laetrile in a dosage of one gram three times a week for 30 days was started and then changed to two grams per week for a total time of ten weeks and a total dosage of approximately 24 grams. In addition, once a week 200 mg. of Laetrile was injected directly into the breast.

On July 27, 1962 a blood study revealed a hemoglobin of 11.6 grams, a hematocrit of 42%, and a while cell count of 3,000. On October 17th the hemoglobin was 13.4 grams, the hematocrit again 42%, red cells 4.3 million, and white cells 8,700. Urinalyses were essentially normal.

Results:

The record contains claims largely of subjective improvement such as a better appetite, lessening of fatigue, weight gain of 10 pounds and a blood picture showing a three fold increase in white cells, but otherwise with very little change.

Impressions:

Reviewer No. 1 - No objective evidence of therapeutic benefit from Laetrile therapy.

Reviewer No. 2 - A review of this record would indicate that the response of the patient could very likely be due to the oophorectomy which was carried out in addition to the Laetrile administration. Review of the films and histologic sections would be in order before a definite opinion could be given.

Reviewer No. 3 - This is a 33-year-old-woman who had a biopsy apparently of the left breast and bilateral oophorectomy on May 25, 1962, with a statement that she left the hospital improved. Final diagnosis was called a simplex carcinoma left breast with osteolytic metastases to the vertebrae and cranium. She was started on Laetrile 3 vials a week per month, and 2 vials a week for a month and the drug was accompanied by 2 cc of Vitamin B-15 I M, although the Laetrile was given intravenously. The patient had no pain; as far as we can

96-492 O - 77 - 11

tell the diagnosis of osteolytic metastases in the vertebrae and cranium had not been definitely established because the radiology report hedges and we do not have the X-rays. We cannot tell when the drug was started but it appears to be May 15 to October 1, 1962 which means that it was started at about the time of her oophorectomy so that one would not be able to distinguish if she did indeed have metastases which of these two modalities of treatment influenced her tumor. This is an inadequate record from several standpoints.

Case No. 14, Mr. R.S. (from North End Medical Center, Montreal)

Summary:

On March 3, 1963, an inguinal mass was biopsied and found to be metastatic adenocarcinoma. On March 13, a cystoscopy was performed and examination of tissue from bladder neck and prostate revealed adenocarcinoma of the latter organ. The patient was placed on 5 mg. of Stilbestrol per day and arrived at Montreal for treatment with Laetrile on May 27, 1963. He was placed on Laetrile and received a total of 100 grams but concurrently he also received 80 mg. of Estradurin intramuscularly every two weeks. Blood studies were as follows:

	Hgb.	WBC	RBC	Alk.Phos.	Acid Phos.	Ceph.Floc
5/27/63	13.1 gm	9,100	4.09	5.0 KAU	22.0 KAU	
6/13/63	13.	5,000	4.43	5.0 KAU	18.0 KAU	neg.
7/26/63					30.0 KAU	

Urinalyses on two occasions were negative. X-rays of lumbosacral spine on July 12, 1963 were negative for metastases.

Results:

There was a weight gain of ten pounds, a blood picture which was essentially unchanged except for an initial fall and then a marked rise in acid phosphatase. It was reported that the abdominal mass became soft and freely movable.

Impressions:

Reviewer No. 1 - The diagnosis of infiltrating adenocarcinoma of the prostate is reported as having been confirmed, but no actual pathology report is provided.

There is insufficient documentation provided to permit evaluation of the effect of therapy with Laetrile and Pangamic acid. Dates of therapy are not provided and there is no information as to whether or not stilbestrol was continued as therapy. The reported gain in weight might be explained

by several factors unrelated to administration of Laetrile or Pangamic acid. Reports of hemoglobin levels show no improvement and the blood acid phosphatase increased in level, presumably during the period of therapy.

The report presents no evidence of the therapeutic effectiveness of Laetrile and Pangamic acid.

Reviewer No. 3 - This patient had metastatic adenocarcinoma of prostate, received stilbestrol and estradiol. If this therapy was given concurrently with any new agent, the new agent cannot be evaluated. In this particular case there is no evidence of beneficial effect as yet from any therapy as documented in the records supplied us.

Excerpted from: Treatment of Cancer with Beta-Cyanogenetic Glucosides ("Laetriles")
Cancer Advisory Council, State of California,
Department of Public Health, 1963

APPENDIX 16 - LAETRILE REPORT

Report by Dr. Ross

UNIVERSITY OF CALIFORNIA MEDICAL CENTER

Los Angeles 24, California

December 11, 1962

California State Department
of Public Health
2151 Berkeley Way
Berkeley 4, California

Attn: Dr. Kenneth Ernst

Dear Dr. Ernst:

The California State Department of Public Health has submitted 9 clinical records to me for evaluation in connection with Cancer Advisory Council activities. The records were furnished the Department by Mr. Andrew R. L. McNaughton of the McNaughton Foundation, Montreal, Canada on behalf of Mr. Krebs and the John Beard Memorial Foundation, manufacturers of the drug "Laetrile." It is my understanding that the records were submitted by them for the purpose of showing the beneficial effects of Laetrile on cancer patients.

The records that I have received are for the following patients:

G.G. - #26871
J.S.B. - #623861
A.G. - #61-756
L.G. - #61201
J.J. - #66732
B.J. - #52474
A.K. - #74125
L.M. - #74016
G.M. - #61-4798

These records fail to indicate that the patients treated with Laetrile secured either palliation orrregression of their cancerous affliction as a consequqnce of the therapy. In several instances there is absolutely no evidence presented as to the response of the patient to the therapy, and in other instances objective evidence is not provided that documents statements of benefit.

Specific comment, summary review of the nine cases, and an epitome of each case are appended.

It is my conclusion from review of these records that several are inadequate to permit an evaluation of the effectiveness of Laetrile, and that those that are adequate do not indicate that therapeutic benefit resulted from treatment with Laetrile, and do not indicate that this agent is of value in the treatment, cure, or palliation of cancer.

Very sincerely yours,

/s/ Joseph F. Ross
Joseph F. Ross, M.D.
Chairman and Director

JFR:smo
Encls.

Report of Evaluation of Case Reports
of Laetrile Treated Patients
Whose Records were Submitted by
the McNaughton Foundation

Evaluation by J. F. Ross, M.D.
12/8/62

Nine case reports were reviewed; an epitome of findings are summarized on the appended tables.

Eight cases showed no evidence of therapeutic response, as judged from evidence presented.

One case, A.G. #61-756, (carcinoma of tonsillar pillar) is stated to have shown regression of tumor and considerable clinical improvement, attributed to Laetrile therapy. Except for the very brief and cursory statements given by the examining physician, there is nothing to document the effect of therapy except weight gain of 11 pounds. Patient had received radiation therapy approximately one year before Laetrile therapy. Insufficient data given to make evaluation of effect of radiation therapy. The impression gained from careful study is that there may have been regression of tumor and subjective improvement, but it is impossible to document this conclusion.

Review of these nine case records does not indicate that Laetrile therapy of these patients was effective in causing palliation or regression of tumors.

Joseph F. Ross, M.D.

JFR:smo

APPENDIX 16—LAETRILE REPORT (Continued)

Evaluation of Cases Treated with Laetrile
Submitted by McNaughton Foundation

Case Initials	#	Sex	Age	Diagnosis	Histological Confirmation	Laetrile Therapy Dates	Amount	Other Therapy	Evaluation of Effect
G.G.	26871	M	55	"Epithelioma of Esophagus"	None	6/2/62 Continuing	45 + gms Not given	None	1. Diagnosis not established unequivocally. 2. No objective evidence of improvement not consistent with that expected from supportive therapy. 3. Claim of palliation not documented; no weight gain indicated on chart.
J.S.B.	623861	F	61	Adenocarcinoma left breast with metastases Resected 1/4/61	Yes	7 July 62 Continuing as of 8/13/62 1000 mgm/day	Not given	Radiation 1/4/62	1. Claim softening and diminution of edema of arm. 2. No evidence of improvement presented.
A.G.	61-756	M	44	Epidermoid ca. Left Anterior Tonsillar pillar 2/6/60	Yes	3/22/61 - 12/5/61 4/3/62 Continuing	1 - 2 gms per week	B15 Radiation therapy since August 1960; ? how much	1. Claim subjective improvement and regression of tumor; wt. gain 11# 2. Not possible to corroborate from record. No objective evidence except weight gain.
L.G.	61201	F	73	Left pulmonary cancer with pleural involvement. Site of origin not established.	Malignant cells in pleural fluid - "yes"	Daily 5/10/61 - 8/29/61 - Then 3x week until 10/26/61		None	1. Nature of tumor not established. 2. No evidence of improvement or effect.
J.J.	66732	F	70	Adenocarcinoma peritoneum ? ovarian 4/4/59	Yes	5/12/61 - 5/26/61	84 gms	Radiation therapy 4/15/59 Ileocolostomy 5/4/61	1. No evidence of effect.

APPENDIX 16—LAETRILE REPORT (Continued)

Case Initials	#	Sex	Age	Diagnosis	Histolcgical Confirmation	Laetrile Therapy Dates	Laetrile Therapy Amount	Other Therapy	Evaluation of Effect
B.J.	52474	F	49	Ca. right breast with metastases. Mastectomy 10/30/59	Yes	10/16/61 11/4/61 2/5/62 - 5/30/62		Operation	1. No evidence of improvement.
A.K.	74125	F	35	Ca. right breast 1/3/62	Yes	3/8/62 - 3/25/62	30 gms	Radiation therapy 2/28/62	1. No record of any effect, whatever.
L.M.	74016	F	50	Adenoca. pelvis Source unknown ? stomach Laparotomy 3/15/62	Yes	3/14/62 - 4/13/62	30 gms	None	1. Absolutely no information as to any effect.
G.M.	61-4798	F	53	"Epithelioma of Ascending colon" Resection 8/20/61 Recperated 2/20/62	Yes	2/23/62 - 3/13/62	57 gms	None	1. Stated to be improvement in general health. Reduction in pain and spasm. 2. No objective evidence of effect.

APPENDIX 16--LAETRILE REPORT (Continued)

G. G. #26871 Male Age 55 Epithelioma of Lower 1/3 of Esophagus

Diagnosis:
1) No biopsy
2) No esophagoscopy
3) X-ray: 1. Barium meal May 7, 1962 Describes "nodules and ulceration of esophagus" Barium meal passes the stomach and duodenum.

2. Diagnosis of pneumonia left lower lobe of lung with effusion. May 19, 1962 to 6/4/62

3. 7/27/62 - X-ray of esophagus: constriction, thickening, and ? "mucus pieces". However, barium meal passes without obstruction.

Conclusion: 1. Diagnosis: not proven

2. Probably but not absolute on basis of X-ray report.

Tumor persisted seven weeks after start of Laetrile.

Therapy: Beginning 6/2/62, Laetrile 1000 mg each day for 30 days; then every 3 days.

Response: Subjective: Chart doesn't establish degree of relief. Stated to have required less sedative, but still got it each night. It is stated that ability to swallow improved, but chart doesn't document this.

Fever 6/3/62 to 6/9/62 102°; normal thereafter.

Weight 6/2 112
6/14 100
6/17 114
6/21 104
6/24 104

On 8/3/62 - statement "Gained 12# in 15 days". This is not documented on chart.

	Hb	WBC
6/4	10.2	14,000
6/25	11.5	11,600
7/7	11.8	12,500

APPENDIX 16--LAETRILE REPORT (Continued)

G. G. #26871 Male Age 55 Epithelioma of Lower 1/3 of Esophagus

Conclusion: 1) Diagnosis of Ca of esophagus not proven, but it probably is correct.

2) Result: stated to have been subjective improvement; weight gain not established; fever subsided (probably due to subsidence of pneumonia); hemoglobin increase of 1.5 gm% in 1 month.

Impression: ? symptomatic improvement; consistent with supportive therapy; no proven effect of Laetrile.

J.S.G. #62-3861 Female Age 61

Diagnosis: Adeno-carcinoma, left breast, with metastases to axillary nodes - resection 1/4/61 followed by radiotherapy 1/4/61; ? how much, where, when.

Therapy: Laetrile Therapy:

Laetrile 1000 mgm every day, administered intravenously.
Record states "15 days - still under treatment."
Response: No pain before or after.
No weight loss or gain.
No blood change.
Statement: "Softening and diminition (sic) of the edema of the arm."
No objective information given in chart.

Conclusion: No evidence of effect.

A.G. #61-756 Male Age 44

Diagnosis: Epidermoid carcinoma (Grade I) left anterior tonsillar pillar
Biopsy 2/6/60 epidermoid carcinoma, Grade I
P.E. confirms this.

Therapy: "Cobalt therapy" June, July, August 1960 - ? how much.

APPENDIX 16--LAETRILE REPORT (Continued)

Laetrile Therapy:

3/22/61 Laetrile 1 gram I.V. 1 - 2 times per week
and "Panganic" acid ("$B_{16}H_8$")
4/4/61 - Stated to show general improvement and regression of lesion.
6/27/61 - weight gain 11 lbs. Lesion "almost disappeared." No adenopathy.
12/5/61 Stopped Laetrile.

1/9/62 "Double pneumonia"
4/3/62 Restarted Laetrile: "Well"

	Hb	Hemat.	RBC
10/2/61	13.6	43	4.7
3/20/62	12.8	40	4.3
6/12/62	14.1		4.6

Conclusion: No proof of claimed subjective or objective improvement. Notes suggest that improvement did appear. Unable to document.

L. C. #61201 Female Age 73

Diagnosis: "Left pulmonary cancer with pleural involvement."
Pleural needle biopsy = pleural fluid + for neoplastic cells. No primary demonstrated on X-ray or elsewhere.

Therapy:

Laetrile Therapy:

500 mgm Laetrile administered intravenously every 2 days
5/10/61 to 8/29/61
Then 1 gm 3 times a week until 10/26/61.
Response: Pleural fluid stays the same. ?"decreased malignancy of pleural fluid malignant cells"
Weight stayed the same.

Conclusion: 1) Carcinoma of pleura - ? primary site
2) Condition stationary
3) No proven response to Laetrile

APPENDIX 16--LAETRILE REPORT (Continued)

J. J. #66732 Female Age 70

Diagnosis: April 4, 1959 Adenocarcinomatosis of peritoneum - frozen pelvis ? primary site
Biopsy - adenoca. - ? ovarian origin

Therapy: Cobalt teletherapy (? how much? 4/16/59
Ileo transverseostomy 5/4/61

Laetrile Therapy:
5/12/61 Laetrile 5/12/61 500 mgm I.V. every other day + B_{15} + H_8 1 mg per day

5/26/61 Laetrile 1000 mgm 3 times per week I.V.

Total dose of 84 grams Laetrile by 5/4/61

Response: Weight

5/6/61	100
5/9/61	92
5/14/61	94
5/20/61	94
6/5/61	96
6/6/61	97
6/15/61	98
6/19/61	99
6/23/61	99
8/4/62	89 (?? 99)

Discharge August 12, 1962, stated to have been "improved."

Conclusion: Biopsy proven adenocarcinoma of the abdomen (? ovarian origin)
Laetrile 84 grams
From the record, no objective evidence of any effect.

B. J. #52474 Female Age 49

Diagnosis: Carcinoma right breast 10/30/59.
Mastectomy 10/30/59
Histology Diagnosis "Mammary Carcinoma, Gr. III with metastases"

Course and Treatment

10/16 - 11/4/61	Pain after mammectomy
10/17/61	Laetrile, 2 gram/day, i.v.
11/4/61	Laetrile, 30 grams "Discharged improved"

APPENDIX 16--LAETRILE REPORT (Continued)

2/5/62 Laetrile given by infiltration. Wt. 141
5/30/62 Laetrile, 1 gram, i.v. and B^{15}, 2 c.c., i.m.
6/6/62 Wt. 130
11/4/62 Wt. 142

Conclusion: Record does not indicate improvement in any way that can be documented.
Record of "infiltrative" administration of Laetrile, but no data as to effect.

A.K. #74125 Female Age 35

Diagnosis: Carcinoma of Right Breast.
1/3/62 Histological Report:
"Papillary intracanalicular carcinoma, metastatic to lymph nodes."

Therapy: 3/28/62 Radiation therapy to internal mammary region, right sub-clavicular and axillary areas.
Surgical castration advised, but no record of being done.
Laetrile Therapy:
3/8/62 to 3/25/62 Laetrile 1 gram administered intravenously daily. Total 30 grams.
Weight at start, 152 lbs. No other weight recorded.

Conclusion: No record of any effect and no evaluation of therapy.

74016 Female Age 50

Diagnosis: Adenocarcinoma of pelvis, source unknown (? stomach).
3/15/62 Laparotomy with biopsy and histological confirmation.

Therapy:
Laetrile Therapy:
3/19/62 - 4/3/62 Laetrile 1, 2, and 3 grams by intravenous injection daily. Total 30 grams.
Response: absolutely no information in regard to effect or response.

Conclusion: No evidence of any kind as to effect of Laetrile therapy.

APPENDIX 16 -- LAETRILE REPORT (Continued)

G.M. #61-4798 Female Age 53

Diagnosis: "Glandular epithelium of ascending colon. Resection, with histological confirmation."

Course and Therapy:

8/20/61 Operation with resection
2/20/62 Reoperated with demonstration of recurrence with invasion and metastases to mesenteric nodes. Ileotransverse colostomy performed.

Laetrile Therapy:

Between 2/23/62 and 3/13/62.
Given Laetrile by intravenous injection every two days, or daily, for total dose of 57 grams.
Evaluation of effect: Stated to be "improvement of general health, pain diminished, diminution of spasm."

Conclusion:

No evidence to document any effect.

Supplemental Evaluation of Laetrile (Continued)

* * * * * * *

Later in the year, 36 clinical records translated into English from the French were received and evaluated by the Cancer Advisory Council at its December 1962 meeting. Records reviewed by Dr. Joseph F. Ross and Dr. Maurice H. Simmers are reported in detail in Appendix 16. They will be summarized below.

The cases evaluated by Dr. David A. Wood include the following:

1. A.D. - #4974
2. A.F. - #41339
3. G.F. - #63880
4. C.C. - #59631
5. J.F. - #64656
6. R.B. - #4984
7. F.B. - #39609
8. R.C. - #74462
9. C.D. - #72472
10. H.D. - #72037

Dr. Wood summarized his evaluation as follows: "Five of the 10 cases were gastrointestinal, three were of the breast, one cancer of the tongue, one carcinoma of the kidneys. Some of these were cases apparently localized, in other words, anatomical stage one carcinomas; some were those that apparently had metastasized. While there were three deaths, with autopsies in each instance, one

Supplemental Evaluation of Laetrile (Continued)

carcinoma of the kidney, and two carcinomas of the stomach, there was absolutely nothing in the autopsy reports to be able to arrive at an opinion whether or not there had been any cancerostatic or carcinolytic effects from the agents administered.

Throughout these histories or records there was common emphasis on Laetrile for purpose of palliation. The allegations of improvement were all of a subjective nature. There was nothing in these reports that indicated any objective evaluation or any means of arriving at objective results.

I was impressed in a number of these charts where subjective improvement had occurred for maybe a period of a few days. These patients had received Durabolin, an anabolic agent, radiation, narcotics. There was absolutely nothing in these charts in reference to additional dosage of Laetrile, or maintenance dosage and schedules. So my conclusion was that all the records are inadequate for the purpose of evaluation of the efficacy of Laetrile in the treatment or palliation of cancer."

At the end of Dr. Wood's summary, he was asked by Dr. Cline specifically if in those records he found any evidence of palliation or of alleviation? Dr. Wood's reply was "absolutely none".

Dr. Ross summarized his evaluation as follows:

"There were nine records submitted to me. These records have been furnished by Mr. McNaughton of the McNaughton Foundation on behalf of Mr. Krebs and the John Beard Memorial Foundation, manufacturer of the drug Laetrile. It was my understanding that these records were submitted by them for the purpose of showing the beneficial effect of Laetrile on cancer patients.

APPENDIX 7

The Treatment of Cancer with "Laetriles"

A Report by the Cancer Commission of the California Medical Association

THE INFORMATION that a new agent designated as Laetrile was being advocated for the treatment of cancer first came to the officers of the Cancer Commission of the California Medical Association in the form of inquiries from a number of magazines with national circulation in September 1952. Within the next several weeks following these original inquiries, information was sought by representatives of the major news services and by a majority of the metropolitan daily newspapers in California, usually through the science editors of these newspapers. In one instance we are informed a list of patients was given to a newspaper by a physician, who invited the representative of the newspaper to interview and photograph the patients at their homes as examples of the dramatic results of Laetrile treatment. The need for a thorough study of the claims which were being made finally became apparent when a member of the attending staff of the Los Angeles County Hospital requested permission for the investigational use of Laetrile in cancer in that institution. The request was originally presented to the tumor board of the Los Angeles County Hospital and was denied, but subsequently limited permission for the trial use of Laetrile in the hospital, upon patients informed and assenting, was obtained through another committee of the hospital.

1. *Nature of the treatment method.* Laetrile is supposed to affect malignant neoplasms by "focally triggering off lethal quantities of nascent hydrogen cyanide." The term Laetrile is derived from the fact that the chemical is a laevo-rotary-nitrile. It is claimed that this type of therapy was first used in human cancer by Ernst T. Krebs, Sr., shortly after 1920, when "substantial clinical results" were obtained from the use of a beta-cyanogenetic glucoside named amygdalin. Amygdalin is readily obtained as an extract of apricot pits.

The claim made during 1952 by Mr. Ernst T. Krebs, Jr., was that he had synthesized a new Laetrile designated roughly as beta-cyanophoric-glucuroniside which, in the presence of an enzyme, beta-glucuronidase, released quantities of nascent hydrogen cyanide. As a significant number of cancers previously have been demonstrated to develop greater amounts of beta-glucuronidase than most non-neoplastic tissues, it was maintained that the "triggering" effect of the glucuronidase on the Laetrile in cancer could produce release of free HCN in such amount as to be lethal for the cancer cell with some degree of specificity. The fact that a margin of safety exists is maintained to be due to the excess of the enzyme beta-glucuronidase in cancerous tissue.

Subsequent to our first acquaintance with the stated chemical formula of this synthetic Laetrile, Mr. Krebs has stated that related synthetic Laetriles have been developed, and he now refers to the product offered for clinical use as "Laetriles."

In addition to the foregoing sort of chemical theory offered by the proponents of this preparation they state that the fundamental biologic rationale for Laetrile therapy derives from a unitarian or trophoblastic theory of cancer, concerning which doctrine Krebs *et al.* have previously published a long treatise. So emphatic is their conviction, that Mr. Krebs has stated in correspondence that no physician should use Laetrile who does not subscribe wholeheartedly to the unitarian theory of the genesis of cancer, and that no physician can use Laetrile intelligently unless he is indoctrinated in this theory.

2. *Proponents of Laetrile treatment.* Chief claimant to the development of synthetic Laetrile is Mr. E. T. Krebs, Jr., who designates himself as a research biochemist. Associated with him is his father, Ernst T. Krebs, Sr., M.D., of San Francisco, and B. A. Krebs, D.O. Laetrile and other drugs are produced and distributed by the John Beard Memorial Foundation, organized by the Krebs and in honor of a Scottish anatomist who is said to be the originator of the unitarian theory of cancer. There are actually two John Beard Memorial Foundations, one of which is incorporated as a non-profit affair, while the other is just a "foundation."* In past years the Krebs have produced and advocated another agent for the treatment of cancer, chymotrypsin. Chymotrypsin was also said to derive its rationale in cancer from the unitarian theory of Beard, and although chymotrypsin has been quite discredited as having any effect on cancer, it is still sold and used in a limited fashion both for cancer, and for such other purposes as dissolution of blood clots in cerebral and other thromboses.

Mr. Krebs also claims to have synthesized "vitamin B_{15}," which is advocated for use in arthritis and cardiovascular disease. Various other esoteric products are distributed by the John Beard Memorial Foundation, concerning which the Cancer Commission has little or no information.

---

* Note: The addresses of the two "John Beard Memorial Foundations" in San Francisco are, respectively, 642 Cripp Street and 1095 Market Street. These foundations are not connected. There is also the "Krebs Research Foundation of Los Angeles," and the "Butterworth Cancer Research Grants, Inc. Los Angeles." The latter was founded by Mr. Bert Butterworth, publisher and editor of *West Coast Druggist*, with offices at 1606 N. Highland Avenue, Hollywood; the founders are Mr. A. A. Butterworth, Mrs. A. A. Butterworth, and Mr. A. W. Butterworth.

3. *Experimental evidence offered.* No satisfactory experimental evidence has been provided. Mr. Krebs states that he has demonstrated *in vitro* the triggering action of "tumor glucuronidase" on Laetrile to release nascent HCN. The Secretary of the Cancer Commission visited Dr. Ernst T. Krebs, Sr., in an attempt to obtain definitive information concerning experimental work, including toxicity tests and any available data concerning the use of Laetrile in experimental neoplasms. Dr. Krebs stated that limited trials of toxicity in laboratory animals had been performed with satisfactory results, but that the animals had been destroyed, as had the records of these trials. Dr. Krebs stated, in conversation with the Chairman of the Cancer Commission, that following demonstration of the above *in vitro* phenomenon, and satisfactory tests for toxicity, there was no point in using the agent on experimental neoplasms and that he preferred to see the agent used forthwith in human cancer.

4. *Clinical evidence offered by proponents of Laetrile.* A verbal report of the effect of Laetrile on several cases of human cancer was offered to the Secretary of the Cancer Commission by Dr. Krebs, Sr. One of these supposedly dramatic clinical situations will be representative. The story concerned a young man with a "huge cancer of the sigmoid and obstruction" (according to Dr. Krebs). The patient was "critically ill." Dr. Krebs stated that within a few minutes of administering the first dose of Laetrile the patient "could feel the action of the drug in the cancer and had a bowel movement with dramatic relief of his obstruction." Inquiry revealed that the patient had been in the Stanford University Hospital eight years previously with diffuse polyposis of the colon and rectum; he refused surgery. Two years previously he was found to have rectal carcinoma and again refused surgery. Two weeks before going to Dr. Krebs he was found by clinical and x-ray examination to have extensive rectal cancer, plus the diffuse polyposis coli, but absolutely *no* obstruction!

5. *Autopsy data offered by proponents of Laetrile.* None.

6. *Experimental evidence developed by the Cancer Commission and independent investigators.* At one medical center in Southern California an experienced experimentalist and pathologist in cancer tested Laetrile in a small group of A-mice carrying C-1300 neuroblastoma, giving 3 to 4 times the dosage employed in patients on a weight for weight basis. A similar number of control animals were used under appropriate conditions. There was no recognizable effect, gross or microscopic. The final observations were made in mice in which the neoplasms became so large under treatment with Laetrile that they were autopsied shortly before the progression of the tumor would have produced their death. It should be noted that the C-1300 neuroblastoma is a very labile neoplasm, easily controllable by a single dose of 500 roentgens of x-radiation or by one milligram per kilogram of nitrogen mustard.

A supply of Laetrile was submitted to Dr. A. P. Rinfret of the department of chemistry of Stanford University, and on January 23, 1953, Dr. C. Griffin of that department submitted the following report:

> Initially we attempted to find out how much of the preparation laboratory mice could be injected with. Two or four mg. injections had no apparent ill effects on Swiss mice. Thirty dba line 2 mice were inoculated with acute lymphatic leukemia. Two days after the tumor inoculation half of these animals were given daily injections (s.c. 2 mg. per day, the Laetrile was dissolved in saline such that 1 cc. contained 10 mg.). The remaining animals were maintained as tumor controls. All of the controls died in the period from 11 to 13 days following the tumor inoculation. Two of the Laetrile treated animals died before the 10th day, presumably from the drug itself, and the remaining animals all died between the 11th and 13th days. From this single observation involving an acute leukemia, the Laetrile exerted no effect whatsoever on the course of the disease.
>
> At the present time we are injecting Laetrile into mice bearing ear tumors. Daily injections have been made for the past four weeks. At this time it would not appear that the drug has altered the course of these skin tumors. One other point may be worthy of mention. We were informed that the brown bottles contained 50 mg. of Laetrile while actually we observed that these vials contained from 25 to 35 mg. of this drug as determined by weighing on our analytical balances. A further report will be made when more data have been obtained.

John B. Field, M.D., who conducts a project in experimental screening of potential chemotherapeutic agents at U.S.C., reported as follows:

> Laetrile was studied in the cancer screening program of this department. When given at a level of 500 mg./kilogram to mice with implanted Crocker sarcoma 180, no inhibition of tumor size was obtained. This is in distinct contrast to the marked inhibition obtained in this tumor with doses of triethylene melamine at a level of .75 mg./kilo and with amethopterin at a dose of 1.5 mg./kilo.
>
> TOXICITY STUDIES
>
> The Laetrile was dissolved in saline solution and given by stomach tube to mice and found to be safe at all doses below 300 mg./kilo. However, at all oral levels of 400 mg./kilo and higher, the animals expired. Deaths were relatively in a matter of minutes with 500 mg. or higher and a matter of approximately one hour at 400 mg./kilo.

7. *Clinical evidence discovered by the Cancer Commission.* Following the initiation of the use of Laetrile at the Los Angeles County Hospital by a member of its staff, the Tumor Board and the Research Committee of the hospital decided, with the approval of the administration, that the extraordinary claims which were being made for the agent could best be either verified or disproved by a carefully controlled clinical investigation. The Tumor Board appointed a group from its Committee on

TABLE 1.—*Treatment of Cancer with Laetriles. Summary, January, 1953.*

Total patients treated	44
Alive—no evidence of cancer	1*
Alive—with cancer	17
Static	6
Progressive	8
Terminal	3
Untraced with disease at last note	7
Dead	19
Autopsies	9

* Pre-invasive carcinoma uterine cervix, biopsy diagnosis; "post-treatment" biopsy failed to show the lesion. Microscopic sections not available.

Chemotherapeutic Agents to set up and direct the investigation, the group consisting of a clinician with special experience and interest in cancer therapy, a tumor pathologist, a biochemist and a senior resident. A substantial grant was obtained from a private foundation for the support of the investigation. The proposal was to treat a series of some 30 to 50 patients over a period of six months and to follow these patients carefully over a further period of six months, recognizing that while the true effectiveness of a therapeutic agent for cancer can only be determined by long range observations over a period of years, the initial response and short term follow-up will serve to indicate whether or not an agent is worthy of further trial.

The clinician in charge of the proposed investigation at the Los Angeles County Hospital then began a frustrating experience in an attempt to obtain the promised supply of Laetrile. By this time a "foundation" had been set up in Los Angeles by the Krebs, which organization they designated as the Crabtree Research Foundation, with a Mr. C. W. Wylie as business manager. Although Laetrile was being freely issued to certain physicians for use in their offices for the treatment of cancer, Mr. Wylie and Mr. Krebs offered repeated and various excuses why Laetrile could not be furnished for the hospital investigation. Over a period of several weeks repeated assurances were given that Laetrile would be made available. Finally a communication was received in which a set of criteria was set forth, the observance of which would result in a supply of Laetrile becoming available. Most of the criteria were acceptable and conformed with good practice in pursuing a clinical investigation, but one demand was that a physician who is not a member of the attending staff of the hospital, Dr. Clifford L. Bartlett of Pasadena, be placed in charge of the investigation. The medical director of the hospital properly replied that such a demand could not be complied with, and emphasized the fact that such an investigation should be carried out by completely unbiased workers. Shortly thereafter a communication was received from Dr. Bartlett in which he undertook to notify officially the Los Angeles County Hospital that the use of Laetrile was being denied the hospital, and implied that the proposed investigation was set up with the intent of discrediting the agent. In this letter Dr. Bartlett also implied that he had done the original developmental work with Laetrile together with a biochemist, and that later the Krebs had entered the picture.

With this avenue of direct investigation thus closed, the Cancer Commission undertook to obtain information as to the clinical course of patients under treatment. On November 6, 1952, the chairman of the Cancer Commission, by invitation, reviewed a group of eight patients under treatment with Laetrile for cancer by various physicians at a sanitarium in Santa Monica. Six other patients had begun treatment with Laetrile at the Los Angeles County Hospital as described above. From these and other sources the Commission has been able to collect information on a total of 44 patients as listed in Table 2. All of the patients were treated by physicians in Southern California except two reported by Ernst T. Krebs, Sr., M.D., and one by a urologist in New Jersey.

In Table 1 is summarized the follow-up as far as it has been obtainable as of January, 1953. The information thus recorded constitutes proof that *no objective benefit* has been realized by the use of this agent in cancer. The clinical observations of several members of the Cancer Commission who have reviewed the information collected, and in some instances had an opportunity of seeing the patients thus treated, indicate that Laetrile may exert a temporary metabolic effect, probably on nitrogen metabolism. Thus some of the patients have an increase in sense of well being and appetite, and temporary gain in weight of the sort that is frequently observed with the use of any of a number of non-specific agents. Claims have been made that Laetrile produces relief of pain in cancer, but this observation has not been verified.

Interviewing the claims which have been made for the effectiveness of Laetrile in cancer, observers for the Commission have been impressed by the fact that in almost every instance the alleged therapeutic results were ascribable to other factors. Most of the alleged improvement occurring with Laetrile was associated with one or more of the following events in the patient's disease:

(a) Subjective improvement was interpreted as being evidence of the agent's affecting the neoplasm, rather than being due to the general effect on the host, whether by metabolic or psychologic reasons. Thus, all of the physicians whose patients were reviewed spoke of increase in the sense of well being and appetite, gain in weight and decrease in pain, as though these observations constituted evidence of definitive therapeutic effect. Several patients were seen with

objective evidence of progressive neoplastic disease, two of whom came to autopsy within several weeks of their treatment with Laetrile, and yet their subjective response of increased intake of food, or the development of a euphoric mood, or some slight reduction in their use of narcotics, was accepted as objective evidence of improvement under treatment.

(b) Phases in the natural history of malignant neoplasm not infrequently observed in patients who are receiving no treatment whatever were interpreted as being due to the therapy employed. Thus a woman on exploratory laparotomy was found to have a bulky ovarian carcinoma with extensive peritoneal implants. Shortly after this surgical procedure, at which nothing more than biopsy for confirmation of the diagnoses was done, she began treatment with Laetrile. Her subsequent improvement generally, the failure of the ascites to recur, and the fact that she became ambulatory and fairly active, were interpreted as therapeutic effect. It is common knowledge among clinicians of experience that occasional patients with widespread peritoneal carcinomatosis will exhibit remarkable spontaneous arrest, or even regression of their disease following simple exploratory procedures. The same observation has been made in patients explored with the finding of extensive tuberculous abdominal lesions.

(c) Most often the patients reported as showing regression of cancer with Laetrile were either receiving concurrent treatment by other methods, or had in their recent past been treated by some more conventional techniques and were exhibiting a degree of control of their disease entirely attributable to the previous treatment. An example of a situation of this sort was illustrated by a man who was presented to a member of the Commission as being a dramatic example of control of bronchogenic carcinoma, with metastases, by Laetrile. Serial roentgenograms were shown of a patient who had a left pulmonary apical lesion, with enlarged left supraclavicular nodes, biopsy of one of which had shown metastatic carcinoma compatible with a primary bronchogenic lesion. Over a period of some three months, during which time he had had treatment first with chymotrypsin, and then with Laetrile, the roentgenograms showed almost complete regression of the pulmonary lesion. When the patient was examined there was noted a residual erythema and early tanning of the skin over a rectangular area which lay directly over the pulmonary lesion, and extended upward over the supraclavicular area. Inquiry revealed that the patient had, some six weeks previously, completed a full course of high voltage x-ray therapy, but the physician who had employed the Laetrile was unaware that the radiation had been directed toward the pulmonary lesion, thinking that anatomically the field had covered only the lymphnodal metastases.

(d) A few of the patients treated did not have proof of the presence of cancer in the form of histological diagnoses, the evidence being more or less inferential, as radiographic observation of lesions in the lung, or a surgeon's diagnosis of a lesion as cancerous on observations of gross pathology at operation, without confirmation with biopsy.

(e) Very few of the clinical records to which the Cancer Commission has had access contain any sort of satisfactory evidence as to objective, accurate evaluation of the progress of the primary neoplasm or its metastases while under treatment. In the instance of accessible lesions there was no record of any actual measurement of the presenting neoplasm.

In short, the clinical observations offered on the course of patients treated with Laetrile are all too frequently distorted by a lack of appreciation of the natural history of cancer on the part of the physician using the agent. This is not to say that the physicians in such a situation are not without ability in their own field. An internist, however, may

TABLE 2.—*Clinical Summary—Laetrile.*

No. and Diagnosis	Present Status	Autopsy
1. Multiple myeloma	Alive with disease	
2. Squamous ca. lt. antrum	Alive with disease	
3. Not recorded	Active disease	
4. Adenoca. of ovary with metastases	Terminal	
5. Ca. of the vulva	Progressive disease	
6. Pulmonary and skeletal metastases	Progressive disease	
7. Adenoca. of ascending colon, Gr. III with metastases	Not known	
8. Melanoma—primary in scalp	Progressive disease	
9. Adenoca. of lt. breast, Gr. III with metastatic adenoca. of axillary nodes Cystic adenoca. of the ovary	Bedridden	
10. Ca. of right ovary	Alive with disease	
11. Metastatic tumor causing obstruction rt. kidney	Progressive disease	
12. Multiple myeloma	Active disease	
13. Ca. rt. breast, Gr. III	Progressive disease	
14. Papillary serous cyst-adenoca. Gr. II, lt. ovary with extensive metastases	Not known	
15. Testicular tumor	Died	Yes
16. Neoplasm involving entire stomach with extensive metastases	Unimproved	
17. Papillary epidermoid ca. low grade, gingiva	Active disease	
18. Squamous epithelioma, primary lt. lung upper lobe, with metastases	Alive with disease	
19. Postop. adenoca. rt. breast, Gr. IV	Alive with disease	
20. Preinvasive epidermoid ca. of uterus	Well	
21. Infiltrating epidermoid ca., Gr. II-III, uterine cervix, Gr. IV	Alive with disease	
22. Hypernephroma with metastases	Died	No
23. Metastatic ca.—primary in ovary	Died	No
24. Ca. of rectum	No change	
25. Ca. of colon	No change	
26. Ca. of lung	Bedridden	
27. Ca. of bladder	Progressive disease	
28. Metastatic ca. of liver	Died	Yes
29. Reticulum cell lymphosarcoma	Died	Yes
30. Gastric carcinoma	Died	Yes
31. Ca. of breast	Died	Yes
32. Ca. of colon	Died	Yes
33. Ca. of cervix uteri	Died	Yes
34. Ca. of pancreas	Died	Yes
35. Teratoma of testis	Died	Yes
36. Ca. of breast	Died	No
37. Ca. of breast	Died	No
38. Leukemia	Died	No
39. Invasive ca. of uterus	Died	No
40. Adenoca. rt. alveolar ridge, massive neck metastases	Died	No
41. Ca. of breast, metastases	Died	No
42. Sq. cell ca. rt. lung	Died	No
43. Anaplastic adenoca., primary site unknown	Died	No
44. Generalized carcinomatosis of abdomen	Not known	

have little knowledge of the natural history, and response to treatment, of some forms of gynecologic or urologic cancer. Generally there has also been a failure to differentiate between subjective and objective response, and specific and non-specific effects of treatment.

One further example of an unwarranted claim for this agent is the instance of a patient who was treated for a preinvasive carcinoma of the uterine cervix. The reported observation of carcinoma *in situ* being present in the pre-treatment biopsies, is of no possible significance. It is known that carcinoma *in situ*, particularly in the uterine cervix, is capable of undergoing spontaneous regression. Further, it has been established repeatedly that occasional women showing this lesion on biopsy will come to total hysterectomy, and the pathologist will be unable to find further malignant change in the surgical specimen even with a large number of serial sections of the cervix. Finally the differentiation between atypical epithelial hyperplasia and actual preinvasive carcinoma may be a debatable issue in some instances, and the Commission has not had an opportunity to have the sections in this particular case reviewed.

8. *Autopsy data reviewed by the Cancer Commission.* Adequate information in the instance of six autopsies of patients treated for cancer with Laetrile and microscopic sections of the neoplasm were obtainable for review in nine cases. The material from six of these autopsies was collected at one time, wet tissue was obtained from the pathologist who did the autopsies, and sets of microscopic sections were prepared for review. The cases so collected at this time appear in Table 2 as Numbers 28 to 33 inclusive. This material was sent to three consultants who have had particular experience and interest in tumor pathology, Louisa E. Keasbey, M.D., John W. Budd, M.D., and J. L. Zundell, M.D. Subsequently microscopic sections were obtained from autopsies done in three additional cases appearing in Table 2 as Numbers 13, 34 and 35. Two of these latter cases were reviewed for the Commission by Weldon K. Bullock, M.D. and the other by A. R. Camero, M.D. In addition, the sections from the original group of six autopsied patients were submitted to Fred W. Stewart, pathologist to the Memorial Center for Cancer and Allied Diseases in New York.

The unanimous opinion of these consultants was that in no instance could any recognizable effect of a chemotherapeutic agent be observed in the histology of these various neoplasms. Some of the proponents of Laetrile had reported microscopic observations in the form of necrosis and hemorrhage in some instances, and sclerosis in others, which they interpreted as being the result of specific action of Laetrile on the neoplasm. Although both of these changes were observed by the consultants in a number of the cases studied, such changes in each instance were entirely consistent with vascular changes, necrosis and stromal sclerosis regularly seen in such neoplasms, both treated and untreated. Even in those cases showing considerable necrosis, particularly in hepatic metastases, there were invariably large areas of well preserved and viable tumor tissue. No evidence of cytotoxic changes was observed by any of the consultants. Dr. Fred W. Stewart reported, "I don't see anything in any of these cases that is the least bit suggestive of treatment effect, nor do I see anything that is foreign in appearance to appearances at autopsy of any cases of the corresponding type."

9. *Consultants' reports.* As outlined under Item 1 of this report the claim by Krebs and his associates for the possible value of the Laetriles in the treatment of cancer was based on the concept that an excess of the enzyme beta-glucuronidase in cancer tissue acted as a focal trigger mechanism in producing the release of free HCN from the Laetriles, and thus there might be a specificity of parenterally administered Laetrile on foci of cancer in the host. In a copy of a manuscript written by Ernst T. Krebs Jr. *et al*, presumably for publication, the following statements are made:

(a) That the natural nitriles as obtained from apricot pits are beta-cyanophoric glucosides, that these natural glucosides were used by Krebs Sr. in the early '20s of this century with "substantial clinical results" due to the presence of a "beta-cyanogenetic glucoside (amygdalin)."

(b) The claim of Krebs Jr. that he has synthesized a laetrile which he designates as a beta-cyanophoric glucuronoside. The manuscript states that "the natural laetriles have been abandoned for the more specific synthetic laetrile tailored as specific glucuronosidic substrates for the tumor beta-glucuronidase." The manuscript also states that the synthetic laetrile has the advantage of being a smaller molecule with less possibility of proving antigenically or otherwise reactive.

It seemed essential, therefore, to obtain expert opinion as to the theoretical basis for this supposed action, and to obtain an analysis of the product distributed by Krebs as Laetrile.

The opinion of Dr. Jesse P. Greenstein, chief of the laboratory of biochemistry at the National Cancer Institute was obtained in respect to the distribution of beta-glucuronidase in neoplastic and non-neoplastic tissues, and as to the implication that there was a "tumor" beta-glucuronidase enzyme. The fact is, reported Doctor Greenstein, that beta-glucuronidase is found in all tissues of the animal body and in particularly high concentration in spleen, liver and endocrine organs, as well as in plasma and in tumors arising from estrogen influenced tissues. Per gram of tissue the spleen and liver have a higher concentration of beta-glucuronidase than do

most tumors, and these normal organs together weigh far more than most tumors. In other words, there is much more "normal" beta-glucuronidase than "tumor" beta-glucuronidase in any animal body.*

For analysis samples of Laetrile were submitted to the chemical laboratory of the American Medical Association, in the form of a box of four ampules containing a white crystalline powder and labelled as Laetrile. Comparison of this material was carried out by various chemical methods with a sample of amygdalin purchased on the open market. Comparison was also made between the two materials by ultra-violet absorption spectra. The conclusion of this analysis and comparative study was that the Laetrile tested was essentially amygdalin with a small amount of other material present.

An analysis on samples submitted as Laetrile is being done by John W. Mehl, M.D., professor of biochemistry at the University of Southern California. A preliminary report was submitted by Dr. Mehl on February 27, 1953, as follows:

> We have tested the material for the presence of carboxyl groups, which must be present in a *glucuronoside*. The amount is so small that this could constitute only about 1 per cent of the total material. I would conclude that the material, if a glycoside, is probably a glucoside as suggested by the examinations of others.
>
> I also made an attempt to hydrolyze the material with beta-glucuronidase, and to collect any evolved HCN by inserting a wick of filter paper which had been moistened with dilute NaOH in the stopper. After 48 hours at 25° C, no HCN was detectable by the alkaline picrate test, carried out as a spot test.
>
> These results are inconclusive, and will be extended, but they do not support the claims made for Laetrile.

10. *General comments.* The efforts of the Cancer Commission to develop information concerning the Krebs and their various foundations, the distribution of Laetrile and its use by a number of physicians have been attended by a constant series of conflicting statements, claims being made and then denied, supplies of Laetrile repeatedly being promised for clinical or experimental use and eventually refused, and above all repeated implications that the intent of the Cancer Commission was only to discredit out of hand this proposed treatment for cancer. In one of a series of long communications Mr. Krebs remarked "it is extremely unlikely that any paper describing positive findings for Laetrile could achieve early publication in J.A.M.A., though it is virtually a certainty that a paper describing no results would find ready acceptance." At times Mr. Krebs has said that he makes no claim for any established value of Laetriles in cancer, at other times he describes the remarkable results obtained—offering as supportive evidence the sort of necrosis referred to in the description of the autopsy material in this report. Mr. Krebs also wrote to the Cancer Commission maintaining that "during the past 50 years a number of terminal cancer patients have recovered as the result of the use of either trypsin or chymotrypsin." Dr. Krebs, Sr., however, when pressed by the secretary of the Cancer Commission, stated that he could not produce any examples of cancer control by chymotrypsin.

In further communication with the Commission, Mr. Krebs wrote to outline his ideas of how a clinical project should be set up to evaluate the efficiency of a treatment for cancer, and wrote that they had criteria other than that of tumefaction by which they evaluated Laetrile therapy.

Their preferred criteria as listed were: (1) Decrease in pain, (2) Increase in appetite, (3) Increase in weight, (4) Increase in muscular strength and general sense of well-being, (5) Decrease in sedimentation rate, (6) Some decrease in tumefaction, (7) Increase in life expectancy, (8) Histological changes, (9) Necrotic involution and (10) Intense local reaction in the primary and secondary lesions.

When information reached Mr. Krebs that preliminary results of the analysis of Laetrile being done at the A.M.A. chemical laboratory indicated that only amygdalin was present, he began a new round of correspondence to remind his group and the Commission that he had always said that the natural laetrile, or amygdalin, was part of the "remedy," and gave more emphasis to his previous statements that he did not maintain that laetrile was necessarily an effective treatment for cancer.

The financial background of the production and distribution of Laetrile has naturally been of some interest to investigators. Krebs maintains that the development of the agent has been extremely costly, while some of the physicians who have been using the material in private practice have maintained that their charges have been modest indeed. The Commission has a witnessed statement from a patient who visited one of these physicians to discuss treatment of his Hodgkin's disease with Laetrile. The patient's statement certifies that he was advised to try one week of treatment, during which three injections of Laetrile would be given at a cost of $50.00 each. In addition, three injections of vitamins would also be given, presumably the so-called Vitamin B_{15}, also manufactured by Krebs, and the cost of this would be $10 each time. Thus the trial period of one week's treatment would cost this patient, a young man with modest income, a total of $180. One of the physicians using Laetrile has informed the Commission that it is supplied to him by Krebs at the cost of $10 per ampule, and the Vitamin B_{15} at a cost of $3 per ampule.

* Dr. Greenstein writes in a letter dated November 10, 1952: "Such a statement as . . .'the malignant cell . . . is virtually an island surrounded by a sea of beta-glucuronidase' is sheer nonsense."

In one instance of a patient with an operable gingival carcinoma under treatment with Laetrile, three requests were made for serial biopsies of the lesion while under treatment, as a pre-treatment biopsy was already in our possession. Repeated assurances were given us that biopsies would be obtained. We offered to assist in any way desired, but no material was received.

11. *Conclusions of the Commission.* Laetriles have been advocated for the treatment of cancer on the basis of the following claims:

(a) That one or more synthetic laetriles have been synthesized.

(b) That in the presence of the enzyme beta-glucuronidase, supposedly present in excess in cancer tissue, a chemical reaction occurs resulting in the liberation of nascent HCN.

(c) That the HCN thus produced has, at least to some extent, a selective cytotoxic effect on the cancer cell.

The evidence accumulated by the Cancer Commission and its consultants indicates the following defects in these claims, in the following order:

(a) Chemical analyses done independently for the Commission have identified in the product distributed as Laetrile only the presence of a natural laetrile termed amygdalin.

(b) The enzyme beta-glucuronidase, while present in some excess in some types of cancer, is also present in similar concentrations in normal tissue such as liver and spleen. In fact, the total amount of beta-glucuronidase present in normal tissues in almost any cancer patient considerably exceeds that which is present in neoplastic tissue.

(c) No satisfactory evidence has been produced to indicate any significant cytotoxic effect of Laetrile on the cancer cell.

The Commission has collected information concerning 44 patients treated with Laetrile, all of whom either have active disease or are dead of their disease, with one exception. Of those alive with disease, no patient has been found with objective evidence of control of cancer under treatment with Laetriles alone.

Nine patients dying from cancer after treatment with Laetrile have been autopsied, and histological studies done for the Commission by five different pathologists have shown no evidence of any chemotherapeutic effect.

In two independent studies by experienced research workers, Laetrile has been completely ineffective when used in large doses on cancer in laboratory animals, in lesions which are readily influenced by useful chemotherapy.

APPENDIX 8

CLINICAL INEFFECTIVENESS OF LAETRILE: ABSENCE OF OBJECTIVE RESPONSE OR OF EXTENSION OF LIFE SPAN IN FIFTEEN PATIENTS

by

Wallace I. Sampson, M.D.

Lawrence A. William, M.D.

From: The Department of Medicine
Stanford University School of Medicine
Stanford, CA 94305

Reprint requests to Wallace I. Sampson, M.D.
2500 Hospital Drive #9
Mountain View, CA 94040

INTRODUCTION:

Laetrile is the commercial name for the compound, amygdalin. It is one of a family of plant compounds, the cyanogenic glycosides, common in various plants and seeds. For the past 25 years it has been proclaimed as an anticancer agent, first as a drug, and more recently as an "anticancer vitamin". The action is supposedly by specific release of cyanide within a cancer cell, normal cells being protected by the enzyme, rhodanese. Various authorities in biochemistry and cancer have disputed the claims both on biochemical, and clinical grounds. The position of the Food and Drug Administration, as well as the California State Department of Health, has been that there is no reproducible activity in animal studies. In addition, there is absence of positive clinical observations. Case reports submitted by proponents purporting to show activity of the substance, have on review been poorly documented, or to have received standard therapy which could account for the patients' improvement.

Nevertheless, there is now a national movement to "legalize" the substance for cancer therapy. In response, the National Cancer Institute is preparing a multi-institution clinical trial of Laetrile to begin this fall, to attempt to determine whether or not there is any objective response in cancer patients. In view of the absence of control clinical data to date, we reviewed the

effectiveness of Laetrile from a different perspective, which is the life span of patients treated with Laetrile as opposed to those ~~without~~ not receiving laetrile. The study is retrospective over the period, 1971-1976.

METHODS:

The courses of 15 patients known to have taken Laetrile for more than two months, or from time of diagnosis to death, were reviewed and compared with three each of randomly selected disease-matched controls from our files. Most Laetrile patients rejected standard methods of care for significant periods of time, some accepted no standard treatment after diagnosis. All cases, Laetrile as well as control patients, were treated by the two of us, or had been seen at least once in consultation, with the records made available to us by referring physicians. Most of the patients were under our care through the entire course of disease, whether or not they accepted standard treatments. The control patients were all under our constant care and supervision, and received fairly consistent therapy including radiation when needed, and chemotherapy and hormone manipulation when appropriate.

The lung cancer patients and their controls had squamous or adenocarcinoma or their variants. No case of oat cell carcinoma is included in this preliminary study, although they will be included in a subsequent one. Most of these lung cancer patients received no intensive chemotherapy.

RESULTS:

In lung cancer, survival was nearly the same for Laetrile and control groups, although the latter survived slightly longer (figure 1.). Mean survival of Laetrile patients from time of diagnosis was 12.0 months, and that of control patients was 13.4 months. The survival from time of metastasis detection was 7.2 months for Laetrile patients, and 9.0 months for controls.

In breast cancer patients, the Laetrile treated group fared worse than those who took standard therapy. From time of diagnosis, the mean survival of the Laetrile group was 41.25 months, while that for controls was 71.4 months. From discovery of metastasis, the times were 22.5 months for Laetrile patients, and 46.1 months for controls.

In the remainder of the Laetrile-treated patients, were a mix of gastrointestinal adenocarcinoma, ovarian carcinoma, prostatic carcinoma, and renal carcinoma. (Our file had only two control patients for the one renal carcinoma.) Taken as a group, there was no significant prolongation of survival for these Laetrile-treated patients. It is important to note, as well, that there was no objective reduction in size of any tumor mass, nor any improvement in X-ray or laboratory examination in any of the Laetrile-treated patients, other than was easily explained by some other therapy.

For the total group of 15 Laetrile-treated patients, the mean

survival from time of diagnosis was 22.4 months, and that for controls was 36.1 months. From time of metastasis discovery, the Laetrile patients lived a mean of 14 months compared to 24.5 months for controls.

Analysis of these data (Wilcoxon two-tail test) does not show statistical significance to the shortened life span of the separate groups ($p. > .10$). This is because of the small number of patients. What can be said with greater confidence, especially for the fifteen patients as a group, is that Laetrile did not prolong life.

DISCUSSION:

For the entire group of 15 patients, it is seen that there was no prolongation of life span. As a matter of fact, given both breast cancer and lung cancer groups, as well as the mixture of other carcinomas, the patients receiving standard treatment lived longer. Several reasons for this seem possible.

First, only two Laetrile patients cooperated enough with standard treatments to have completed adequate courses of hormone or chemotherapy. Six Laetrile patients had abbreviated courses of therapy which were delayed or cut short by the patients themselves. Seven Laetrile patients avoided all standard medical approaches after the initial diagnosis or the metastasis diagnosis was made. Among the control patients, the large majority cooperated with approved

treatments. We have had a very conservative approach to squamous and adenocarcinoma of the lung, and have avoided treating most of our patients with vigorous chemotherapy until very recently. Therefore, the lung cancer patient control group, can for all intents and purposes be regarded as a non-treated group. This is especially since no oat cell cancer patient was included (These are more responsive to standard approaches.). Thus, the shortening of survival of Laetrile patients in the lung cancer group could indicate some deleterious effect from Laetrile.

The second possibility, then, is some effect of Laetrile which is detrimental. Most authorities believe that intravenous Laetrile is inert in very high doses because of minimal amounts and activity of the enzyme beta-glucosidase in human tissue. However, patients on oral Laetrile might be more likely to develop cyanide poisoning because of the higher concentration of beta-glucosidase in the gastrointestinal tract and in accompanying food. Most of the Laetrile-treated patients did take oral pills of Laetrile, in amounts varying from 500 mg to 2 or 3 grams per day. The taking of this material was quite irregular, and was done on the advice of non-professionals for the most part. It should be noted that the intravenous therapy was given in the range of 3 grams to close to 100 grams a day, usually administered by a physician or nurse in the area. Three of the lung cancer patients had muscle weakness which was considered at the time to be carcinomatous myopathy. However, two did also have some sensory components, either hypesthesias, paresthesias, associated with that, and a diagnosis of carcinomatous neuropathy was made.

It is possible, since neuropathies are common in chronic cyanide poisoning, that these problems were associated with the ingestion of Laetrile instead. However, we have no proof of that at this time.

Three patients, not included in this group, developed acute toxic reactions to Laetrile. One had a cardiac arrest in a Laetrile doctor's office and recovered spontaneously. Another had vomiting and electrolyte disturbance which responded to replacement therapy in a hospital. This occurred several times. Another developed malaise and vague symptoms after taking Laetrile by any route and had to stop it.

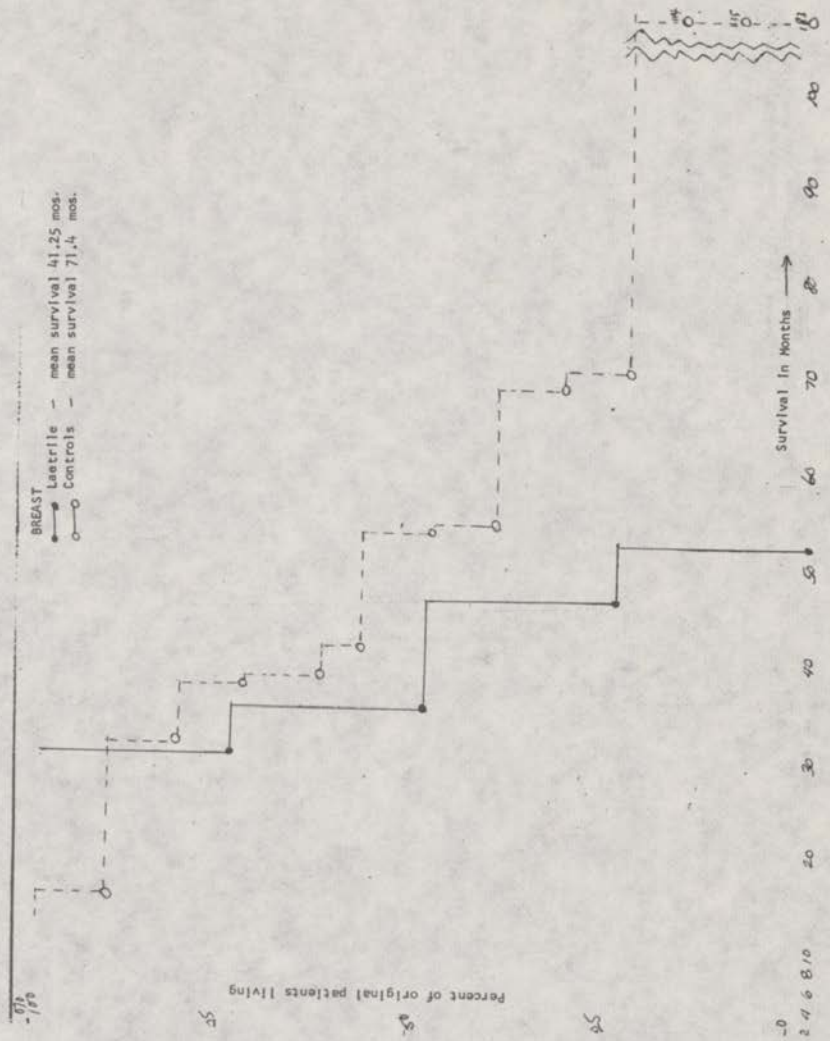
Only two of our patients are now taking Laetrile. One has a lymphoma and was treated in Mexico with Cytoxan as well as Laetrile, but she attributes the response to Laetrile. The second has advancing breast cancer while on Laetrile. Two of the patients in this report had metastases discovered while on Laetrile, but their faith in the material was not shaken they went along with recommendations by Laetrile proponents to increase the dose.

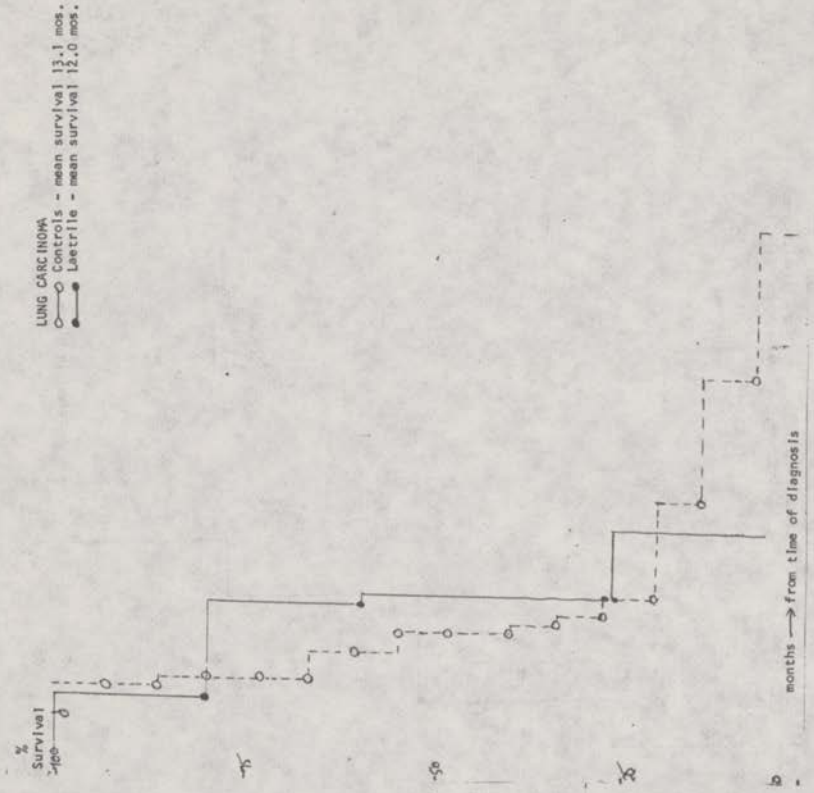
A separate study of 25 Laetrile-taking patients, including some of the above plus others who are not under our care(to be reported in a separate communication) showed that Laetrile patients avoid standard approaches to cancer and tend to have serious arguments or breaks with their physicians. They also become involved in more than one unapproved method of cancer care, and they also

tend to misinterpret their doctors' words and instructions significantly. Resistance to the standard medical cancer care system seems to be part of the personality complex of a group of patients, who turned most easily to Laetrile and other unapproved methods. We believe that avoidance of care, contributes significantly to their shortened survival.

CONCLUSION:

In the retrospective study of 15 Laetrile-taking patients, it was found that Laetrile did not result in either remission of cancer mass, improvement of X-ray appearance or laboratory or value, or extend life span when compared to disease matched controls. In fact, they generally fared less well, living only about half as long from time of initial diagnosis or from time of discovered metastasis when compared to their controls. Avoidance of standard therapy and chronic cyanide poisoning are possible reasons for these poor results with Laetrile.


BREAST
Laetrile – mean survival 41.25 mos.
Controls – mean survival 71.4 mos.
Survival In Months
Percent of original patients living


LUNG CARCINOMA
Controls - mean survival 13.1 mos.
Laetrile - mean survival 12.0 mos.
% Survival
100
months ⟶ from time of diagnosis

Senator KENNEDY. Our next panel consists of Herbert Hoffman, assistant U.S. attorney, San Diego, Calif.; Mr. John Keeney, Deputy Assistant Attorney General, Department of Justice; Mr. Louis Castro, deputy attorney general, State of California; Dr. Joseph Cosentino, chief medical director, board of medical examiners, State of California; and Mrs. Carol Hehmeyer, assistant district attorney, San Francisco, Calif.

Would you all rise, please, and raise your right hand?

Do you swear the testimony you will give will be the truth, the whole truth and nothing but the truth, so help you, God?

[Messrs. Hoffman, Keeney, Castro, Dr. Cosentino, and Mrs. Hehmeyer answered in the affirmative.]

Senator KENNEDY. Mr. Hoffman, we will start and we will ask some questions that will be helpful to this committee.

For the benefit of both the members of our committee and of our hearing this morning, you have no written testimony.

We will just start off by asking you why did you prosecute Dr. Richardson and Mr. Bradford, Mr. Salamon and Mr. Bowman?

STATEMENT OF HERBERT B. HOFFMAN, ASSISTANT U.S. ATTORNEY, SAN DIEGO, CALIF.; JOHN KEENEY, DEPUTY ASSISTANT ATTORNEY GENERAL, DEPARTMENT OF JUSTICE; LOUIS CASTRO, DEPUTY ATTORNEY GENERAL, STATE OF CALIFORNIA; JOSEPH COSENTINO, M.D., CHIEF MEDICAL DIRECTOR, BOARD OF MEDICAL EXAMINERS, STATE OF CALIFORNIA; AND CAROL HEHMEYER, ASSISTANT DISTRICT ATTORNEY, SAN FRANCISCO, CALIF., A PANEL

Mr. HOFFMAN. These gentlemen were prosecuted——

Senator KENNEDY. Let me interrupt.

We see Governor Brown here, the former Governor of the State of California. We welcome you here. If you want to take a seat up here, Governor.

Mr. HOFFMAN. Senator, the U.S. Criminal Code contains a section which prohibits the smuggling of merchandise from any country into the United States. That section prohibits the unlawful entry of undeclared merchandise.

Dr. Richardson, Mr. Bowman, Mr. Salaman and Mr. Bradford were engaged in a conspiracy to smuggle Laetrile from Mexico into the United States and thereafter to distribute it throughout the United States. This conduct was in violation of the U.S. Code, and they were prosecuted for those offenses.

Senator KENNEDY. Were they convicted?

Mr. HOFFMAN. They were all convicted after a 3-month trial, lasting from January to April of this year.

Senator KENNEDY. Would you tell us briefly how was the smuggling operation carried out?

Mr. HOFFMAN. The Laetrile in question was manufactured in Tijuana, Mexico, at a laboratory named Cyto Pharma de Mexico. Thereafter it was smuggled into this country usually by Mexican nationals who are known around the border area as mules—people who

96-492 O - 77 - 13

are paid $50 or $100 to drive an automobile across the border with Laetrile usually concealed under the seat or in a secret compartment.

Thereafter, the merchandise was delivered into the San Diego area where it was stored, sometimes in an airport locker, or sometimes in what is known as a drop house. Thereafter, it was delivered to northern California to Mr. Bradford or Dr. Richardson by couriers on airplanes with the material usually contained in suitcases.

Senator KENNEDY. Was there an operation to get people into Mexico for treatment as well?

Mr. HOFFMAN. We have experienced in the border area some cases involving people who run boardinghouses. These are places where patients from throughout the country come to San Diego to stay. The patients are picked up at the airport and taken to the houses where sometimes as many as 20 are kept in three- or four-bedroom houses.

The patients are transported to Tijuana for treatment every day, particularly at the Contreras Clinic. They are returned to the United States by the people who run the boardinghouses. The patients are also sold Laetrile that had been smuggled by the operators of the boardinghouse, and then sometimes, they are mailed Laetrile after they return to their homes.

Senator KENNEDY. Is this a lucrative business in terms of the boardinghouse owners?

Mr. HOFFMAN. The boardinghouse owners, our information showed, were charging anywhere from $80 to $100 a week per patient for the services they provided. That included car transportation to and from the border, breakfast and dinner, and transportation back to the airport. I feel it was a fairly lucrative business.

Senator KENNEDY. It was not uncommon to make, as I understand it, $100,000 a week—or $100,000 a year, excuse me?

Mr. HOFFMAN. I think that is a fair estimate, about $100,000 a year.

One woman I am referring to is named Ernestine Luther, who ran a boardinghouse for a few years in the San Diego area.

Senator KENNEDY. Who sold Laetrile to the people at the boardinghouse?

Mr. HOFFMAN. The Laetrile was sold by Mrs. Luther or one of her assistants, Emma McClure, after they had smuggled the Laetrile into the United States. They would purchase it for approximately $5 or $6 for a 3-gram vial and would sell it to patients for about $9 or $10 a vial.

Senator KENNEDY. Were they licensed physicians?

Mr. HOFFMAN. They were not licensed physicians. In fact, Mrs. Luther represented herself to be a registered nurse which was not the case.

Senator KENNEDY. Two of the witnesses on the next panel, Mr. Bradford and Dr. Richardson, were convicted at this trial, were they not?

Mr. HOFFMAN. That is correct.

Senator KENNEDY. Tell us the nature of the case presented against Mr. Bradford.

Mr. HOFFMAN. Mr. Bradford held the position of president of the Committee for Freedom of Choice in Cancer Therapy, which is an organization in Los Altos, Calif. As such, he had a close relationship

with the manufacturers in Laetrile in Tijuana, the owners of the Cyto Pharma de Mexico lab. He would receive the smuggled merchandise from them or their couriers.

There was no evidence that Mr. Bradford actually participated in smuggling the Laetrile across the border. He would receive the Laetrile from agents or couriers from Cyto Pharma after the merchandise had been smuggled, and thereafter, he would distribute the merchandise either through the United Parcel Service, or through the airlines, mostly by false labeling or false invoicing to his distributors who were located in other parts of the country.

Senator KENNEDY. Were those doctors?

Mr. HOFFMAN. Senator, there were some doctors, but there were mostly nondoctors.

From Mr. Bradford's own books and records which were seized by customs agents, he identified two of his principal distributors. One person, Douglas Heinsohn in Gatlinburg, Tenn., to whom Mr. Bradford sold an enormous amount of Laetrile was not a physician. He also sold a tremendous amount of Laetrile to a Stephen Michaelis, who was purported to be a pharmacist around Columbus, Ohio.

Senator KENNEDY. From your information, did he have any control on how Laetrile was used after it was sent to these people?

Mr. HOFFMAN. I have no information that he controlled how Laetrile was used at all.

Senator KENNEDY. What was the financial incentive for Bradford to be involved in this?

Mr. HOFFMAN. Senator, when Mr. Bradford was arrested on December 20, 1975, found in the trunk of his Cadillac underneath a spare tire were his books and records reflecting his distribution of Laetrile for the past 2½ years. These books and records were analyzed by an auditor and certified public accountant employed by the U.S. Customs Service.

It was the auditor's opinion, as testified at the trial, that for the 2½-year period, Mr. Bradford sold approximately $1,400,000 worth of Laetrile in which it was estimated that he made a profit of approximately $675,000.

Senator KENNEDY. Within a 2½-year period?

Mr. HOFFMAN. That is correct.

Senator KENNEDY. How do you know, or do the books show, whether he had any other income besides this?

Mr. HOFFMAN. No. I think the evidence showed that Mr. Bradford was engaged solely in Laetrile endeavors, as president for the committee and as distributor for the merchandise.

Senator KENNEDY. So that is effectively the sole source of his income; at least, that was your conclusion?

Mr. HOFFMAN. That is correct.

Senator KENNEDY. How do you respond to Mr. Bradford's statement that this was basically a humanitarian act bringing needed treatment to people and at high cost requiring the intake of considerable money and no one has really become rich on Laetrile?

Mr. HOFFMAN. If Mr. Bradford's efforts were truly humanitarian, it was inconceivable to me that he would spend the amount of time that he did, engaging in the distribution aspects of the business.

For example, Mr. Bradford purportedly represented himself to be concerned with the legalization of Laetrile in the States, and with

conducting symposiums and clinics that doctors would attend to learn about Laetrile. These were tremendous duties in and of themselves. To spend his time meeting couriers and picking up merchandise, and traveling to airports in San Jose and San Francisco to pick up merchandise for distribution, led me to argue in his trial that he had other motives.

I might add that in his own books and records were documents which reflected his desire to control the distribution of the material, obviously at a profit to him.

Senator KENNEDY. What do you mean by that?

Mr. HOFFMAN. For example, there was a letter that was seized from Mr. Bradford that was written by a gentleman in Orlando, Fla., to Cyto Pharma de Mexico, the manufacturer of Laetrile. This particular gentleman's name is Bonner, and the letter inquired if Bonner could obtain 1,000 vials of Laetrile which he intended to sell for approximately $7.50 per vial.

When arrested, Mr. Bradford possessed a note which stated to the effect that Mr. Bonner should be cut off from Cyto Pharma as a distributor. A short time thereafter Bradford's books and records reflected that Bonner was now purchasing his Laetrile from Mr. Bradford.

All of this ends up in marking up the price that the cancer patient has to pay for the merchandise.

Senator KENNEDY. Did you conclude upon your investigation that Mr. Bradford cut off some individuals from receiving Laetrile when he found out they were competing with his distribution efforts?

Mr. HOFFMAN. Yes; that is correct.

There were two specific instances from Mr. Bradford's own records and notes, which notes were written to himself, that so-and-so should be cut off by Cyto Pharma. He had such a close relationship with the manufacturers of Cyto Pharma, who produced the material, that he was able to do that. Thereafter these people had to buy their merchandise from Mr. Bradford, which paid a profit to him and which also upped the price that the consumer had to pay for the material.

Senator KENNEDY. Does that support the humanitarian argument?

Mr. HOFFMAN. I think not.

Senator KENNEDY. Would you make the financial records available to us and submit them for the record?

Mr. HOFFMAN. They are part of the court case. I have copies that I could submit to the committee; yes, sir.

(Editor's note: Due to the voluminous nature of the material referred to and in the interest of economy, the same was retained in the files of the subcommittee.)

Senator KENNEDY. Could you tell us about the case you presented against Dr. Richardson?

Mr. HOFFMAN. From the middle of 1973 and through part of 1974, Dr. Richardson, who was a practicing physician in Albany, Calif., and a dispenser of the Laetrile to his patients, was initially purchasing his Laetrile from Mr. Bradford. He was paying Mr. Bradford something like $9 for a 3-gram vial.

Thereafter, the evidence indicated that he possibly became dissatisfied that he was paying Bradford so much money for the material, and he began to receive shipments directly from Mexico and the

manufacturers, which he sold to his patients. Dr. Richardson also had what seemed to be a mail-order house business in which he mailed Laetrile throughout the country.

He had a price list which contained different prices for Laetrile and other drugs which he was selling around the country.

Senator KENNEDY. Do you know whether he mailed oral tablets?

Mr. HOFFMAN. Yes; he mailed tablets. I am not certain whether he mailed vials of liquid, but he did mail tablets.

Senator KENNEDY. So, at least to your information, there were oral tablets for oral consumption obviously?

Mr. HOFFMAN. Yes.

Senator KENNEDY. Was this a lucrative business for him, both treatment and distribution?

Mr. HOFFMAN. I can only give the committee certain financial information which we obtained about Dr. Richardson.

First of all, we subpenaed Dr. Richardson's financial records from his bank account in Albany, Calif., at the Mechanics Bank. Those records indicated that from January 1973 to March of 1976, Dr. Richardson deposited to a checking account approximately $2,800,000.

We also, obtained bills from patients which Dr. Richardson had issued to them. These bills usually averaged from $50, which was the normal cost for one injection, to as much as $100 or possibly more per bill.

In two instances of separate patients who received bills, we subtracted the last bill number from the first bill number. By this procedure, you can tell how many bills the doctor issued over a certain time period on the assumption that the bills are all in numerical order, which they were.

In the case of one patient, whose bills we analyzed from the period of February 1976 to April 1976, a 2-month period, Dr. Richardson issued 4,500 medical bills. If the average bill is $50 or $100, he could generate as much as $225,000 or $450,000 in a 2-month period.

We did the same analysis in the trial with another patient for an earlier period in 1973. We showed that from November 1973 to December 1973, in a month period, that Dr. Richardson issued approximately 2,000 bills.

By analyzing these bills in this way, you can get an idea as to the amount of income that Dr. Richardson generated.

Senator KENNEDY. Now, we have a copy of the court records from San Diego concerning the information of Dr. Richardson's income.

In 4 of the 6 years prior to 1973, Dr. Richardson had no taxable income. In 1973, the reported net income was $103,734; in 1974, net income, $172,000.

Is that your understanding?

Mr. HOFFMAN. That is correct.

Senator KENNEDY. It is a rather dramatic step-up, would you not say, between that income and at least what Dr. Richardson deposited in one bank account from 1973 to 1976?

Mr. HOFFMAN. Yes, sir.

Senator KENNEDY. Do you draw any conclusion from this?

Mr. HOFFMAN. I can draw the conclusion that it was the profitable endeavor. I should be so lucky.

Senator KENNEDY. We can go to Dr. Cosentino and Mr. Castro.

Perhaps it is the appropriate time for you to make a comment.

You are with the California Board of Medical Examiners, as I understand it, Dr. Cosentino?

Dr. COSENTINO. Yes, Senator.

Senator KENNEDY. You are with the medical assurance board, is that correct?

Dr. COSENTINO. Board of Medical Quality Assurance, State of California.

Senator KENNEDY. Did that board revoke the license of Dr. John Richardson?

Dr. COSENTINO. Yes; it did

Senator KENNEDY. And why was that done?

Dr. COSENTINO. Mr. Castro, who is with me, was the attorney general who prosecuted the case against Dr. Richardson, and after a 7-day hearing, and after review of the clinical management of a number of patients by Dr. Richardson, the administrative law judge submitted a proposed decision to the Division of Medical Quality, which is the enforcement arm of the board of medical quality assurance, proposing revocation.

The Division of Medical Quality is made up of four physicians and three laypersons. Only three physicians on the division at the present time, with three public members. It was the unanimous opinion of the opinion to approve the decision of the administrative law judge to revoke Dr. Richardson's license.

Senator KENNEDY. Why was this done? What were the grounds for it? Does Mr. Castro want to elaborate on that?

Mr. CASTRO. Senator, Dr. Richardson was charged with various violations of the State Medical Practice Act. He was charged with, for one, shipping interstate Laetrile, as Mr. Hoffman indicated, he was distributing it to individuals outside the State of California. That particular charge was based on information that the Federal Food and Drug Administration developed.

The second aspect of the charges against him dealt with utilizing unlicensed people in his office. Dr. Richardson utilized an individual by the name of Ralph Bowman. He utilized a registered nurse by the name of Jenkins. He utilized his own son, Steven Richardson, to in effect treat and give injections to patients.

Many times in his absence——

Senator KENNEDY. These are all unlicensed people?

Mr. CASTRO. With the exception of Ms. Jenkins, who had a nurse's license. However, in California, nurses can only perform such functions within the scope of their license. She cannot practice medicine in the doctor's absence.

In many of these cases we developed, in the board case, Dr. Richardson was not available to the patients, and the unlicensed personnel were the ones that were treating the patients.

Senator KENNEDY. These are cancer patients?

Mr. CASTRO. These were patients that had cancer, or thought they had cancer.

The third aspect of the charges, I think, were the most serious. We charged Dr. Richardson with gross negligence in the treatment and management of the patients. And I think that we have previously made a copy of the board's decision available to you. It has an appendix listed there.

You will note that it gives the case histories of certain patients treated by Dr. Richardson.

In effect it was found that Dr. Richardson's treatment and care of his patients was an extreme departure from the standards of practice.

I would just like to focus on one patient, if I may. I might add that I do not think any of these case histories appear in Dr. Richardson's book.

The one I would like to focus on is Helen Schneck. The history of this particular patient indicates that she went to Dr. Richardson initially for a complaint of nerves and neurolgia. It was during the course of treatment with Dr. Richardson that she apparently developed a malignancy.

Senator KENNEDY. Do I understand that she did not have that—the evidence, as far as you have it, is that she did not have it prior to the treatment?

Mr. CASTRO. That is correct, that she did not have a malignancy problem prior to seeing Dr. Richardson. She started treatment with him approximately December 18, 1972.

Interestingly enough, we have the patients records of Dr. Richardson for this particular patient. He made a notation on December 2, 1972, of Hodgkins with a question mark.

On December 11, 1972, he made a notation of lymphona with a question mark.

On December 29, 1972, he makes a comment in his records, "right breast discolored."

In the course of the management of this patient, she was referred ultimately to a physician who took a biopsy, and they did diagnose adenocarcinoma. She went back to Dr. Richardson. She refused conventional treatment. That is to say she did not want to undergo surgery or whatever was being offered at that particular time.

Dr. Richardson then referred the patient to Dr. Krebs.

Senator KENNEDY. Is Dr. Krebs a physician?

Mr. CASTRO. Dr. Ernst Krebs is not a physician. It is my understanding he calls himself a doctor, but he holds an honorary degree, I believe, from Tulsa University, I believe. He represents himself as being a biochemist.

This patient was referred to Dr. Krebs by Dr. Richardson, according to the husband, because Dr. Krebs was a leading authority in this particular field. Dr. Krebs diagnosed the condition, or was of the opinion that the patient really had an infection. She went back to Dr. Richardson.

On February 2, 1973, Dr. Richardson incredibly, having received some type of history from his patient, that she had cats and dogs, and they had frequently eaten raw meat, made a diagnosis of trichonosis of her condition.

Also, incredibly, he took a photograph of this particular patient, and we have the photograph attached to the patient records of Dr. Richardson. The condition that is depicted on this particular patient shows an inflammatory disease, which was cancer, going on.

Subsequently, the patient was admitted, because at that time she was in too much pain, to a hospital in Marin County. She proceeded to undergo conventional treatment, and I have photographs here of the condition she was in approximately at the time that she was admitted to the hospital.

The point I am making is that essentially the condition that is depicted on these photographs is essentially the condition that she presented to Dr. Richardson, and the condition he continually treated with Laetrile. That is one example.

There are other examples in the appendix——

Senator KENNEDY. What happened to her?

Mr. CASTRO. She died. She died shortly after being admitted to the hospital in Marin.

Senator KENNEDY. What diagnosis?

Mr. CASTRO. Inflammatory carcinoma of the breast. She died on October 4, 1973. At that point in time the disease was too far along, and treatment was only palliative.

Senator KENNEDY. Was that diagnosis ever made by Dr. Richardson, accordingly?

Mr. CASTRO. Yes; that diagnosis had been made by a physician at the hospital in Albany——

Senator KENNEDY. I meant by Dr. Richardson.

Mr. CASTRO. The records and the information we have would indicate that he was aware of the diagnosis, he was informed by the physician, another physician, that the diagnosis had been made, so he had knowledge of it.

As far as he himself having made the diagnosis, there is some indication in the records that he suspected that the patient might be suffering some type of inflammatory disease.

Senator KENNEDY. Do you know whether he discouraged her from undergoing any other therapy?

Mr. CASTRO. One of the findings made in the decision was that at no time, during his management of Schneck, did the respondent recommend any of the conventional modalities in the treatment of cancer, and the respondent in fact discouraged Schneck from undergoing said treatment.

There was evidence to that effect.

Senator KENNEDY. Let me ask you, during this whole period from March of 1972 to the time of her death, was she using Laetrile frequently? You just mentioned it at the very end.

Mr. CASTRO. Yes; she was being given Laetrile injections by Dr. Richardson.

Senator KENNEDY. Prior to the time that she developed symptoms?

Mr. CASTRO. Yes, sir.

Senator KENNEDY. Do you want to just review that briefly? Was she getting a series of injections during this time?

Mr. CASTRO. Yes; she was. From March through October 1972, she was undergoing a series of injections of 10 cc's each. I believe that worked out to about 6 grams. It was initially prescribed as a preventive treatment for cancer. He additionally was prescribing some vitamin therapy. At that time the injections were $20 each, plus $20 for the Laetrile tablets.

Senator KENNEDY. What was the total amount during this period of time?

Mr. CASTRO. I do not have the exact dollar figure. She was receiving Laetrile injections on a daily basis almost, for $20 each. Subsequently, the price went up to $25 each.

In November of 1972 she was still receiving them.

Senator KENNEDY. Then I understand they increased to 30 cc's, at a cost of $70 per injection?

Mr. CASTRO. That is right. It was his unlicensed personnel, at times, that were in fact giving injections.

Senator KENNEDY. During this period she was getting frequent injections?

Mr. CASTRO. Yes.

Senator KENNEDY. As the treatment?

Mr. CASTRO. Yes; as the treatment of choice, it was Laetrile.

Senator KENNEDY. Do you want to briefly describe the *Hansen* case? Just briefly.

Mr. CASTRO. I will let Dr. Cosentino do that.

Dr. COSENTINO. Ela Hansen was a case that came to Dr. Richardson with vaginal bleeding. This occurred in 1974. She had had vaginal bleeding since December 1973. She so advised Dr. Richardson.

In March 1975, Dr. Richardson told Mrs. Hansen that he could find nothing wrong with her, and he had done all he could to treat her.

In June 1975, she was admitted to Saint Helena Hospital, and at this time diagnosed by the attending physician at Saint Helena Hospital, as having chronic diarrhea, which possibly might be due to antibiotics.

She did have a past—or her history of dysentery, or possibly a tumor. Her vaginal bleeding, uterine bleeding, was suggestive of uterine cancer. The patient was anemic. A biopsy confirmed she did have adenocarcinoma, which is a common form of cancer of the uterus—lining of the uterus.

Senator KENNEDY. Is that a treatable disease?

Dr. COSENTINO. Yes; it is one of the more treatable cancers. Mrs. Hansen advised the unlicensed persons—well, Jenkins is an RN, and Bowman is an unlicensed person—of her condition. They recommended increased dosage of Laetrile.

In August, 1975, this lady was readmitted to Saint Helena Sanitorium. At this point she had swelling of her abdomen and lower extremities. She was suffering moderate to severe pain.

At this time it was quite evident she had metastatic carcinoma. It was felt by the consultants that reviewed this case that the vaginal bleeding is quite indicative of, or can be indicative of malignancy until proven otherwise.

There are usual and conventional methods of diagnosis, and conventional treatment does produce a rather high percentage of cure.

Using a pap smear might not make a diagnosis of uterine cancer, of the lining of the uterus, but a curettement would be a positive way of making this diagnosis. It was felt that this was an extreme departure from the standard of practice of medicine, and the management of this case was deemed to be grossly negligent.

Senator KENNEDY. Jenkins and Bowman were in the same clinic with Dr. Richardson, is that right?

Mr. CASTRO. Yes; that's correct.

Senator KENNEDY. And they——

Mr. CASTRO. Mr. Bowman, I think was described as an office manager; served in that capacity.

Senator KENNEDY. And after this biopsy confirmed the carcinoma, as I understand, both Jenkins and Bowman advised increased dosages of Laetrile. Is that correct?

Mr. CASTRO. That's correct. Regrettably, both of these patients, Hansen and Schneck, initially rejected conventional treatment. In talking, for example, to Mr. Schneck, this unfortunate choice occurs from the faith that you have in your physician, as they did in Dr. Richardson. And it was only when it was too late that they finally resorted to conventional therapy, which was mostly palliative at that point.

Senator KENNEDY. OK.

Well, there are seven other cases—and we're not going to take the time, but they'll be made a part of the record.

[The information referred to follows:]

BEFORE THE BOARD OF MEDICAL QUALITY ASSURANCE
DIVISION OF MEDICAL QUALITY
FOR THE STATE OF CALIFORNIA

In the Matter of the Accusation against JOHN A. RICHARDSON, M. D. 514 Kains Avenue Albany, California License No. G-2848 Respondent.	No. D-1605 N 6369

DECISION

The attached Proposed Decision of the Administrative Law Judge is hereby adopted by the Board of Medical Quality Assurance for the State of California as its Decision in the above-entitled matter.

IT IS SO ORDERED October 28, 1976.

This Decision shall become effective on November 29, 1976.

Blanche C. Bersch

Blanche C. Bersch, Secretary-Treasurer
Division of Medical Quality

BEFORE THE BOARD OF MEDICAL QUALITY ASSURANCE

FOR THE STATE OF CALIFORNIA

In the Matter of the Accusation against JOHN A. RICHARDSON, M. D. 514 Kains Avenue Albany, California License No. G-2848 Respondent.	No. D-1605 N 6369

PROPOSED DECISION

This matter was heard before Stewart A. Judson, Administrative Law Judge, State of California, Office of Administrative Hearings on August 3, 4, 5, 6, 9, 10 and 11, 1976 in San Francisco, California.

The Board of Medical Quality Assurance of the State of California was represented by Louis C. Castro, Deputy Attorney General.

John A. Richardson, M. D., although duly served with copies of the Accusation, First Amended Accusation, Statement to Respondent including Discovery Rights, form Notice of Defense and a Notice of Hearing, and although having duly filed a Notice of Defense signed by his counsel requesting a hearing, was not present or otherwise represented. On the morning of August 3, 1976, prior to the commencement of the proceeding, a written communication bearing the name of John A. Richardson, M. D. was received containing a request for a continuance for the reasons stated therein.

No documents in support of said request were received. Said request was denied for lack of good cause shown pursuant to Section 11524 of the California Government Code, and the matter proceeded as a default pursuant to Section 11520 of said Code.

Accordingly, the following decision is herewith proposed, certified and recommended for adoption:

FINDINGS OF FACT

I

Raymond Reid is the Executive Secretary of the California Board of Medical Quality Assurance and made the Accusation and First Amended Accusation in his official capacity and not otherwise.

II

On August 12, 1954, the California Board of Medical Examiners (predecessor to the Board of Medical Quality Assurance) issued to John A. Richardson, M. D. (hereinafter respondent) physician's and surgeon's certificate No. G-2848. Said certificate is and has been at all times mentioned herein in full force and effect.

III

Respondent did possess and furnish, either personally or through his agents, Laetrile (also known as Amygdalin or Vitamin B-17) for the prevention, arrest, treatment, alleviation or cure of cancer to the following patients on the below described dates:

a) Charles Little - May, 1972.

b) Helen D. Schneck - From March, 1972 to February, 1973.

c) Daryl Figueroa, also known as John William Davis - March and April, 1974.

d) Harry Matchler - March, 1975.

e) Kapitan P. Zema - From December, 1974 to June, 1975.

f) Ela M. Hansen - From October, 1973 to January, 1974.

g) Poul H. Olsen - From October, 1973 to January, 1974.

h) Dorothy Jane Soroka - From January, 1976 to April, 1976.

i) Margaret Baldock - January, 1976.

A brief history of each of said patients is set forth in Appendix A, attached hereto and incorporated herein by this reference.

IV

a) Respondent aided and abetted the unlicensed practice of medicine by permitting unauthorized persons, to wit: Angela Jenkin, Steve Richardson or Ralph Bowman, to treat and care for the following patients:

1. Daryl Figuera
2. Harry Matchler
3. Kapitan P. Zema
4. Ela M. Hansen
5. Helen D. Schneck
6. Poul H. Olsen
7. Margaret Baldock

Respondent also permitted an unlicensed person, to wit: Ernest T. Krebs, Jr., to examine Helen D. Schneck. Angela Jenkin is a registered nurse duly licensed as such by the California Board of

Registered Nurses. Neither Steve Richardson nor Ralph Bowman possess licenses issued by the Board of Medical Quality Assurance, the Board of Vocational Nurse Examiners or the Board of Registered Nurses.

b) Each of said aforenoted patients, and including Dorothy Jane Soroka, were prescribed, dispensed or furnished dangerous drugs (within the meaning of Section 4211 of the California Business and Professions Code) including, but not limited to Laetrile and Pangamic Acid, by respondent, without a good faith examination and medical indication therefor.

V

The conventional and medically accepted modalities in the treatment of cancer are excission of the tumor or mass, radiation therapy, chemotherapy and use of hormones, separately or in combination with each other. Vitamin Therapy is often prescribed in conjunction with the aforenoted modalities.

VI

Respondent utilized Laetrile and Pangamic Acid as therapeutic agents in the treatment of cancer. Laetrile and Pangamic Acid are not recognized vitamins in human nutrition. Laetrile has no known nutritional value and is unsafe for self-medication in that it contains a toxic substance, to wit: cyanide, whose fate in the human body is not completely known. Neither Laetrile nor Pangamic Acid have therapeutic validity in the treatment of cancer.

Those patients described in Finding III (a) through (i) hereinabove received no more than placebo therapy.

VII

Respondent, personally and his agents, advised and discouraged Helen D. Schneck, Kapitan P. Zema, Poul Olsen and Margaret Baldock from seeking conventional cancer therapy.

VIII

The standard of practice of medicine in the treatment of cancer includes the use of the conventional modalities described in Finding V hereinabove. The management of cancer patients with Laetrile, Pangamic Acid and vitamins, as prescribed by respondent, as the sole treatment of choice by the physician, to the exclusion of the aforenoted conventional modalities is an extreme departure from the standard of practice of medicine.

IX

With respect to those patients described in Findings III (b), (e) and (h) hereinabove, treatment with Laetrile and other substances, including Pangamic Acid, was initiated by respondent and his agents prior to a diagnosis by respondent that said patients were, in fact, suffering from cancer. Said treatment was based primarily upon said patients' own personal history. It is true that respondent and his agents obtained blood for tests, urine specimens for analysis and hair samples for mineral analysis. However, treatment, as noted above, was commenced prior to the results of said tests and analyses and at a time when respondent was not

privy to prior medical records reflecting such diagnosis. Hair analysis is not recognized as being within the standard of practice of medicine to determine vitamin or mineral deficiencies. The standard of practice of medicine requires that a diagnosis be made that cancer is, in fact, present, prior to treatment for same. Respondent's treatment of said patients, in this regard, was an extreme departure from the standard of practice of medicine.

X

Those patients described in Finding III (a) through (i) hereinabove had advised respondent and his agents that they believed they suffered from cancer. Although respondent and his agents described, on occasion, respondent's treatment as nutritional or metabolic therapy, said patients were also advised by respondent and his agents that respondent's treatment would arrest, palliate and prevent cancer. Respondent promoted the use of Laetrile as a cure for cancer through literature available for distribution in his office.

XI

Amygdalin, in connection with the treatment of cancer as a preventative or cure, is a "new drug" within the meaning of 21 USC 321(p), and there is not on file, nor has there been on file, an approved new drug application permitting the distribution in interstate commerce of Amygdalin for administration into the human body. There is not on file with the United States Food and Drug Administration an acceptable Notice of Claimed Investigational Exemption for a New Drug permitting the investigational use of

96-492 O - 77 - 14

Amygdalin nor has there ever been on file with said agency a claimed investigational exemption identifying respondent as an investigator or sponsor engaged in the investigational use of Amygdalin.

XII

a) On or about January 30, 1975, respondent did ship Amygdalin in interstate commerce from Albany, California via United Parcel Service. Said drug was contained in a box consigned to "Betty Mulkey, H & S Drug, Post Falls, Idaho 83854" with return address indicated as "510 Kains Ave., Albany, California 94706".

b) On or about January 30, 1975, respondent did ship Amygdalin in interstate commerce from Albany, California via United Parcel Service. Said drug was contained in a box consigned to "Dr. J. G. Bermeialer, Route 1-Box 220, Hortonville, Wisconsin 54944" with return address indicated as "510 Kains Ave., Albany, California 94706".

c) On or about January 30, 1975, respondent did ship Amygdalin in interstate commerce from Albany, California via United Parcel Service. Said drug was contained in a box consigned to "Audrey Muelter, Box 71, Rockville, Minnesota 56369" with return address indicated as "510 Kains Ave., Albany, California 94706".

d) On or about February 4, 1975, respondent did ship Amygdalin in interstate commerce from Albany, California via United Parcel Service. Said drug was contained in a box consigned to Dr. Eleazer Coverton, 2105 Warrier Road, Five Points, West Birmingham,

Alabama 35211" with return address indicated as "510 Kains Ave., Albany, California 94706".

e) On or about February 5, 1975, respondent did ship Amygdalin in interstate commerce from Albany, California via United Parcel Service. Said drug was contained in a box consigned to "Dwight Morgan, Route 3-Box 3625, Roseburg, Oregon 97470" with return address indicated as "510 Kains Ave., Albany, California 94706".

In each of the aforenoted instances, respondent's individual United Parcel Service Account number appeared on each of said parcels. It was not established that respondent shipped Pangamic Acid (also known as Pro-Vitamin 15 or Pangemeten) in interstate commerce.

DETERMINATION OF ISSUES

I

Laetrile and Pangamic Acid are dangerous drugs pursuant to Section 4211 of the California Business and Professions Code.

II

Findings III, IV(b), XII: Respondent, in each instance, violated Sections 26650 (Possession of Misbranded Drugs), 26619 (Possession of Adulterated Drug) and 26621 (Receipt or Delivery of Adulterated Drug in Commerce) of the California Health and Safety Code, and cause for disciplinary action thereby exists, in each instance, separately and severally, pursuant to Section 2391.5 in conjunction with Sections 2361, 2351(e) and 2372 of the California Business and Professions Code.

III

Findings III, IV(b), X: Respondent has violated in each instance Sections 10400.1(c) and (d), Title 17, California Administrative Code ("Laetriles" for Treatment of Cancer) in conjunction with Section 1709 of the California Health and Safety Code, and cause for disciplinary action thereby exists, in each instance, separately and severally, pursuant to Section 2378.5 in conjunction with Sections 2361 and 2372 of the California Business and Professions Code.

IV

Findings III, IV(b), X: Respondent has violated in each instance Section 1707.1 of the California Health and Safety Code (Unlawful Sale of Drugs...for Alleviation of Cancer), and cause for disciplinary action thereby exists, in each instance, separately and severally, pursuant to Section 2378.5 in conjunction with Sections 2361 and 2372 of the California Business and Professions Code.

V

Finding IV(a): Cause for disciplinary action exists in each instance, separately and severally, pursuant to Section 2392 (Employment of or Aiding or Abetting the Unlicensed Practice of Medicine) in conjunction with Sections 2361, 2361(a), 2361(e) and 2372 of the California Business and Professions Code.

VI

Finding IV(b): Cause for disciplinary action exists,

in each instance, separately and severally, pursuant to Section 2399.5 (Prescribing Dangerous Drug Without Good Faith Prior Examination) in conjunction with Sections 2361, 2361(e) and 2372 of the California Business and Professions Code.

VII

Findings XI, XII: Respondent violated, in each instance, 21 USC 355(a) and 21 CFR 312.1, and cause for disciplinary action thereby exists, in each instance, reparately and severally, pursuant to Section 2391 in conjunction with Sections 2361, 2361(e) and 2372 of the California Business and Professions Code.

VIII

Findings VII, VIII: Gross negligence was established in each instance, and cause for disciplinary action thereby exists, in each instance, separately and severally, pursuant to Section 2361(b) in conjunction with Section 2372 of the California Business and Professions Code.

IX

Findings III(b), (e), (h) in conjunction with Finding IX: Gross negligence was established in each instance, and cause for disciplinary action was established in each instance, separately and severally, pursuant to Section 2361(b) in conjunction with Section 2372 of the California Business and Professions Code.

X

Findings III(b), (e), (h); Cause for disciplinary action

was not established in each instance, pursuant to Section 2361(c) in conjunction with Section 2372 of the California Business and Professions Code.

ORDER

Certificate No. G-2840 of John A. Richardson, M. D., respondent above-named, is revoked pursuant to Determinations I through IX inclusive hereinabove, separately, severally and jointly.

DATED: September 7, 1976

STEWART A. JUDSON
Administrative Law Judge

APPENDIX A

A. Charles Little

1. On May 19, 1972, Little visited respondent's office at the request of an undercover investigator of the California Department of Consumer Affairs. Little suffered from Hodgkins disease and, upon his arrival, completed a personal history form indicating said condition as his chief complaint. Little's blood pressure and temperature were taken by respondent, who also physically examined Little for lumps. Little advised respondent that he had been undergoing radiation treatments for his condition.

2. Respondent thereafter explained the nature of Laetrile and its action in the body. Respondent also explained the "trophoblastic" theory of carcinogens and the role therein of the pancreas and the enzyme rhodanese. Respondent stated that cobalt treatment has no effect upon the underlying cause of cancer and that Laetrile attacks the tumor by releasing cyanide.

3. After permitting Little to peruse various articles concerning Laetrile and its effect on cancer, respondent advised that cobalt treatment and surgery for cancer were unnecessary and that Laetrile is a treatment which, if administered in sufficient quantities, will cure cancer. Respondent also stated that cobalt treatment destroys healthy tissue while Laetrile attacks the problem.

4. On said date, Little received, among other pills, Laetrile tablets and paid respondent a total of $55.00 for said pills and consultation. Additional vitamins prescribed by respondent were

purchased by Little at a pharmacy at a cost of $24.80. Little did not undertake said treatment nor did he return to respondent's office.

B. Helen D. Schneck

1. From March through October, 1972, Schneck underwent a series of Laetrile injections of 10cc each prescribed by respondent as a preventative treatment for cancer. In addition, respondent prescribed vitamin therapy including various enzymes, Pangamic Acid and Laetrile tablets. The cost of said injections was $20.00 each plus $20.00 for said Laetrile tablets and an additional amount for said vitamins.

2. In November, 1972, Schneck developed a small lump on her neck. Respondent advised that Laetrile injections would cause said lump to disappear and prescribed a series of 15 such injections at a cost of $25.00 each. By December, 1972, Schneck had developed a rash with bumps on her left shoulder. In January, 1973, said rash extended to her left breast. Respondent advised that Schneck undergo a biopsy at Albany Hospital. On January 23, 1973, adenocarcinoma was diagnosed by her attending physician (not respondent). Respondent had administered approximately sixteen injections of Laetrile during Schneck's hospital stay. Although her attending physician recommended conventional therapy, Schneck opted to continue with respondent, who recommended tripling the injection dosage of Laetrile to 30cc, at a cost of $70.00 per injection, to control the cancer. Said injections were administered by respondent and his agents, including one Ralph Bowman.

3. By February, 1973, said rash and swelling had spread. Respondent made an appointment for Schneck with one Ernest Krebs, Jr.,

a biochemist located in San Francisco, California, who examined Schneck and advised that she did not have cancer but rather a serious skin infection. Respondent thereafter treated Schneck with anti-biotics and administered injections of 10cc of Laetrile. On February 14, 1973, with no demonstrable improvement in Schneck's condition, and upon being advised by Schneck that she had, years before, eaten raw meat, respondent diagnosed her condition as trichinosis. Respondent continued to administer Laetrile.

4. On February 24, 1973, Schneck was unable to leave her bed. A physician, called by her husband, ordered her immediate admission to Marin General Hospital. Schneck was diagnosed as having inflammatory cancer in the left breast ranging from her collar bone to jaw, and an enlarged liver, presumably cancerous. The primary site was inflammatory carcinoma of the breast. Schneck thereafter underwent radiation therapy and chemotherapy which, as a result of her advanced stage of cancer, was for palliative purposes only. Some relief from pain was noted. Schneck died on October 4, 1973 from her condition.

5. At no time during his management of Schneck did respondent recommend any of the conventional modalities in the treatment of cancer. Respondent, in fact, discouraged Schneck from undergoing said treatment.

C. Daryl Figueroa, also known as John William Davis

1. On March 15, 1974, Figueroa, in the capacity of an undercover investigator for the California Department of Consumer Affairs, called respondent's office for an appointment, indicating to the receptionist that he had cancer. Figueroa did not, in fact, have cancer. On March 18, 1974, Figueroa appeared at respondent's office and, after completing a personal history form indicating that he had cancer, was told by Angela Jenkin that Laetrile would prevent the cancer from spreading and was more effective than surgery, radiation or chemotherapy. Figueroa was administered an injection of Laetrile by Angela Jenkin, who thereafter advised him to undergo treatment consisting of a thirteen week series of Laetrile injections, six days per week, six grams per day, to be followed by a rectal infusion program, at a total cost of $2,000.00. Jenkin stated that Laetrile would kill the cancer cells in his body.

2. On March 19, 1974, Figueroa returned and was advised by an employee that, in lieu of Laetrile injections, Figueroa could take two pills of Laetrile daily at a cost of $1.00 per pill.

3. On March 28, 1974, Figueroa returned and was advised by Jenkin to self-administer rectal infusions of Laetrile at $12.50 per vial and thereby reduce the cost of treatment. Jenkin discouraged Figueroa from undergoing chemotherapy and stated that cancer is a vitamin deficiency disease whose growth would be prevented by Laetrile. Jenkin further explained the unitarian trophoblastic theory of cancer and gave Figueroa a brochure entitled "The Laetriles-Nitrilosides In the Prevention and Control of Cancer".

Jenkin further told Figueroa that his hematology report indicated the presence of a malignancy and sold Figueroa some additional Laetrile tablets at $1.25 each.

4. On April 3, 1974, Figueroa returned to respondent's office. Ralph Bowman discouraged Figueroa from seeking conventional cancer therapy and described the trophoblastic theory of cancer and the use of the rectal infusion apparatus. At said time, Figueroa was sold two vials of Laetrile by Jenkin and Bowman. Figueroa did not return thereafter.

D. Harry C. Matchler

1. On March 13, 1975, Matchler visited respondent's office. A personal history form was completed at said time by Matchler's daughter. Respondent then saw Angela Jenkin, who was told that Matchler had cancer of the throat. Jenkin then discussed Laetrile and how it cures cancer by building up one's body. A hair sample was taken for vitamin analysis and a urine specimen was obtained.

2. Jenkin administered an injection of Laetrile and advised Matchler to undergo daily Laetrile treatments. Additional substances, including Laetrile tablets, Pangamic Acid and vitamins, were provided Matchler at a cost of $218.50. Matchler was advised that the entire course of treatment would cost $2,000.00. At no time did Matchler see or speak with respondent.

3. On April 9, 1975, Matchler returned to respondent's office at the request of the California Department of Consumer Affairs and spoke with respondent. Said conversation was monitored by investigators for said Department. Respondent discussed cancer and stated that Matchler's prior cobalt treatment had "messed up" Matchler. Respondent then prescribed Pantothenic Acid. Matchler did not return thereafter.

4. Matchler underwent a total laryngectomy on September 22, 1975.

E. Kapitan P. Zema

1. In October, 1974, X-rays revealed a lesion in Zema's chest. Zema rejected surgery and visited respondent's office on December 19, 1974, where he completed a personal history form. Zema then met Ralph Bowman, who discussed Zema's condition, possible surgery and respondent's treatment. Bowman discouraged surgery, recommended Laetrile injections six days per week and explained the trophoblastic theory of cancer. Bowman stated that respondent's treatment would resolve Zema's problem. During the course of said treatment, Zema received Laetrile injections from Bowman, Jenkin and Steve Richardson, respondent's son.

2. In May, 1975, Zema began coughing up blood. In March, 1975, Zema's throat was X-rayed by another physician. Zema exhibited said X-rays, with the original X-rays, to respondent, who indicated that no change had occurred. Respondent recommended that Zema receive Laetrile injections for the remainder of his life, on a reduced basis. In truth, said latter X-rays revealed that Zema's aforenoted lesion had grown to three centimeters in size from two and one-half centimeters. Zema continued to cough up blood.

3. On June 6, 1975, a sputum sample taken by said other physician indicated a malignancy. This was the first histology in Zema's case. Zema was no longer considered operable, and radiotherapy was recommended by a radiation oncologist. The standard of practice of medicine requires a histology prior to treatment. Respondent's treatment of Zema without a histology is an extreme departure from the standard of practice of medicine.

4. Following initial radiation therapy, prognosis was poor due to Zema's long-standing carcinoma, its extent and size. In December, 1975, a brain scan revealed metatastic spread to the brain. In February, 1976, a brain scan indicated decreased activity with the right portion of the medial occipital area affected. Radiation therapy to the brain was completed in January, 1976. Treatment is primarily palliative.

F. Ela Hansen

1. Hansen first began receiving Laetrile treatment from respondent in 1974. Hansen had been experiencing vaginal bleeding since December, 1973 and so advised respondent. In March, 1975, respondent advised Hansen that he could find nothing wrong with her and that he had done all he could to treat her. In June, 1975, Hansen was admitted to St. Helena Hospital and was diagnosed by the attending physician as having chronic diarrhea, possibly due to anti-biotics, a tumor or her past history of amoebic dysentery. Her bleeding from her uterus was suggestive of uterin cancer. She was anemic. A biopsy confirmed adenocarcinoma of the uterus. Upon discharge, Hansen opted to continue her Laetrile treatments with respondent.

2. Hansen advised Jenkin and Bowman of her condition, and both recommended increased dosages of Laetrile. Bowman, on one occasion, contacted a pharmacy to prescribe an anti-biotic for Hansen. From January, 1975 to August, 1975, Hansen's expenses for respondent's treatment amounted to $1,955.50.

3. In August, 1975, Hansen was readmitted to St. Helena Hospital. Her abdomen and lower extremities were swollen, and she was suffering moderate to severe pain. Metatastic carcinoma to the abdominal cavity and liver was diagnosed. Hansen was discharged at her own request and died on October 14, 1975 from advanced cancer.

4. Vaginal bleeding is indicative of a malignancy until proven

otherwise. The standard of practice of medicine requires a physician to biopsy the lining of the uterus, notwithstanding the results of a pap smear test which can be given little clinical weight in determining the cause of vaginal bleeding. Respondent's care of Hansen in 1974, following her vaginal bleeding, is an extreme departure from the standard of practice of medicine. When properly diagnosed and treated, patients suffering from uterin cancer can experience a 60 to 80 per cent success rate with five years survival.

96-492 O - 77 - 15

C. Poul Olsen

1. Olsen was first diagnosed as suffering from terminal lung cancer on April 1, 1973 at Sequoia Hospital. Prognosis was approximately eight months. Olsen visited respondent's office on October 16, 1973 after advising respondent's receptionist that he had cancer. Olsen received various pamphlets from respondent's office pertaining to Laetrile and cancer therapy. Olsen completed a personal history form and saw Ralph Bowman, who advised that an extra charge would be made to see respondent. Bowman stated that Olsen's prior medical records were not needed and that Laetrile would prevent the cancer from growing.

2. Olsen received an injection of Laetrile from Bowman and a variety of vitamins, including Pangamic Acid, at a total cost of $119.00. Olsen received daily injections of Laetrile from Bowman and Angela Jenkin until December 12, 1973 at a cost of $50.00 per day plus a $3.00 tip on Saturdays for the nurses.

3. Olsen's condition deteriorated, and he was readmitted to Sequoia Hospital in December, 1973. Olsen died on January 31, 1974 from cancer of the lung.

H. Dorothy Jane Soroka

1. Soroka was advised to undergo a biopsy of a mass located in her left breast in September, 1975. Declining to do so, Soroka visited respondent's office in December, 1975 after receiving literature from respondent pertaining to metabolic therapy. Respondent examined Siroka, who had previously mailed in a completed personal history form. Respondent described his metabolic, or nutritional, therapy as being designed to improve her general health. As a result of said consultation and the aforenoted literature, Siroka understood that Laetrile would attack and destroy cancer cells.

2. Soroka agreed to undergo Laetrile treatment and began receiving injections of Laetrile on January 7, 1976. Soroka's father agreed to pay no more than $2,000.00 for said treatment, which sum was expended by February 20, 1976. During said treatment, injections of Laetrile were administered to Soroka, at times, by Steve Richardson, respondent's son. Soroka continued receiving said treatment until April, 1976.

3. In April, 1976, Soroka was examined by an oncologist who observed that she was pale and had an exoplytic mass in the upper left quadrant of her left breast which was draining and odiferous. Her entire chest was hard as though protected by a Roman breastplate. At said time, Soroka rejected conventional cancer therapy.

4. In June, 1976, Soroka was hospitalized due to fluid filling

her lungs. She was in acute respiratory stress, and a thoracentesis was performed. A cytology revealed adenocarcinoma, with the left breast as the probable primary site. The aforenoted oncologist was permitted to start chemotherapy and radiation therapy which has palliated her condition. Prognosis is poor.

5. The standard of practice of medicine requires that a diagnosis be made prior to the treatment of a patient. Respondent's treatment of Soroka prior to making a diagnosis was an extreme departure from the standard of practice of medicine.

I. Margaret Baldock

1. Baldock was diagnosed in October, 1974, by her physician, as having adenocarcinoma of the colon and rectum. She underwent a colostomy, has had thirty-two cobalt treatments and has undergone chemotherapy on three occasions.

2. On January 23, 1976, Baldock visited respondent's office and completed a personal history form. Prior to this, Baldock had explained, by telephone, about her cobalt treatments and chemotherapy and had received, by mail, from respondent's office, various literature pertaining to the use of Laetrile and cancer therapy. Baldock saw Angela Jenkin, who was in possession of some medical records pertaining to Baldock's colostomy.

3. Jenkin advised Baldock that respondent would not see her until after her twentieth visit. Jenkin also described various successes in treating cancer and Hodgkins disease by use of Laetrile. A urine specimen was obtained from Baldock, who was then administered an injection of Laetrile by Jenkin.

4. Upon departing, Baldock received a package of vitamins and Laetrile tablets and was billed a total of $236.50. In addition, Baldock was told to purchase some enzymes at a pharmacy for $85.00. Baldock was advised by Jenkin to receive two injections of Laetrile for twenty days at a cost of $5.00 per day. Baldock never saw or spoke with respondent and did not return thereafter to respondent's office.

Senator KENNEDY. Is there any question in either of your minds that the medical behavior of Dr. Richardson could only be described as gross negligence?

Mr. CASTRO. No doubt.

Dr. COSENTINO. I agree.

Senator KENNEDY. Mrs. Hehmeyer, you prosecuted Ernest Krebs, is that correct?

Mrs. HEHMEYER. That's correct.

Senator KENNEDY. Why did you do that?

Mrs. HEHMEYER. Initially, in 1971, we prosecuted him because he was practicing medicine without a license, and because he was violating the California Cancer Act by recommending Laetrile in a prescribing situation as a treatment or palliative for cancer. He eventually pleaded out to the violation of the Cancer Act, nolo contendere.

Senator KENNEDY. Could you describe the Zema case to us?

Mrs. HEHMEYER. All right. Later in 1976—he was given probation—in 1976 we moved to revoke his probation—in large part because a woman came to us named Mrs. Zema. Mrs. Zema was an elderly—a very nice, elderly Russian woman whose husband, Kapiton, had a very small dot of lung cancer that was diagnosed by an onocologist in the Davis area, in October, I think, of 1975. The doctor told him that this was a very treatable condition with a 90 to 95 percent chance of complete recovery with surgery.

The Zemas—who I might point out, spoke very poor English, because they were from Russia—were very frightened at the thought of surgery. Unfortunately for them, about that time, on "60 Minutes," there was a program on Laetrile—Mike Wallace's 60 Minutes—and the Zemas saw it. After they saw that show, they purchased Mr. Culbert's [sic] book, World Without Cancer, and read it, and became convinced that the answer was Laetrile.

They looked up Mr. Krebs in the San Francisco telephone book, where he is listed as Dr. E. T. Krebs. They called him. He diagnosed the case over the telephone.

Senator KENNEDY. Is that a usual procedure?

Mrs. HEHMEYER. No; especially not for a nondoctor. In fact, especially for somebody who just has a general LLB, and nothing else himself, academically, it's not usual.

He diagnosed it over the telephone, told the woman, "your husband has an excellent chance of survival if only you get him to Laetrile." He recommended three doctors, and one of them was Richardson.

She went to Richardson because he was the closest of the three. The other was Jones down in south San Francisco, and the other one was Contraras down in Mexico.

They went to Richardson for treatment. However, throughout the treatment with Dr. Richardson, the Zemas kept consulting with Mr. Krebs. She always called him Dr. Krebs, and she testified she thought he was a medical doctor. Of course he did nothing to alleviate her of that misinformation.

She kept calling Mr. Krebs as the progress of her husband's disease became worse. She became a little more concerned. Mr. Krebs gave the line that they always give you: "the lump or bump always gets larger with Laetrile treatment, ma'am. But the cancer's gone. It's just the lump or bump that's getting larger. Don't worry. If someone were

to take that lump out of your husband's lung and biopsy it, there would be no cancer there." That's what he told her over the telephone. And she trusted him.

Senator KENNEDY. That's what she told you?

Mrs. HEHMEYER. That's what she testified, and you have the transcript of her testimony here.

Finally, when her husband began spitting up blood, they took him in for X-rays, and the cancer had metastasized, or as I would describe it in lay terms—colonized—spread—all over his body, including his brain.

At that point, she called Mr. Krebs, and she was desperate, she was hysterical. He got furious at her. He said: "You mean you went for X-rays? That's self-treatment? You didn't trust Laetrile. The X-rays are what's going to kill your husband. It has nothing to do with Laetrile." And hung up on her.

This is your humanitarian.

Mr. Kapiton Zema is dead, and I firmly believe he would have lived had he received conventional treatment through conventional medicine.

I might add, if I may, that at the end of the hearing—during which Mrs. Zema, of course, was crying—we had to adjourn for her—she clung to my arm, and she looked up at me, and she said, "Mrs. Hehmeyer, you're the government. You know—you know these things. Why didn't you help us? Why didn't you do something? Why didn't the government tell me?"

I would submit to you that a lot of these people out there are going to trust the decisions that their governmental officials make, and rely on them very heavily. They expect a lot from us.

Senator KENNEDY. Did Mr. Krebs make any money from his involvement in Laetrile?

Mrs. HEHMEYER. When we issued the search warrant back in, I think, 1971—I can't remember the exact date; it's in your records—I had the investigators total up what financial records they could get at the 642 Capp Street location, where they had their little mail-order business with Laetrile, and they totaled up a quarter of a million dollars in mail-order business. I believe the period of time was about 18 months. I may be mistaken; it may have been less time.

That was just from that one little business. He had quite a practice of medicine going.

Senator KENNEDY. How much? I'm sorry, I missed it.

Mrs. HEHMEYER. Quarter of a million dollars. The—at the hearing we established about $300,000 worth of B–15 activity; that's another nutritional supplement that Mr. Krebs was involved in very recently. That was a 3-month period.

Money was found in his home—cash in excess of $10,000—during probationary searches.

Senator KENNEDY. I think a point is made with regards to this whole issue in terms of the availability of Laetrile that there's this great conspiracy: of the Federal Government, of Congress, cancer research, the medical professions, lawyers, not only in this country, it's around the world, trying to deny people a legitimate cure in terms of cancer.

Now, in reviewing the record of various town meetings and rallies that are held—and maybe Mrs. Hehmeyer could comment here—what's said out in the field in the townhalls and public meeting places about this particular substance versus what's said in terms of the coolness of testimony. And maybe you'd just elaborate on that.

Mrs. HEHMEYER. Yes. We had the advantage at this hearing of having Mr. Krebs on tape, because his speeches are commercially available. So we had tape recordings of some of his speeches.

Of course, he speaks extensively, and I want to affirm—to stress the fact that he's introduced as an eminent scientist, a sage, a brilliant doctor, the persecuted Linus Pauling or whatever—Louis Pasteur, I think, is the word they use.

He speaks constantly and tells the audience—this is with no equivocation whatsoever—that "Laetrile is to cancer as vitamin C is to scurvy, as niacin is to pellagra, as vitamin D is to rickets"——

Senator KENNEDY. Let me just stop you. Vitamin C to scurvy, obviously, is a key.

Mrs. HEHMEYER. It's a cure.

Senator KENNEDY. It's a cure.

Mrs. HEHMEYER. It's a cure. It's not just a treatment. It's a cure.

Senator KENNEDY. All right. So your comments in this is that at least from your investigations—or from these statements—that they are suggesting that this is actually the cure for cancer in these areas.

Mrs. HEHMEYER. I think that is what they're telling the audiences. I don't think there's anything very subtle about it. You have a transcript of some of those tapes here.

I also would like to point out, if I may, that they recommend oral doses in these speeches. And he goes on and on about the amount you should take orally, daily, as a preventative.

Senator KENNEDY. We'll include in the record the appropriate references that indicate that.

Just finally, how does this panel react to the suggestion that this is all a conspiracy to try and deny the American public a cure of cancer?

Why do you think that there are so many people that may actually believe that? Why do we find that the people are using it, and using it in the cases that you've commented on, to the exclusion of other treatment, with the resultant failure, in at least one case that was mentioned here, of death?

Dr. COSENTINO. I can only respond, Senator, as a physician, from the moral issue. In reviewing this specific case, Laetrile treatment itself, if the individual physician feels that this is a treatment, might possibly be some sort of an answer for that specific physician. But when the physician doesn't utilize adequate methods of diagnosis in order to make a positive diagnosis microscopically, or at least a stage disease in this complicated thing that we call cancer, then I think it's correct and right to revoke a license.

Senator KENNEDY. What do you think, Mrs. Hehmeyer? Why has it gone as far as it's gone?

Mrs. HEHMEYER. I think there are several reasons.

With respect to the victims I've seen, which go beyond Mrs. Zema—in the original prosecution, we had victims, too—these people are told that this is the magic bullet, and we all believe in magic bullets these days. We believe in science having these miracles available to us.

They're told it's a magic bullet. You're not going to have to go through cutting, burning, and poisoning. This is the cure; this is the answer.

A lot of people turn to Laetrile because they want the total answer, because they're afraid of the adverse side effects of regular treatment.

Second, Laetrile has a very expensive, a very effective promotion. I think there's Mafia money behind it. At my hearing, Andrew McNaughton—and you have that transcript, too—stated in response to my question on that topic, "probably is, probably has been."

I think that the expensive promotion nationwide of these—these lectures, you must realize, aren't factual scientific lectures. They're almost messianic. People are screaming and shouting. They're desperate. And the Laetrile propagandists use their desperation, build them up to a furor over this. Very expensive promotion.

There isn't that kind of comeback, with refutations, from the doctors. The doctors aren't going out and talking to the people the way these proponents of Laetrile are.

And then, third, in our country I think that all of us—we aren't the type in the United States that necessarily kowtow to the establishment. I think people will believe that the establishment might be doing something that's not right for them; they're ready to accept that.

One thing, orthodox doctors don't make these fabulous promises to you. And so you have these wonderful humanitarians who say they are here to save your life and that they're devoting their lives to save you. Your own doctor is not going to do that for you. The most he's going to do is to tell you there's a 50-percent chance or you have a 90-percent chance to live. He's going to tell you all the horrible things that could happen to you.

The promises of Laetrile proponents are much more extravagant and very well promoted with extensive campaigns because, as we've all said before, there is money in Laetrile for a few people, and several of them are in the audience today.

Senator SCHWEIKER. Mrs. Hehmeyer, based on your experience, what people or groups would you list as involved in this promotional effort? Mr. Krebs, Dr. Richardson? Who else is behind this Laetrile campaign or is involved in promoting it?

Mrs. HEHMEYER. Bradford. I think Herb Hoffman could give you a better list than I could, because I've only been involved with Ernst Krebs. Andrew McNaughton, of course, I'm sure you all know, is the chief financier here, the money man. He's famous as that.

Mr. Krebs is really, as far as I can tell—he's less—one of the—financially—he's less benefited—maybe a couple hundred thousand dollars a year, but not much—than some of the others. And Mr. Krebs is important because of the fact that the proponents—he's the scientific sage behind the movement. That's his function in the movement. His academic record shows him to be far from a scientific sage.

Senator SCHWEIKER. The promotional effort, I take it, got a tremendous boost from Mike Wallace's show?

Mrs. HEHMEYER. I don't know. It certainly caused Mrs. Zema to decide to investigate. And I didn't see the show, but I understand it was a presentation of both sides. I asked Mrs. Zema why she was convinced to go to Laetrile, and it was because they were desperate.

Senator SCHWEIKER. Fine. Thank you very much.

Thank you, Mr. Chairman.

Senator KENNEDY. I want to move on to the final panel, but just before we do, I think the things which I find most troubling is that we have heard from those that have special responsibility in the science areas in both public and private research that there is no efficacy in the applications of this substance. Second, that a distinguished researcher, supported by other members of the panel, believe that the toxic substance can cause serious danger and harm, and believes that that will be the case, with increase of usage of this substance.

Now, we hear the testimony of this panel that indicates that in the applications of the utilization of this substance extraordinary amounts of resources and money are being accumulated. We hear about gross negligence in the application of medical—or failure of medical procedures or practices. We hear about the utilization of unlicensed physicians. We hear about the distortions and misrepresentations which are made in the emotional settings of town meetings or rallies.

It seems to me that, given this background, and given the fact, as I mentioned in my opening statement, that we're in a climate or atmosphere where I don't believe there is any disease which brings such enormous concern to the American people as the issue of cancer, and where this movement apparently practices, the deceitful misrepresentation in terms of what this can really mean in terms of the well-being of the American consumer, is at least the climate which we find ourselves in.

[The prepared statements of Dr. Cosentino and Mrs. Hehmeyer follow:]

STATE OF CALIFORNIA—AGRICULTURE AND SERVICES AGENCY EDMUND G. BROWN JR., Governor

DEPARTMENT OF Consumer Affairs

BOARD OF MEDICAL QUALITY ASSURANCE
1430 HOWE AVENUE, SACRAMENTO, CALIFORNIA 95825
ALLIED HEALTH PROFESSIONS (916) 322-5043
APPLICATIONS AND EXAMINATIONS (916) 322-5040
COMPLAINTS (916) 322-5030
DISCIPLINARY INFORMATION (916) 322-2341
FICTITIOUS NAMES AND CORPORATIONS (916) 322-5040
VERIFICATIONS OF LICENSES (916) 322-2831

A REVIEW OF THE CALIFORNIA BOARD OF MEDICAL QUALITY ASSURANCE ACCUSATION IN THE CASE OF JOHN A. RICHARDSON, M.D., RELATING TO HIS MANAGEMENT OF CANCER PATIENTS UTILIZING LAETRILE (AMYGDALIN OR VITAMIN B-17) AND PANGAMIC ACID (VITAMIN B-15)

PRESENTED BY:

JOSEPH P. COSENTINO, M.D.
CHIEF MEDICAL CONSULTANT

BOARD OF MEDICAL QUALITY ASSURANCE
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

My name is Joseph P. Cosentino, M.D., Chief Medical Consultant for the Board of Medical Quality Assurance of the Department of Consumer Affairs of the State of California.

I was the Acting Executive Director for the Board of Medical Quality Assurance during the period that the decision on JOHN A. RICHARDSON, M.D. was rendered and became effective.

Mr. Louis Castro, Deputy Attorney General of the Attorney General's Office of the Department of Justice of the State of California is present with me today. The Attorney General's Office serves as legal counsel for the Medical Board in disciplinary matters, and it was Mr. Castro who prosecuted Dr. Richardson on behalf of the Board. Any opinion or comment rendered by Mr. Castro reflect the opinions and comments of the Medical Board and should not be construed as opinions or comments which reflect the position of the Attorney General's Office of the Department of Justice.

I will summarize the pertinent findings of fact and determination of issues of the decision relating to Dr. Richardson's use of Laetrile on patients for the treatment of cancer. A copy of the decision has been made available tc the Subcommittee.

The California Board of Medical Quality Assurance filed charges against Dr. Richardson's medical license on April 23, 1975.

After seven days of hearing, a proposed decision was rendered by Administrative Law Judge Stewart A. Judson, which was adopted unanimously by the Board of Medical Quality Assurance, effective November 29, 1976. The decision ordered revocation of Dr. Richardson's license to practice medicine in California for violating various provisions of the State Medical Practice Act.

The respondent, Dr. Richardson, although served with the accusatory pleadings, did not appear or defend himself at the hearing.

The gravity of the decision deals with Dr. Richardson possessing and furnishing, either personally, or through his employees, Laetrile for the treatment of cancer in nine patients.

In treating these patients, it was additionally found that Dr. Richardson aided and abetted the unlicensed practice of medicine by permitting unlicensed employees to treat and care for his patients.

Each of the patients mentioned were prescribed, dispensed, or furnished dangerous drugs, including but not limited to Laetrile and Pangamic Acid, by Dr. Richardson without a good faith prior examination and medical indication.

Treatment with Laetrile and Pangamic Acid was initiated by Dr. Richardson and his employees prior to a diagnosis of cancer having been made. The treatment was primarily based on the patient's personal history.

Dr. Richardson did not avail himself, in all cases, of prior medical records reflecting the patient's medical history. No biopsy or microscopic evaluation was made on suspected tissue from any of the patients prior to the initiation of treatment. This was considered an extreme departure from the standard of the practice of medicine constituting gross negligence. It was also found that Dr. Richardson, or his employees, in many of the cases discouraged the patients from receiving conventional therapy.

In the course of the treatments, Dr. Richardson or his employees, would advise the patients that the treatment was nutritional or metabolic, but the patients were advised, as well, that the Laetrile treatments would arrest, palliate or prevent cancer.

The decision also described that Dr. Richardson shipped Laetrile from his office in Albany, California, to other states in violation of federal law.

The appendix to the decision outlines briefly the clinical history and management of the nine patients treated by Dr. Richardson and his employees. Eight of the nine patients were diagnosed as having cancer by conventional means by physicians other than Dr. Richardson. As previously mentioned, all the patients were treated with Laetrile without utilizing conventional means to diagnose and stage the disease.

One patient, Daryl Figueroa, did not in fact, have cancer, but was referred to Dr. Richardson by the State Department of Health as an undercover operative. This patient was treated with Laetrile in spite of never having had a diagnosis of cancer.

Another patient, Charles Little, had Hodgkins disease diagnosed by conventional means at a medical center and was receiving conventional therapy. This patient was in remission at the time of visiting Dr. Richardson's office, and he too was utilized as an undercover operative.

Another patient, Harry Matchler, with laryngeal cancer subsequently had conventional therapy (Laryngectomy) following his dissatisfaction with Dr. Richardson's mode of treatment. He is still alive.

Margaret Baldock had received conventional therapy for her cancer of the colon (Resection and Colostomy) and returned to conventional therapy after also becoming dissatisfied with Dr. Richardson's mode of treatment. It is presumed that she is still alive although this is not confirmed.

The other five patients, Helen Schneck, Kapitan Zema, Ela Hansen, Paul Olsen and Dorothy Soroka all died of their disease.

The mismanagement by Dr. Richardson of the patients reviewed in the appendix utilizing Laetrile without making a tissue diagnosis of cancer was found to demonstrate gross negligence.

Four patients treated by Dr. Richardson, namely Dorothy Soroka, Kapitan Zema, Helen Schneck, and Ela Hansen delayed conventional therapy while under Dr. Richardson's treatment with Laetrile, and this decreased their survivability, as well as their possible recovery.

I will be happy to answer any questions which the Subcommittee may wish to ask relative to the Medical Board's decision.

I wish to respectfully thank the Subcommittee on Health and Scientific Research for the opportunity that has been afforded Mr. Castro and myself for the privilege of appearing here today.

STATEMENT OF CAROL M. HEHMEYER
Assistant District Attorney
Consumer Fraud/White Collar Crime Unit
San Francisco, California 94103
(415) 553-1821

My involvement with the "Laetrile" issue arises from the prosecution of Ernst T. Krebs, Jr. for a violation of the California Health and Safety Code through the use of Laetrile. Mr. Krebs was arrested pursuant to a warrant issued on February 16, 1971 by Judge Victor Campilongo of the San Francisco Municipal Court, for various violations which related to Laetrile activity. On April 16, 1973 the terms of probation were signed after Krebs pled nolo contendere to one of the charges against him.

On about April 1, 1976 our Office filed a Motion to Revoke his probation. This Motion was based in large part upon what we may call the "Zema incident." The hearing on the Motion to revoke ended on May 4, 1977, when Mr. Krebs' probation was revoked, and he received a sentence to six months in the San Francisco County Jail. This was the maximum sentence available at law. Mr. Krebs has a stay of execution pending his appeal of the matter.

THE ZEMA INCIDENT

Tamara Zema testified that her husband, Kapiton, contracted cancer of the lung, which was reported to be about 90-95% curable at the time of its discovery by her doctor. She testified that instead of undergoing surgery, her husband was persuaded through her to seek Laetrile treatment. Since Mrs. Zema testified, Mr. Kapiton Zema has died of cancer.

The small cancer of the lung was discovered by Dr. Cardoza of Santa Rosa, California in October of 1974. Mrs. Zema thereafter saw a Mike Wallace, Sixty Minutes, Television program, and read the book World Without Cancer. Based upon this information, she decided to call Dr. Krebs about Laetrile. He was mentioned in both sources.

Mrs. Zema located Dr. E.T. Krebs in the San Francisco telephone book, and called him. He was told that Mr. Zema had been diagnosed with lung cancer, and took the man's symptoms over the phone from Mrs. Zema. Dr. Krebs (she testified) then told her that Mr. Zema's chances of survival were excellent if he used Laetrile treatment. He recommended three doctors to her, and she selected Dr. Richardson of Albany. She later testified that the conversation with Dr. Krebs persuaded her to use Laetrile for her husband, who feared surgery.

In March of 1975 she called Dr. Krebs again. (Each time, she actually spoke to E.T. Krebs, Jr., as his father and brother were both dead.) Her husband had been going to Dr. Richardson for treatment, but the spot of cancer was getting larger. She testified that Dr. Krebs seemed nervous during the phone call, but he told her that if someone were to operate on her husband, they would discover that there no longer was any cancer in his lung. She testified that there had been no X ray of her husband at this point. Mrs. Zema testified that Dr. Krebs told her that the cancer was healing and was actually nearly gone, if not completely gone by that time. He said that it is normal for the spots of cancer or the lumps, to get larger before they get smaller, during Laetrile treatment.

On the basis of Dr. Krebs' assurances, she and her husband continued the Laetrile treatments. Then, in June of 1975, her husband

began spitting up blood. He was taken in for X rays, and it was discovered that the cancer had spread over his body. Mrs. Zema telephoned Dr. Krebs who indicated to her that the spread of the cancer was due to the X ray. He was very angry and accused her of "self-treatment" because she did not keep her husband with the Laetrile therapy.

The Laetrile treatments were given by Dr. Richardson along with other substances, including "Vitamin" B 15 which bore the Krebs labels.

MR. KREBS

A primary personal motive for my spending a year on a motion to revoke which should have taken half a morning, involved my determination to establish once and for all that Mr. Krebs is not the persecuted genius, dripping with academic honors, that the "Laetrile proponents" tout him to be. Kreb's excellent reputation as a martyred academician and sage has done much to lend scientific credibility to the claims of the people who are propagandizing for Laetrile in this Country. Krebs himself is constantly giving speeches and lectures on the subject, and he is usually introduced as an eminent doctor.

Actually, Ernst Theodor Krebs, Jr. attended Lowell High School in about 1927, where he had a mediocre academic record. Then, on October 29, 1941 he entered the University of Illinois, Urbana Campus. He took a general curriculum in the college of Liberal Arts and Sciences, and transferred a large number of credits from other schools in order to graduate. He transferred credits from the University of Mississippi, Memphis Tennessee State Teachers College, San Mateo Jr. College, and the University of California Extension. On February 23, 1942, he graduated with an A.B. (L.A.S.). On October 19, 1973 he received an honorary Doctor of Science from the American Christian College in Tulsa, Oklahoma. These are his only known "advanced" degrees.

Before that time, from October 3, 1938 to July 1, 1941, Mr. Krebs attended Hahnemann Medical College at Philadelphia, Pennsylvania. He took courses in anatomy, physiology, embryology, histology, and pharmacology but did not graduate. He testified that he had to take the first year over. He did second year work in his third year, and was then encouraged to seek his further education elsewhere. Apparently, no credits were transferred to the University of Illinois from Hahnemann, but I have no explanation for this fact.

Finally, in February of 1943, Mr. Krebs did some sort of graduate work at the University of California in Berkeley. He received no advanced degree, and the nature of this work is unclear to me.

THE MONEY MOTIVE

It has always been my impression that aside from enjoying the publicity and prestige he has obtained from the Laetrile "cause," Mr. Krebs has also profited financially from the movement. He denies this.

At the April 1976 hearings on revocation, however, J.R. Jackson, a State Health Department Investigator, testified that the records seized with a search warrant pursuant to the 1971 arrest, showed about $250,000 of income to E.T. Krebs Jr. and his brother, Dr. Byron Krebs, from the 642 Capp Street Laboratory Laetrile activity. This was, as I recall, for about the year and one half preceding the arrest. Apparently the figure did not include Mr. Krebs' income from the practice of medicine as a Laetrile therapist for cancer patients. (unlicensed practice)

During probationary searches at 1348 South Van Ness, the Krebs mansion, huge amounts of cash were located, secreted upon the premises. On September 5, 1975 the investigators found $12,705 hidden in a cache in the ceiling. Before that, a huge pile of money was found on a search,

but was not actually counted.

Mrs. Zema had testified that the B 15 which she purchased for her husband from Dr. Richardson cost $15 per bottle. Jim Eddington, a State's investigator, estimated that the vials of B 15 transported by Mr. Krebs represented over $300,000 worth of B 15 moved since March 8, 1974. This was based upon a $12 per vial estimate of average 'street' value. Mr. Eddington also testified that Mr. Krebs received at least $10,301 from Mr. Bradford between 2-5-75 and 12-1-75, as evidenced in the records of Mr. Bradford upon his arrest.

Interestingly enough, during his approximate 12 days on the witness stand during the revocation hearing, Mr. Krebs denied that every reasonably inferrable source of income to him netted him any money. He persisted in his claim that he had no financial recompense for his speeches, lectures, or for the commercial tapes of his Laetrile speeches. He was reluctant to accept money for tours unless they were out of state, he said, at which time he would accept plane fare, meals, and lodging, only

Yet, Mr. Krebs admittedly lives in a mansion, travels all over the country and the world speaking, holds immense feasts for large numbers of guests at his home, supports a secretary, and drives a station wagon registered to himself, which bears the license plate: VIT B15.

THE CLAIMS

The content of Mr. Krebs' claims for Laetrile was also an issue at the revocation hearing because he had been prohibited, as a term of his probation, from claiming that Laetrile is a cure, preventative, or treatment for cancer. The evidence showed that he had made extravagant claims for Laetrile (Vitamin B 17) as a cancer cure throughout his probation. He told innumerable audiences, for example, that B 17 is to cancer what vitamin C is to scurvy. The claims were in no way the modified ones that Mr. Krebs presents to the press.

Senator KENNEDY. We'll hear from a panel now which I'm sure will challenge those observations. We'll welcome them to speak, and to listen.

But if there's no further questions, we want to thank you very much for your appearance here.

Senator KENNEDY. Stay in order, now.

Dr. John Richardson, Albany, Calif.; Robert Bradford—Mr. Robert Bradford, president of the Committee for Freedom of Choice, Los Altos, Calif.; Mr. Ernst Krebs, from San Francisco, Calif.; Dr. Bruce Halstead, Loma Linda, Calif.

Will you gentlemen rise with me and raise your hands?

I swear the testimony I will give to be the truth, the whole truth, and nothing but the truth, so help me God.

Dr. RICHARDSON. I do.

Mr. BRADFORD. I do.

Mr. KREBS. I do.

Dr. HALSTEAD. I do.

STATEMENT OF JOHN A. RICHARDSON, M.D., ALBANY, CALIF.; ROBERT BRADFORD, PRESIDENT, COMMITTEE FOR FREEDOM OF CHOICE IN CANCER THERAPY, LOS ALTOS, CALIF.; ERNST T. KREBS, JR., SAN FRANCISCO, CALIF.; AND DR. BRUCE HALSTEAD, LOMA LINDA, CALIF., A PANEL

Senator KENNEDY. Mr. Richardson—Dr. Richardson, we'll start with you.

Dr. RICHARDSON. Yes, sir.

With that wonderful introduction, it's very difficult to know exactly where to start. And it reminds—or I should be reminded of the fact that in ancient days, when the king didn't want to hear the message, he simply did away with the messenger.

And, of course, I came here today to discuss Laetrile and not my previous trials and tribulations. I might state that when the license was removed, it was requested that this be done by a Dr. Leventhal of the FDA in Washington on July 22, 1975. And in the letter he said that the best way to get Dr. Richardson to stop using Laetrile is to take his license away. And it dates back even further to the June 14, 1974, memorandum of the—the FDA–HEW memorandum over the signature of Robert A. Tucker for Glenn W. Kilpatrick, in which the FDA stated the different ways that would be used to stop the Laetrile movement.

One way, on page 6, and I will submit this for the record, is to take away the licenses of the doctors. And the second way is ongoing legislation which we feel formed the background for the ex post facto law used against us in San Diego in the so-called, or alleged, conspiracy to smuggle indictment.

Senator KENNEDY. Just on this point, then, do you deny the allegations or the charges of the medical board of California?

Dr. RICHARDSON. Well, of course. I wasn't even allowed to be present at the hearing. It was merely a mock trial, a star chamber procedure. And I am, at the present time, suing 11 top officials in the State of California for deprivation of my civil rights.

However, with your permission, I'd like to go ahead with the Laetrile——

Senator KENNEDY. All right. I'll find out from Mr. Castro, who is here. Was Dr. Richardson denied an opportunity to appear?

Mr. CASTRO. Absolutely not. He was represented by counsel. On the day of the hearing, he did not show up.

Dr. RICHARDSON. Well, that is not true. I was in San Diego, Senator Kennedy. I was in San Diego. I asked for a continuance, and it was denied. I couldn't be in two places at one time.

Mr. CASTRO. I might also add that I believe——

Dr. RICHARDSON. Well——

Senator KENNEDY. I'll let you, on this point, Mr. Castro, if you want to submit something, but it is Dr. Richardson's testimony here. So if you want to give us some additional information on it. But otherwise, I want to hear the witness.

Mr. CASTRO. I had been told that he represented to the court in San Diego that he couldn't attend the hearings there because he was supposed to be in San Francisco. [Laughter.]

Dr. RICHARDSON. I didn't hear that to reply.

Senator KENNEDY. If you did not hear it, I will let you hear it.

Say it again. Now let us have quiet. I was going to let the thing go, but if you want to hear it——

Mr. CASTRO. Dr. Richardson did not appear in San Francisco because I—there was some information that he was in San Diego with Mr. Hoffman's legal situation down there.

Dr. RICHARDSON. That is true.

Mr. CASTRO. I was informed that he had indicated to the court down there that he couldn't be there because he had to be at the hearing in San Francisco.

Dr. RICHARDSON. That is not true. However, you know, this is hearsay, and I don't think, if you will pardon my observation that this is the place to iron this out.

Senator KENNEDY. Fine.

Dr. RICHARDSON. Because we are going to litigation in the State of California. Mr. Castro is one of those being sued.

Let me begin with a short biography. I was in college when our country was attacked and forced into World War II. I quit school and joined the Marine Corps. After successfully completing the officers' candidate school training here at Quantico, I served in Guam, Saipan, and China as a first lieutenant—most of the time as a second lieutenant, finally as a first lieutenant.

Following the war I returned to Hamilton College where I played football and served on the student council and honor court, and incidentally, was a member of the Pentagon, the senior honorary society.

After being graduated, I entered medical school at the University of Rochester, in Rochester, N.Y., and upon completion of my studies received a fellowship for medicine and surgery at Mary Imogene Bassett Hospital in Cooperstown, N.Y. Continuing to prepare myself for practice, I accepted a fellowship in ear, nose, and throat at Kaiser Hospital in San Francisco.

Finally, in 1956, I opened a general practice in Albany, Calif. It grew rapidly, and I became both professionally and financially successful.

And incidentally, there are so many things to defend oneself against here, but we only heard one side of Mr. Hoffman's presentation. We didn't discuss my first wife's prolonged 3-year illness, and how I was out of practice, and how in 1972–73 and 1974, or during that time that Mr. Hoffman said I didn't make much money I was defending myself in court in three trials, after which charges were dismissed. I lost my office personnel, and the practice went to almost nothing.

And in regard to this alleged huge amount of money and without going into it at the present time, in my book that has been published courageously by Bantam Books, on page 77, we have my statement and clarification of how Mr. Hoffman used the total amount of money that was brought in as a gross income in my practice, and multiplied it by two or three times to obtain that figure. And he was discredited in court, and that is a matter of record.

And on page 10 of the transcript, Judge Enwright said, Mr. Hoffman, if you go out on the street, the first 10 doctors you meet will have an income not appreciably or not significantly lower than that of Dr. Richardson.

In fact, the Judge said——

Senator KENNEDY. What was your income?

Dr. RICHARDSON. Excuse me.

What was my personal income? We haven't even had time to discover, but it was about——

Senator KENNEDY. Oh, now.

Dr. RICHARDSON [continuing]. Twelve percent of the total gross.

Senator KENNEDY. Pardon?

Dr. RICHARDSON. Twelve percent of the total gross, Senator Kennedy.

Senator KENNEDY. Well, since you were the one who raised it. What was your——

Dr. RICHARDSON. Well, I think it was approximately $140,000 during one of those years, but I didn't come prepared to discuss the income facts.

Senator KENNEDY. No; but the point that you're making is to discredit a previous witness, who was under sworn testimony in terms of the figures. You raised it; we didn't.

Dr. RICHARDSON. Well, this is all a matter——

Senator KENNEDY. Well, I know that. But you raised this now, and you raised the fact that the judge said that other doctors would have—might have the same income. So I'm just asking you what that income was, and what amount of it came from Laetrile.

Dr. RICHARDSON. Well, what Mr. Hoffman presented. He has it right with him. You can ask him. I've forgotten. It's already——

Senator KENNEDY. You've forgotten?

Dr. RICHARDSON. Well, yes. Mr. Hoffman brought it with him. 1974? Mr. Hoffman, do you have it?

Senator KENNEDY. Well, I was just asking you.

Dr. RICHARDSON. Well, I would like to give under oath a correct figure, and I don't have the income tax figure with me.

Senator KENNEDY. Well, a round figure——

Dr. RICHARDSON. Well, I said around 140,000, I believe. I believe.

Senator KENNEDY. And what amount from Laetrile?

Dr. RICHARDSON. My practice is largely Laetrile, which I will get to.

I first heard of Laetrile in 1969 through Ralph Bowman, who is now my office manager. While——

Senator KENNEDY. Just finally, did you deposit, in excess of $2 million in a bank account?

Dr. RICHARDSON. On page 77 of the book I go through this, and I state that we did, but it was in several different bank accounts. One was gross, and from that amount, our lawyer told us to take half for vitamin purchases. The Government came along and added them both together, and said, ah hah—he put into banks this amount of money. But remember we had 24 people working for us. Now there are three doctors working in that clinic.

I first heard of Laetrile in 1969 through Ralph Bowman, who is now my office manager. While traveling and doing promotional work in a nonmedical field, Mr. Bowman quite by chance met a woman who had been declared a terminal cancer victim. This lady's cancer had been brought under control through the use of Laetrile.

Mr. Bowman, who had been a close personal friend for a number of years, enthusiastically brought me an armload of literature on the subject. I was curious, but dubious, as are all trained physicians about claims concerning mysterious, magic potions which purportedly slay the cancer dragon.

Some weeks later, while taking a brief vacation, I began to delve into the literature on Laetrile, or as it is also known, amygdalin, or prunasin (?) or vitamin B–17. This vitamin is extracted from apricot seeds, and contains a substance from a family known as nitrilosides.

I discovered that these nitrilosides occurred in nature, not only in apricot seeds but also in peach seeds, bitter almonds, and some 1,200 different natural sources. Tonight, if you have lima beans for your dinner, you will be ingesting nitrilosides, or amygdalin.

I—the idea of a vitamin just coming on the scene is not so. It's always been a vitamin. A rose is a rose by any other name. And I will submit into the record an article in which I replied to Dr. Ross and Dr. Greenberg concerning the vitamin characteristics of amygdalin.

I learned that there are parts of the world where the everyday diet is high in nitrilosides; and I noted that the higher the natural diet is in this substance, the lower the incidence of cancer. It was hypothesized that these nitrilosides are connected to the immunity system which exists in each of our bodies. One noted, for example, that in the last century, millet, which is high in nitrilosides, was a staple in the American diet. Since that time, wheat, which is low in nitrilosides, has replaced millet on our tables even as the incidence of cancer has been steadily increasing.

Such information was fascinating, but strictly academic, since I did not treat cancer patients as part of my practice. Then one day my nurse, Charlotte Anderson, came to me almost in tears to announce that her sister had cancer. She wanted to know if I would treat her with Laetrile shots. Whether to do this was a very difficult decision. I told her that the proponents of Laetrile did not claim that it was a cure for cancer—you know, we do not talk about cures; we've never talked about cure—but that it often acted as a control, much in the way that insulin, not a cure for diabetes, serves to control that disease.

My nurse believes that her sister's chances were better with Laetrile than through the traditional forms of treatment composed of surgery, radiation, and chemotherapy.

At that time I had no idea of how political the treatment of cancer had become, and how politics and self-interest now so often supersedes the search for medical cures. I did know that the treatment of cancer with Laetrile was frowned upon by the medical establishment. But my Hippocratic oath as a physician was, and is, more important to me than politics, the whims of bureaucrats, and the vested interests of drug companies and research institutions, or even the current fads of those who claim to speak for the medical profession. I knew I could not refuse to treat my nurse's sister without betraying my Hippocratic oath and becoming a traitor to my conscience. What I did not then realize was that I was about to bring down upon myself and my family the vengeance and hatred of a professional machine that felt its authority threatened.

Kaiser Hospital had biopsied a melanoma on the arm of my nurse's sister, and wanted to amputate immediately. Consider what it meant to her and all of us when she responded beautifully to the Laetrile treatment. I saw her recently—that's seven years later—at a wedding, and gentlemen, she came up to me and grabbed both my hands with both of her hands.

With such splendid results, I began using Laetrile with other patients—excuse me.

Senator KENNEDY. Just before we go on. You indicated on the bottom of page 2 that you never believed that this was—"I told her that the proponents * * * did not claim that it was a cure for cancer, but that it often acted as a control * * *"

Of course, Mr. Krebs, you've indicated that you believe it was a cure for cancer, have you not?

Mr. KREBS. No, sir, Senator Kennedy, I never have.

Senator KENNEDY. Well, do you remember the statement you made that "we hope before very long to see vitamin B–17 available so that we can prevent cancer in the same way that we prevent scurvy?"

Mr. KREBS. That's correct.

Senator KENNEDY. Well, do you think Laetrile prevents cancer?

Mr. KREBS. Very definitely. We look at Laetrile—

Senator KENNEDY. All right, well, then, I'll just get back, just to make it part of the testimony on this part, which Dr. Richardson had indicated that the proponents do not claim that it was a cure for cancer. Dr. Krebs believes that it does prevent it, in the same way.

Do you believe that, Dr. Richardson?

Dr. RICHARDSON. Yes. It's a preventative and a controller—any more than——

Senator KENNEDY. You do believe that it prevents cancer?

Dr. RICHARDSON. Yes. Water will prevent thirst, it will not cure it. You have to keep drinking water. And the same thing with vitamin C or any of the other vitamins.

Senator KENNEDY. Do you believe that if everyone takes Laetrile that we won't have cancer?

Dr. RICHARDSON. Yes, and probably you have had Laetrile in your diet sometimes during—in the past week, if you've had lentils, or macadamian nuts, or any of these things. And the fact that you have is largely responsible for the fact, in my belief, that you have not yet had clinical cancer. But it's the absence of the vitamin that allows progression of the disease.

Senator KENNEDY. You believe therefore that if we, as a country, if everyone took Laetrile, that we wouldn't have cancer in this country?

Dr. RICHARDSON. I believe that in 20 years cancer would be relegated to the dusty pages of history.

Senator KENNEDY. And what about Mrs. Schneck?

Dr. RICHARDSON. Mrs. Schneck, Senator Kennedy, is another allegation that I was not allowed to defend myself against in this trial. However, in a previous trial, contrary to the dictates of double jeopardy, or against double jeopardy, I was—this case was brought against me in 1972–73 and in this trial I brought out—and I have the papers here, anticipating that this would be used against me—showing that the Marin General Hospital, 4 years before, had excised a parotid tumor, which 50 percent turn into a malignancy. We have those slides, and we found that she had malignant cells. And when she came to me in 1973, she only had a maintenance, 100-milligram-a-day dosage, with all the other vitamins.

Her cancer was progressing, and it was not our fault, it was due to the doctors in Marin General Hospital that missed it. And we have the slides, and they missed the diagnosis.

Senator KENNEDY. Wait a minute.

Dr. RICHARDSON. Yes, they excised it—the tumor, but they did not diagnose cancer. And we have reviewed the slides and found malignant clusters that should have warranted a wide excision.

Senator KENNEDY. Well, the facts will remain on the record. And rather than getting into that, let me get back to this other point, that you believe that just with Laetrile that we could eliminate cancer. All forms of cancer?

Dr. RICHARDSON. I believe that 99 percent, just as you see some clinical cases of scurvy today, or some clinical cases of pernicious anemia that respond to vitamin B–12, which also contain cyanide——

Senator KENNEDY. Why is it that you have believed this, that evidently the scientific community reaches completely contrary conclusions.

Dr. RICHARDSON. But that's not so. The scientific community is not on the throne. The scientific community does not have to—I know a head of chemical——

Senator KENNEDY. The who?

Dr. RICHARDSON. Excuse me, chemistry departments who are very firm advocates of Laetrile.

Senator KENNEDY. Who are they?

Dr. RICHARDSON. Well, I know Dr. Caisson at University of California in Berkeley, for one.

Senator KENNEDY. Which campus? Dr. Caisson?

Dr. RICHARDSON. Yes.

Senator KENNEDY. And Dr. Caisson believes that Laetrile will cure all cancer, or prevent it?

Dr. RICHARDSON. Well, now you're using a word that we don't like to use. Prevent, yes.

Senator KENNEDY. Dr. Caisson's from which campus?

Dr. RICHARDSON. University of California at Berkeley.

Senator KENNEDY. At Berkeley, Dr. Caisson believes that it will prevent all cancer?

Dr. RICHARDSON. Yes, he's a very firm believer in the whole principle, the whole vitamin-preventative principle of vitamin B–17. That's just one. And there are others. But I——

Senator KENNEDY. Let me ask: Why is it so complex? Why isn't it a simple matter to be able to show? Why do we find that the Cancer Institute reaches a different conclusion, the National Institutes of Health, the medical professions, the legal professions, the medical professions——

Dr. RICHARDSON. Well, not one of them——

Senator KENNEDY. The medical board in California.

Dr. RICHARDSON. In California, there's only one doctor on the medical board.

Senator KENNEDY. Why do all these groups reach one conclusion, and you reach a different one? And what is the basis of the scientific information for judgment that you have that evidently they don't have?

Dr. RICHARDSON. Senator Kennedy, how many of them have used Laetrile? None of them. I have. I have used Laetrile on human beings. Dr. Ross hasn't used Laetrile——

Senator KENNEDY. Well, we don't question that. We heard testimony that some of them died.

Dr. RICHARDSON. Well, how can he make a judgment?

Senator KENNEDY. We don't question that.

What we do question is that if they are prepared to submit this to scientific examination, or testing, would you be willing to abide by that?

Dr. RICHARDSON. Yes, but they have to improve their ways. I think there should be an independent outfit that would monitor, because for a long time the FDA has claimed that it has tested Laetrile, and there was the Bohannon Court that found that they never had. So that there's too much hanky-panky going on on high levels. I think that the NCI should test it. But if they're just going to use it for dying patients, they've only got part of the story.

Senator KENNEDY. On the best possible kind of a profile, in terms of either getting the National Institute, the Cancer Institute, with the FDA, would you be willing to abide by that decision?

Dr. RICHARDSON. Well, again——

Senator KENNEDY. I want to tell you, that with the best that can be devised, in terms of our scientific information, if that shows that you're right—if that shows that you're right—I'll be down there leading the charge on the floor of the U.S. Senate to legitimize it.

Dr. RICHARDSON. This is what we've been driving for.

Senator KENNEDY. But I want you to also say, if it does not show this in terms of scientific information, that you're going to be prepared not to mislead the American people into thinking that they're going to get either a prevention or a cure for it.

Now, will you make that kind of——

Dr. RICHARDSON. Absolutely, absolutely.

Senator KENNEDY. Kind of agreement?

Dr. RICHARDSON. Just as you said.

Senator KENNEDY. What about it, Commissioner Kennedy, since you're now here. Can you help us reach a——

Dr. KENNEDY. I'm grateful for that guarantee. I hope he'll tell us what it is before he asks that we test it, that's all. It would be very convenient. He's called it amygdalin, Laetrile, prunasin, and nitriloside so far today.

Dr. RICHARDSON. Chemically it is: L-mandelo nitrile-beta-glucauroniside [sic] or L—Dr. Krebs?

Mr. KREBS. Laetrile is: Laevo-mandelo-nitrile-beta-diglucoside. It was first isolated in 1832. The molecular weight is known. It is reported consistently in the literature for the past century as being devoid of toxicity when parenterally administered; if administered orally in sufficient quantities it has what we call an LD_{50} or 450 milligrams per kilogram of body weight. If we take the enzyme, beta-glucoside, mix it with Laetrile, and administer it to dogs, the enzyme, beta-glucoside, breaks the Laetrile down to free cyanide, and will exert the toxic and even lethal effect. This is the mechanism claim for the action of Laetrile, or vitamin B–17. It is claimed that the malignant lesion is characterized by a high focal concentration of beta glycosidase that selectively breaks down that molecule to free cyanide and benzaldehyde.

Senator KENNEDY. Well, maybe—that's a lot for a layman to understand. Maybe the doctors can understand.

Mr. KREBS. Yes, Senator.

Senator KENNEDY. Maybe Dr. Kennedy can understand.

Dr. KENNEDY. Well, first, two things, one for Dr. Richardson, one for Mr. Krebs. I guess Mr. Krebs, since he had the last word, is to be believed. He's described the structure of amygdalin to you, which is the diglucoside. Dr. Richardson started to tell you about a gluconic acid derivative, which is a different molecule.

That typifies the confusion about this substance. If we now can have all of the proponents at the table agree that they want us to test pure amygdalin and specify which isomer, we begin to see the basis for a starting point.

Dr. RICHARDSON. There shouldn't be any confusion.

Senator KENNEDY. He's an expert in this.

Dr. RICHARDSON. He doesn't seem to be.

Mr. KREBS. Yes, I know that's—Senator Kennedy, may I clarify what Laetrile is? Laetrile is the term used for amygdalin. The chemical term for amygdalin is laevo-mandelo nitrile-beta-diglucoside. Mr. Kennedy is completely in error when he suggested there are a number of formulas for it. Nitriliside, amygdalin, vitamin B–17, and Laetrile are all synonymous.

Senator KENNEDY. You mean his analysis of that description is not correct? Is that what you're saying?

Mr. KREBS. That's correct, Senator Kennedy.

Senator KENNEDY. Well, what is the correct one?

Mr. KREBS. The correct analysis of Laetrile, as it is available now, is a refined form of amygdalin, to wit, the laevo isomer, laevo-mandelo nitrile beta-diglucoside. And it may be very quickly checked out in any competent chemical laboratory in about 10 or 15 minutes by putting it into a poloemeter and checking its specific optical rotation.

Senator KENNEDY. Do you understand that, Dr. Kennedy? [Laughter.]

Dr. KENNEDY. Yes. Our chemists keep having this problem, that there's a lot of *d*-isomer in there, and that the amount of amygdalin varies. But if these folks will give us pure *l*-amygdalin, that will get our clinical colleagues at least off to some kind of start at a test. This is an historic day, because it is the first day we've heard some people agree what this stuff is.

Senator KENNEDY. Well, can you provide that substance?

Mr. KREBS. Mr. Kennedy is correct, there are dextro-isomers in——

Senator KENNEDY. He's Dr. Kennedy. You're Mr. Krebs, I think.

Mr. KREBS. Yes. [Laughter, applause.]

Senator KENNEDY. We'll be in order. We'll be in order. Order, please. Order. Order. We'll be in order, please.

Mr. KREBS. Yes, Senator Kennedy, that is part of the character assassination. I feel time is so limited, we haven't gone into personalities. But character assassination is a major instrument in this movement. I happen to be a graduate of the University of Illinois. I've had 3 years of medical school. I've had 2 years of graduate work at the University of California. And the Christian College of Tulsa, Okla., gave me an honorary doctor of science. I don't consider it honorary, because I consider it more than fully earned. But in the political miasma that surrounds this issue, I was denied access to a higher degree on this subject. So I don't propose to stand still for a further character assassination.

Senator KENNEDY. No; I don't think anyone's attempting——

Mr. KREBS. All right.

Senator KENNEDY. I think what we're—there is a standard——

Mr. KREBS. Yes.

Senator KENNEDY [continuing]. In terms of being called doctors, for practicing doctors. They exist in the States, they've been respected by the States, within the medical professions, and I think it so happens that Dr. Kennedy has——

Mr. KREBS. Your Commissioner is a Ph. D. and he is not qualified in the area of cancer. He is totally unqualified, and I would be delighted to put him under cross-examination on the subject.

Senator KENNEDY. Well, he is—we'll be in order.

Mr. KREBS. I spent 25 years in this area, and I know precisely what I am doing and what we are doing in this movement. We have a tremendous power against Laetrile. We have 400,000 Americans a year dying from cancer, and each one who dies spends on an average of $20,000 a year before he dies, and this represents $8 billion a year spent by these dying people. This is a tremendous economic and political force. The man who should be here is neither I nor Dr. Richardson, but it's Prof. Hardin B. Jones of the University School of Medicine, Department of Biophysics, who said in a very scholarly manner, reported before the New York Academy of Sciences in a magnificent monograph entitled "The Demography of the Cancer Population." He reached this conclusion. He said my studies indicate that population of cancer patients left entirely untreated live longer and suffer less than those who are treated. Dr. Jones should be here, should be under cross-examination by the experts of HEW. So should Nobel Prize winner Dr. Watson, who has characterized this cancer scandal as a nasty bill of goods being sold the American people.

The Laetrile movement is not funded——

Senator KENNEDY. Are you suggesting Dr. Watson believes in Laetrile?

Mr. KREBS. No; I do not. Neither does Dr. Jones. But the basic point here is—the basic point here is to make it clear whether or not the present methods of therapy are not actually as Dr. Jones suggests, counterproductive. And Dr. Watson should be asked to explain why he describes——

Senator KENNEDY. Well, he's no stranger to this committee, Mr. Krebs. He's appeared before our committee, and he's always welcome.

Let me ask you: what we're attempting to deal with is to find out, with the Commissioner of FDA here, is, whether, given all of the other problems in terms of Dr. Fredrickson, the ethical questions about how these tests could be established, whether there could be the kind of scientific analysis that you believe you've been denied. And you've got at least the person in this room who could be enormously helpful, with Dr. Kennedy.

We are trying in an open forum—not in meetings, in public halls, not in rallies, not in closets, not in rooms, to try and find out exactly what that substance is that you want tested.

And what I am prepared to do is, with the establishment of the best and the fairest kind of test, to be willing to abide by it. And Dr. Richardson has indicated the same. I think we're making some progress here this morning, in terms of trying to recognize that in a civilized nation and country that we do have to have some basic kinds of standards on it——

Mr. KREBS. We have definite parameters——

Senator KENNEDY [continuing]. Of safety and efficacy.

Now, if we can agree on that, this will be an extremely important——

Mr. BRADFORD. May I address myself to that question?

Senator KENNEDY. I'd like to hear from you just before we leave this point. Now, can we agree on what that substance is, so that we can go back to Dr. Kennedy and say, all right, we've got the substance that should be tested, and now see if we can't work out the ethical. I don't believe that these are easy questions——

Mr. KREBS. We agree on what the substance is. Now as for the test: We would urge that they proceed in this manner: That the existing animal tests showing that vitamin B–17 or Laetrile retards cancer, that these tests be repeated, that Dr. Kanamatsu Sigiura's studies at Sloan-Kettering that proved that vitamin B–17 or Laetrile prevents metastasis of primary mammary cancers to the lung, that these studies should be repeated; that the epidemiological claims should be investigated. Indeed, a Senate committee did look into the Hunzakuts and found that this population is totally devoid of cancer. The World Health Organization has pointed this out. And this is a population that ingests on an average 150 to 250 milligrams of nit——

Senator KENNEDY. Do they take Laetrile?

Mr. KREBS. They receive about 150 to 200 milligrams of Laetrile or vitamin B–17 daily in their diet. They not uncommonly ingest up to 30 to 40 apricot seeds——

Senator KENNEDY. Before you continue, do I understand that you're prepared to give us—I mean, you must agree; you're four of the leaders of the organization here—just the definition of the substance that you want the FDA to test.

Dr. RICHARDSON. Without going any further, let me tell you Senator, that we are prepared——

Senator KENNEDY. May I ask of Dr. Richardson, who is the——

Mr. KREBS. Well, yes, I will repeat——

Senator KENNEDY. Could you write it—why don't you just write it down on a piece of paper? Could you do that now? The exact substance that you want tested. Just write it down now on a piece of paper.

Mr. KREBS. What I want tested.

Senator KENNEDY. Well, what your organization—aren't you speaking for them? You're the head of the organization.

Mr. KREBS. No; I just represent myself, Senator Kennedy.

Senator KENNEDY. What about it, then—well, write it down, anyway.

Dr. RICHARDSON. All right.

Senator KENNEDY. And maybe you could get Mr. Krebs' agreement, and Mr. Halstead—and we'll hear from you.

Yes, Mr. Bradford.

Mr. BRADFORD. I think we have a complete identification, and I'm going to address myself to those points when I get a chance to.

Senator KENNEDY. OK. Do you want to do that now?

Mr. BRADFORD. If you wish, yes.

Mr. Chairman, I am Robert Bradford; I am an electronics engineer——

Senator KENNEDY. If you're going to go all the way through—I thought you wanted to comment on this; I didn't want to interfere with Dr. Richardson. I wanted him to be able to finish. If there was a point that you wanted to make vis-a-vis this other discussion, as we inquired of the panel, the earlier panels to make comments on particular matters, I'd welcome that. But otherwise I'd like to have Dr. Richardson to finish his thoughts.

Dr. RICHARDSON. All right, I'll just finish my thoughts, then——

Senator KENNEDY. I think on the point where you were at the bottom—we were just getting past the bottom of 2 and the top of 3 when I mentioned about this.

You were talking about how cancer has become—how politics and self-interest now so often supersede the search for medical cures, the whims of bureaucrats, the vested interests of the drug companies and research institutions, and the current fads of those who claim to speak for the medical profession.

Do you really think there is a conspiracy?

Dr. RICHARDSON. Well, I've thought so for quite some time, Senator Kennedy. And it was always a ludicrous thought that while I was trying to tell people about a conspiracy, that I was caught up in a conspiracy indictment myself.

But I definitely feel that there is; yes. Conspiracy is not unusual in any time in history, and particularly in this time. And it may be unwitting on the part of many people.

Senator KENNEDY. Who is involved in the conspiracy?

Dr. RICHARDSON. Well, getting on a little further, I think what it amounts to is, the $28 billion a year drug industry, I think the FDA, the American Cancer——

Senator KENNEDY. The drug industry is part of the conspiracy?

Dr. RICHARDSON. Well, you asked me, I——

Senator KENNEDY. All right, yes, I just want to write them down. The drug industry.

Dr. RICHARDSON. And I would like to put into the record the book, "World Without Cancer," to substantiate my thinking on the matter.

Senator KENNEDY. All right, we've got the drug industry. What else? What are the other institutions?

Dr. RICHARDSON. I would say that the people who make up the American Cancer Society, the FDA, the American Medical Association——

Senator KENNEDY. All right, the American Cancer Society.

Dr. RICHARDSON. And if I could explain that.

Senator KENNEDY. OK.

Dr. RICHARDSON. We hear so much about the Army and Navy generals and admirals leaving the service and going into a contract business, and then when they get into that business, they make contracts with their old buddies back in the service. The same things happen, and it's a documented fact, Dr. Rauscher, head of the American Cancer Institute, is not a vice president high up in the American Cancer Society at a considerable—what—at a considerable increase in salary. So in other words, it's a game of musical chairs. And if you play their game, you're fine. If you don't play their game, then you get the treatment, which I have experienced. So one——

Senator KENNEDY. Let's see, now, can we just complete this. We've got the drug industry, the cancer society. The Food and Drug Administration?

Dr. RICHARDSON. Yes; I think people in the Food and Drug Administration.

Senator KENNEDY. Food and Drug Administration. I think you mentioned the American Medical Association, too?

Dr. RICHARDSON. I think they're involved in it also.

Senator KENNEDY. The American Medical Association.

The Congress? You want to——

Dr. RICHARDSON. Oh, certainly not Congress. [Laughter.]

In fact, I miss seeing my old friend Larry McDonald, who's an expert at using Laetrile, and wanted to testify here today. He was not invited. He's Congressman Larry McDonald, from Atlanta, Ga.

Senator KENNEDY. Sloan-Kettering, are they part of it?

Dr. RICHARDSON. Sloan-Kettering—you see, in any of these groups you have differences of opinion. There's a group at Sloan-Kettering which is the Committee for a Second Opinion, which strongly opposes the official attitude of Sloan-Kettering on the Laetrile question.

Senator SCHWEIKER. This group is composed of people who are members of Sloan-Kettering Institute?

Dr. RICHARDSON. Yes; I think——

Senator SCHWEIKER. How many are there?

Dr. RICHARDSON. The man at Sloan-Kettering who actually did the work, Dr. Kanamatu Sigiura, over a period of 3 years, with a series of eight studies, showed that Laetrile decreases the rate of metastasis of

96-492 O - 77 - 17

primary, spontaneous mammary cancers to the lung by 70 to 80 percent, and he says, regardless of what is said, he abides by his original findings, and he added, indeed, this was the first time in the 40 years of my career that any of my findings has ever been questioned.

And Dr. Sigiura's findings are now confirmed by two other institutions in this country, one a college and one a university.

Senator SCHWEIKER. I was aware of Dr. Sigiura's studies when I questioned Dr. Thomas on that very point, when he was sitting at the other end of the table earlier today. What I wasn't aware of was the existence of such a committee at Sloan-Kettering as you described. Are there other researchers——

Dr. RICHARDSON. Senator Schweiker, I do not know that committee. That isn't a scientific committee. It is similar to the other side of the cancer question, it is etiological, it is political, it is economically motivated, it represents something of a labor union within the organization.

This is why in my statement I asked that this serious matter be considered aside from politics and personalities. So I do not lend any weight one way or other to second opinion except, as Dr. Richardson points out, there is indeed a dissension within Sloan-Kettering in which 944 of the employees say there is a coverup on the findings.

I'm not prepared to offer an opinion on that.

Senator SCHWEIKER. Well, are there other scientific names? I know Dr. Sigiura is well respected. Are there other scientific researchers at Sloan-Kettering involved, besides him? Could you give me any more names?

Mr. KREBS. There is his son-in-law, Dr. Schmidt, who worked with him. And Dr. Schmidt also was able in time to confirm Dr. Sigiura. There have not, in our opinion, been studies of a definitive nature. And indeed, Dr. Sigiura was surprised at his results. We were not. Because those results conformed to the theoretical construct in which we are working with Laetrile.

Let me set this down, please, for this committee this fact, and if this fact be challenged, we would pull out of the Laetrile program now. And this fact is as follows: that cancer is a chronic, metabolic, systemic disease. Now we've seen the fiasco of $2 billion going down the rat hole for the fantasy of the viral etiology. Set that aside. In the entire history of science and medicine, no chronic or metabolic disease has ever found prevention and/or cure except by nontoxic factors—water or oil soluble—normal to the diet.

Now, this is an axiomatic statement. And let us invite a refuation of this fact now. We do not believe that cancer is going to prove the first exception to this generalization that to date has known no exception.

Senator SCHWEIKER. Repeat your axiom again.

Mr. KREBS. Yes, Senator Schweiker, I will.

Senator SCHWEIKER. And then I'd appreciate it if you would put it in laymen's terms.

Mr. KREBS. Cancer is a chronic or metabolic disease. It is not produced by some mysterious virus. It is not produced by some extraterrestrial force. There hasn't been some sudden mutation that accounts for the fact that more people develop cancer at an earlier age and die from it today than at any other time in the history of the human race.

This is the expression of a fulminating dietary deficiency. That statement is prefatory to this, and now this is the axiom, Senator.

That in the entire history of medicine——

Senator KENNEDY. Could I just ask Dr. Thomas to react to these other Sloan-Kettering comments. If you've just finished on that point, then we'll be continuing.

Senator SCHWEIKER. Well, had you finished, Mr. Krebs?

Mr. KREBS. No, Senator Schweiker, I haven't.

Senator KENNEDY. Is this still part of the axiom?

Mr. KREBS. This is the axiom. And follow it closely please, Senator Kennedy.

Senator KENNEDY. I'll try. [Laughter.]

Mrs. KREBS. In the entire—and you're invited to refute it, and if you refute it successfully, we will have—we will agree that there is an infirmity in Laetrile.

In the entire history of medicine and science, no chronic or metabolic disease has ever been prevented, and/or cured, except by nontoxic factors, water or oil soluble, normal to the diet, or normal to the animal economy.

The history of the West—now that's the end of the axiom. The history of the Western World was changed when it was discovered that lime juice would change the course of empires——

Senator KENNEDY. Well, if you've finished the axiom, could I ask Dr. Ross, maybe, to comment on that—or Dr.—comment——

Dr. Ross. I do not agree that cancer is a disease such as Mr. Krebs describes. However, I think of a chronic disease known as syphilis, which was a scourge of mankind, that certainly was not cured by agents such as Mr.——

Mr. KREBS. But a chronic or metabolic disease, Senator, we mean a disease that is not produced by a specific micro-organism, that is not produced by bacteria, by virus or rickettsia, or protozoan that is not exogenous, that arises from within the body. We invite, again, a refuation of that axiom.

Senator SCHWEIKER. I need an interpreter, Mr. Chairman.

Mr. KREBS. Let me explain it to you——

Senator KENNEDY. Could Dr. Kennedy just say a word?

Dr. KENNEDY. Yes; I think the axiom's all right. It seems less substantial, however, when you subject it to a reasonable interpretation, and put it in laymen's language. What you've just told us is that a cancer is a vitamin or deficiency disease. The only trouble with that is, that there is no evidence that Laetrile or B–17 is a vitamin. No evidence of any deficiency disease that it cures. No evidence that cancer is in the disease category that you describe.

Mr. KREBS. I have written a reply to Dr. Ross that I would love to have him refute. It was in California ——

Senator KENNEDY. Well, we'll send it to him. I was just getting at the conspiracy, and then I'll ——

We were talking just about the conspiracy, which included the drug industry, the American Cancer Society, Food and Drug Administration, the American Medical Society.

I didn't know, Doctor—or Mr. Krebs, whether you had any others on that? Do you believe in the conspiracy, too?

Mr. KREBS. No. Senator Kennedy, that is an oversimplification. We are all realistic human beings, and you know that when you have a disease that claims 400,000 American lives every year, and that that disease costs $20,000 before each one of these individuals dies, that you have a cash flow of $8 billion, just on those who died. And where you have that movement of money, that movement of wealth and power, you do have a tendency toward an agglomeration of power. You have a tendency toward the perpetuation of that structure.

Senator KENNEDY. Are you suggesting that because of the money aspects of it, that the motivation of the medical profession, the cancer institute, is that they want to keep cancer?

Mr. KREBS. No, not consciously, Senator Kennedy. This is an establishment similar to the ——

Senator KENNEDY. Well, what is their motivation, this establishment?

Mr. KREBS. I can no more give the motivation of their establishment, than I would have given the motivation of the surgical establishment in the days of Ignatz Semelweiss, when Semelweiss was driven to insanity merely because he insisted that doctors, when they left the post mortem theater, wash their hands before they deliver babies. It is a characteristic of man, and human nature, that change is a very painful process, exceeding in pain only by the more painful one of clear thought.

Senator KENNEDY. OK, let's keep order.

Mr. KREBS. Senator Kennedy, I've used up a lot of time on mine. If you don't mind, I think I'd like to go to Dr. Halstead, or ——

Senator PELL. I'd like to go to the question of the axiom for a moment. And as I understood it, you said—what was that word, any metabolic disease?

Mr. KREBS. Any metabolic or chronic disease, and I believe this is worthy of definition.

Senator PELL. What was the word again, metabolic?

Mr. KREBS. Metabolic. Many diseases ——

Senator PELL. What would be another example of metabolic disease besides cancer?

Mr. KREBS. Oh, pernicious anemia, which now has found a resolution. Scurvy, Beri-beri. Pellagra. And you see, after these diseases have found their resolution, then retrospectively, we say, oh, well that was just a chronic nutritional deficiency disease. But there is no chronic, metabolic disease that has ever been prevented and/or cured except by nontoxic factors normal to the diet.

Senator PELL. I heard that. I wish you'd respond specifically.

The question then—I'm trying to get it into my mind—is that cancer is primarily a natural disease, it does not come from bacteria or from germs.

Mr. KREBS. That's correct, Senator Pell.

Senator PELL. And what you're saying is that any natural disease, where the cells grow at untoward speed ——

Mr. KREBS. Yes.

Senator PELL. Or you have anemia, which is, perhaps, a mild form of cancer, that those are curable by natural means. Is that what you're saying?

Mr. KREBS. Yes; pernicious anemia has found its total resolution and prevention by vitamin B–12 and folic acid, for example. And before that, it was at a higher death rate than cancer.

You see, this—the Laetrile—the science of the Laetrile represents a breakthrough into an area that is very—test of credibility, it is so foreign to what is believed.

Senator PELL. But isn't what you're saying is that B–17, or whatever it is, it does not cure cancer. But if you take enough of it every day, you won't catch it. Is that right?

Mr. KREBS. If you take enough of it, you do not develop it.

Now, let me emphasize this. I don't mean taking it in capsules or tablets. But if we ate the seeds of all the common fruits, along with the fruit—if we ate millett, if we ate buckwheat, if we ate bamboo shoots, if we ate lima beans if we turned consciously to increasing the concentration of vitamin B–17 in our American diet up to the level of 50 milligrams a day, I am convinced that cancer would be resolved in the same way that scurvy was, by supplementation with lime juice.

Senator PELL. To give me a short answer, if one took sufficient B–17, you would eliminate cancer. Is that correct? Is that your view?

Mr. KREBS. I believe, Senator Pell, that if we ate the foods that contain vitamin B–17, as the Hunzakuts do, we would have the same incidence of cancer as the Hunzakuts, which is zero incidence.

Senator PELL. To be specific, if you took the adequate number of B–17 pills each day as a general course, would that eliminate cancer?

Mr. KREBS. I do not want to leave myself in the position of recommending pills or tablets. The thrust of my effort is to bring the people to the nutritional practices that will supply them while still in health with an adequacy of vitamin B–17 by pointing to the foods that are rich in it: backwheat, millet, bamboo shoots, lima beans, and also point to the effect of plant hybridization in blindly eliminating this essential factor.

Senator PELL. But what is wrong with taking the B–17 pill form, like you take vitamins in the morning?

Mr. KREBS. Well, you could do that, but that is a partial, or atomistic solution. We have deviated in our diet from that which is evolutionarily appropriate. Remember, we belong to a primate stem about 3 million years of age. Today, we are doing—we have deviated tremendously from biological experience, and we're in a disaster pattern. And just taking vitamin B–17 tablets, or capsules, is not going to solve that overall pattern. Our Foods and Drug Administration is doing some good work there, but it must move more rapidly and more deeply into the elimination of additives from food, improper additives. We must move over to a high concentration of B–17 into the diet.

Time doesn't permit my going into detail on the occupational carcinogens. They are real, but they are overrated.

Senator KENNEDY. OK. Well, I want to have Dr. Halstead.

But the thing that's interesting about your careful choice of words about the impact of this would be you had no reluctance of using the word "cures" or "recoveries" in the transcript here before the California case. It was a tape of the town meeting. And I'll just read:

Some cases have undergone clinical arrests, or for other practical purposes, we might describe as cures or recoveries.

Mr. KREBS. That's correct, Senator Kennedy, and I would like to see Glenn Rutherford of Kansas examined in those terms. Glenn Rutherford says that he is a total clinical arrestment.

Senator KENNEDY. OK.

Mr. KREBS. We do run into semantic difficulty with this term, cure.

Senator KENNEDY. Dr. Richardson—have you got that written out, now, what you want Dr. Kennedy to test? Have you got it written down, that piece of paper?

Dr. RICHARDSON. I will have it, Senator, supply it to you. It will not be available today.

Mr. KREBS. Well, it's simple——

Senator KENNEDY. Well, maybe Dr. Richardson, you can supply it—we'd like all the panelists to describe what they'd like tested. If you'd just write it down.

Dr. RICHARDSON. What is it? I'm just——

Senator KENNEDY. What you want tested? What you'd like——

Dr. RICHARDSON. The chemical?

Senator KENNEDY. Right. What you want tested in terms of——

All right, Dr. Halstead.

Dr. HALSTEAD. I find myself very disturbed at this so-called scientific confusion that exists here this morning. I have a long scientific background. I've published about 175 scientific publications, in many different countries of the world, including three volumes, that run in excess of a thousand pages a volume, that were published by the Army, the Navy, the Air Force, and the National Institutes of Health.

Now, amygdaline has been a very——

Senator KENNEDY. Is any of that on Laetrile? Just so we——

Dr. HALSTEAD. We're talking about Laetrile, and I want to——

Senator KENNEDY. No, just in terms of your publications.

Dr. HALSTEAD. No.

Senator KENNEDY. Any of those documents you refer to on Laetrile?

Dr. HALSTEAD. No, but I've been involved in looking at many different anticancer compounds for this Government. I've worked with the Soviet Union. I introduced into the United States, Tora 4, which I brought in from the Soviet Union.

And I would like to point out to this committee, that any time the Food and Drug Administration, or the National Cancer Institute, wants to get a very well-defined, very good chemical definition of what amygdalin is about, it's defined in the 1976 edition of the Merck Index, which is well known to any bona fide chemist.

Senator PELL. And will this group accept that definition?

Dr. HALSTEAD. They'll have to.

The definition is chemically defined——

Senator KENNEDY. We should have got to you a little earlier, doctor. We'd have saved ourselves——

Dr. HALSTEAD. Well, frankly I've been strangling at the bit here for about 3 hours, trying to get to this issue.

Senator KENNEDY. OK, fine.

Dr. HALSTEAD. Because I'm extremely upset of what I finally convinced myself is garbage.

We find here that the molecular structure is well known. We have known since 1912 that the dextro form of amygdalin—because in the receimic form, which is the combined, we have the combined optical isomers, of the dextro, which rotates to the right, the laevo, which

rotates to the left. We find that the analysis there in 1912 demonstrated that 56.25 percent was in the dextro form, 43.75 percent was in the laevo form. In the studies conducted by the Food and Drug Administration of Canada just here within the last couple of years, the works of Dr. Lævi, demonstrates that the biological activity—and we're talking about its anticancer properties, or whatever other biological properties it might have—varies according to the optical rotation of the compound involved.

Now, the statement was made that this compound has been tested exhaustively. And I intend to invoke the Freedom of Information Act to get this so-called exhaustive studies that have been conducted by the National Cancer Institute, or any other branch of the U.S. Government, on this particular compound.

Now, the National Institutes of Health publish the registry of toxic compounds, and I have the latest edition. And when I go through there, looking for amygdalin, and come up with—the nearest thing to it, mandelic acid, I find a very—a horribly shoddy example of so-called toxicity studies.

Now, since we're dealing with the subject of toxicity, because you've been led to believe that every medicinal compound that has been approved by the Food and Drug Administration is perfectly safe to use, I would like to run through, very quickly, some LD 50's which indicate the lethal——

Senator KENNEDY. Just to be correct, I don't think that's ever been suggested before our committee. What, basically, as I understand is, they——

Dr. HALSTEAD. Senator——

Senator Kennedy [continuing]. Do a relative-safety versus the relative-risk. And that's basically the standards which are used. Not that there aren't some that are approved that are extremely dangerous, where people are going to take various drugs that are very, very dangerous. I know that. My son's taking them. And which no other healthy person would have taken.

So, we're against that background.

Dr. HALSTEAD. Senator, I'm a professional toxicologist. I've listened here now for almost 2½ hours concerning the inferences and the outright statements that have been made concerning the dangers of amygdalin. So let me give you some specific numbers.

Amygdalin—and I take this from the Federal Registry itself, and I'm talking about the Registry of Toxic Substances—the nearest thing I can come to is mandelic acid, and according to the oral rate LD_{50} is 3,000 milligram per kilogram. Vitamin A is listed at 2,000 milligrams per kilogram, which essentially tells you that amygdalin is essentially one-third less toxic and dangerous and to take than vitamin A.

If we look at aspirin, we now begin to get into some very significantly toxic substances, that are involving something like over 100,000 toxications in the United States each year.

I must say that when I look at the Government's own publications——

Senator KENNEDY. Those have all been tested, have they not, for safety and efficacy?

Dr. HALSTEAD. In my opinion, no. I think we're talking about an absolutely irrational——

Senator KENNEDY. But in terms of the food and drugs, they have tested them, have they not? Am I wrong in that?

Dr. HALSTEAD. Oh, yes. But they also claim that the National Cancer Institute has tested exhaustively, and you sat and listened to the National Cancer Institute's testimony this morning that they have exhaustively tested Laetrile.

I'm going to challenge that statement, because I don't think they've exhaustively tested this when they come up with a statement saying they're confused as to what they're even dealing with chemically. And one of the men here couldn't even pronounce the word, Laetrile, far less the correct spelling of it.

Senator KENNEDY. Well, we'll get all the tests that have been done at the Cancer Institute, and we'll make them a part of the record, so you don't have to get it through the Freedom of Information Act.

Dr. HALSTEAD. Senator, I might like to make another comment, because I've been—I've worked over the years with the National Cancer Institute. I'm really not opposed to the organization. I may sound a little vehement this morning, but it's only because I am.

The mortality rate in the United States, using all of the so-called orthodox techniques, depending on whose figures you want to accept, whether we're talking about 365,000 deaths a year—and approximately we're losing 1,000 lives a day.

Now, we're told that if you use Laetrile—and incidentally, there's no way you can prevent using Laetrile, because there are over 1,200 plant compounds that we know today that contain amygdalin. So if they're going to boycott apricot pits, then they also better start trying to—probably cranberries and mung beans and lima beans and a host of other things that everybody eats.

But you're lead to believe today that if these people had not taken Laetrile, these people, probably, their lives could have been saved by cutting, burning, by radiation, in which case many of these people die of aplastic anemia, because of the radiation burns. We're giving them these highly toxic compounds. And I would like, for a moment, to forget the science, and to try to deal with just the sheer rationality and logic of our approach in cancer chemotherapy today. And then I want to terminate with a few statistics that I think supports my thoughts.

We are taking an individual that is very sick, tremendously ill. They're literally on the brink of death. And we're telling them now, that by giving you further toxic drugs, by depleting your immunity mechanism still further, you have an opportunity of getting well.

Now, I don't believe this for 5 stinking minutes. And I fail to see any documentation by the National Cancer Institute, or any other organization, that this particular approach has made a lot of sense.

Let me give you one or two statistics that were supported by the National Cancer Institute, and this was a study on the nutrition, largely of——

Senator KENNEDY. Just before you leave that, that was the very modality that was done with childhood leukemia, and with very, very substantial success. And it was done with regard to Hodgkin's disease, with substantial success.

I know you're hot under the collar, but those happen to be the facts.

Dr. HALSTEAD. I am hot under the collar because I think that there are some other avenues that need to be pursued by this Government,

that are not being pursued by this Government, that have been consistently neglected by this Government, and I don't comprehend this approach whatever.

Now, there's been——

Senator KENNEDY. Before we leave this point, about your suggestions on the cuttings and the burnings and the toxic substances—the fact of the matter is there are hundreds of thousands of Americans who are alive today because they did get surgery, and there are hundreds of thousands that have been treated with radiation, otherwise they would not be alive today. And there are a lot of Americans that are alive because of the use of some of these strong drugs.

Dr. HALSTEAD. Senator Kennedy——

Senator KENNEDY. So, it's important that the American public understand that just because you mention those factors, and dismiss them, as somebody who just believes in some other kind of substance, and where there isn't a scintilla of scientific information to justify it, and which we have challenged as members of this committee, and myself, as the chairman of the committee, say, you get the scientific—the substance you want tested. Let us try to get that kind of test. And if it does prove out to be efficacious on it, you're going to find that you don't have any champion like myself in the U.S. Senate.

But all we're asking is, if it doesn't, and if it fails, that you don't go around and mislead the American people, giving a sense of false hope to thousands of families who are seeing a loved one in the dangers—in the grip of cancer. Don't offer them some kind of hope where the scientific information is unavailable, where the medical profession, food and drug, and every bit of scientific information believes is lacking.

Now, that is the challenge that we pose to you. And whether you're willing to accept that particular factor—that's what we're trying to do. Now, will you accept that?

Dr. HALSTEAD. Senator Kennedy—yes; I will accept it.

Senator KENNEDY. All right.

Dr. HALSTEAD. Let me elaborate—I've come 3,000 miles or a little better to discuss this subject, and I'd just like to get a couple of points across.

First of all, if this study is conducted, I hope that it will be conducted—otherwise it will be an absolute sham—that it needs to be conducted in the way that the proponents of Laetrile and other compounds and other materials are urging that it be done.

Senator KENNEDY. But why do we have to——

Dr. HALSTEAD. Wait 1 minute, may I just——

Senator KENNEDY. OK.

Dr. HALSTEAD. I mean, I listened to your speech, I didn't interrupt you.

Senator KENNEDY. OK.

Dr. HALSTEAD. May I just give mine?

The National Cancer Institute conducted a study of 50,000 Seventh Day Adventists in the State of California, for the simple reason that these Seventh Day Adventists—and a similar has now been conducted with the Latter Day Saints, the Mormons, and we end up with similar statistics, which demonstrate that, for some unknown reason, they do not have—they have a much, much lower incidence of cancer than the rest of the population.

Now, they're now doing a second study on a much larger group of people. But so far, all of these studies have indicated that these people are coming out with a very, very, very substantially lower cancer index than all of the rest of the people in the country.

Let me tell you why I think that this is true. And it is largely true because of their nutritional background, and the things that they do, and the fact that they don't smoke. And I think that we need to look at some of these basic elements.

So I was going to suggest that you read—and I'd like to enter into evidence—a magazine that I just saw for the first time, Newsreel, No. 4, for August 1977. And in there it discusses the research of Dr. Harold W. Manner, a man that I've never met. Chairman of the biology department of the Chicago—in Chicago, of the Loyola University.

The thing that impresses me most about Mr. Manner's work is the approach that he is using, the scientific approach that he is using to try to get to some good, scientific, basic chemical, pharmacological and toxicological procedures.

And the gist of the article is—and I'm assuming that he's doing what they're saying he's doing here—I get the impression that he has at least a chance of coming up with an honest evaluation.

Let me tell you what really concerns me about the so-called NCI and the Sloan-Kettering studies, or whatever. If, due to an improper selection—in other words, I'm not asking or suggesting that anybody select certain rats, certain types of tumor systems; I think they ought to give it the full spectrum of testing.

I think that the toxicological procedures should be completely delineated. I think that they ought to be able to chemically define specifically what they're using in the way of amygdalin. If they're using a dextro-form, they're going to get an inactive form. If they use a lævo form, they will get the active form.

Senator, you made a comment earlier that there's—and I assume that this reflects some of the things that were presented earlier—that there is no scientific evidence anywhere, or clinical documentation, that Laetrile is effective. And that statement is not true. I would challenge that before a court of law anytime, anywhere, where they will give me more than 15 minutes to try and present the information. Because there is documented information.

Now, I agree, and would be the first one to agree, that the documentation is not completely adequate. But I want to assure you, on the basis of information that I have so far, and we now—I've hired, and part of this at my own expense; and I came today—I'm not being paid by anybody. I am not working for the Freedom of Choice group. I've had only two conversations in my lifetime with Dr. Richardson. I haven't had a chance for but one conversation with Dr. Krebs, or Mr. Krebs, however you want to designate him.

The only thing that I am concerned with is that I have been involved with the anticancer business now for a good many years. I've worked on both sides of the line. I've worked with the good guys and the so-called bad guys. I've traveled in 150 countries of the world. I've worked with the Soviet system, and looked at some of their anticancer activities and studies. I've introduced into the United

States compounds which the CIA and the National Cancer Institute told me they had tried to get and couldn't get for several years. I brought them into this country and had them tested. Granted, we never used them, and I still don't know why.

But what I am seriously concerned about is the statistical games that we play. It's like Disraeli and I guess others have said, there are lies, damned lies, and there are statistics.

Now, there is a National Cancer Institute study of the Southern Research Institute; I have copies of part of it here. We will have all of it in the due course of time. There have been a number of statisticians, one from NASA, some from other, very reputable groups, that look at these studies, which totally condemned Laetrile. They used them, interestingly enough, on a very resistant strain, the Lewis lung strain, they used the osteogenic sarcoma, which I don't know too much about, the Ridgeway, the P–38 leukemia, areas where we get our worst results in terms of—at least the evidence I've seen in terms of Laetrile. And the statisticians that have looked at this document, and the data provided by the Southern Research Institute state, openly, freely, it's in the literature, part of their statements are recorded here, that it was a very poorly designed statistical study. Dr. Burke, formerly of the NCI, who has looked at the same set of statistics, claims it proves just the opposite of the claims that they were making here under an NCI grant.

Now, when you talk about, are you willing to conduct the study, that you're personally going to go down there and supervise or whatever, I say, great. But I want to point out to you that the Laetrile proponents, and I'm talking about the serious—the ones that I have dealt with, in terms of serious intellectual proponents—are not trying to sell this as a drug. This particular compound is being sold primarily to the public—I'm talking about salesmanship now—as a food product.

The evidence that I see in the statistics of Seventh Day Adventists, of Mormons, to me indicates that these people for one thing are getting probably fewer microcarcinogenic insults because of the types of things that they do, No. 1. No. 2, I think that they are as a group—are ingesting a greater quantity of amygdalin than possibly most of the others.

We're talking about a preventive thing. Now, I've been working on the subject of drugs from the sea here, in this country, I pioneered this work. I have written probably toxicologically more than almost any living man.

Senator CHAFEE. Mr. Chairman, may I ask a question? Are we talking preventative?

Dr. HALSTEAD. Yes, we are.

Senator KENNEDY. We haven't been before.

Dr. HALSTEAD. Well, I am now. Because I think that the main issues——

Senator KENNEDY. You don't believe that it's curative?

Dr. HALSTEAD. I'm not prepared at this moment to make a final decision in terms of the curative properties. I am talking primarily—I wish I had the time to go through what I believe is the current thinking as to what causes cancer. And I think I could show you the bio-

chemical rationale of what I am talking about. Because it does make good sense.

Senator KENNEDY. We want to hear from Mr. Bradford, and unfortunately, we're going to vote again; one of our colleagues on this committee, Sen. Hayakawa, is offering amendments. So we're going to.

But before we do, Dr. Halstead, the head of the Food and Drug Administration has welcomed any information, any scientific information, any materials that would be useful or helpful. If you have that kind of information, if you have new information, I'd be glad to do everything I could to set up an appointment with him, or with the scientists in research over there, so you could submit that to them.

Dr. HALSTEAD. Senator, this question has been argued for 137 years, and I can't argue——

Senator KENNEDY. There's nothing new, then, in that——

Dr. HALSTEAD. No, this is what I'm trying to tell you. One hundred and thirty-seven years by the clock we've been arguing the issue of the anticancer activity of Laetrile. I think it's high time that a country that has a gross national product of $1.4 trillion, or excess thereof, can certainly take time to find out once and for all as to whether or not this compound is useful, No. 1, as a preventative, No. 2, as a therapeutic agent.

Senator KENNEDY. Well, we agree with that bottom line.

Dr. HALSTEAD. And we're getting nothing but a shower of, frankly, cat crap.

Senator SCHWEIKER. Well, doctor, on that point, you said that if you were given 15 minutes you could outline specific studies that would contradict——

Dr. HALSTEAD. Not 15 minutes.

Senator SCHWEIKER. You could need more than 15 minutes?

Dr. HALSTEAD. We need time, if I could get the time, I would like to slowly go through——

Senator SCHWEIKER. Well, how about this: could you present to this Committee in writing, a summary of what you feel the scientific evidence is that invalidates the claim that no scientific proof is on the side of Laetrile? I would certainly read it, would you do that?

Dr. HALSTEAD. You know, you're asking me to do this at my total, personal expense. Because, when I do this, if you'll look at my three volumes of what I wrote for the U.S. Government, I will do an exhaustive study, or I'm not going to do any. And you're asking me to personally at my personal expense provide the U.S. Government, who has seemingly unlimited amounts of money, and they cannot seem to come up with this data. This data is available in the documented literature. If anybody wants to stand the cost, I would supervise the work.

Senator SCHWEIKER. Well, it was your idea originally, Doctor. I picked it up because it was your suggestion to us that if we would listen to you for more than 15 minutes, you could document the case for Laetrile.

Dr. HALSTEAD. I would like to go through——

Senator SCHWEIKER. I didn't ask you to do it. You volunteered to do it.

Senator KENNEDY. And we'll set it up——

Dr. HALSTEAD. When you have the time, I will appear here and go over the entire thing with you. Because you'll have quite a few——

Senator KENNEDY. Well, I think it'd be more important to set it up with the Commission. And we'll be glad to set it up with the Commissioner. We'll have a secretary, a stenographer, that will take it all down so that you don't have to go to writing, if you could spend just the time—we'll do it this afternoon, just with a recorder, and we'll type it up. If you'd just be good enough to do it that way. We want to hear from Mr. Bradford, but we'll make that a part of the record, we'll send it over there. We'll get you their comments, and you can come back to us in terms of your reaction to it.

I want to hear from Mr. Bradford, if we could, if that's all right.

Mr. KREBS. There is one very short cut, and this was in human pancreatic cancer, where the average life duration after diagnosis is 6 to 8 months, we have 14 such patients through the country under Laetrile that have been surviving 22 months. That one test tumor can give you the answer, if it is done routinely and just subject to simple statistical analysis.

Senator KENNEDY. Mr. Bradford.

Mr. BRADFORD. Thank you, Senator.

I am Bob Bradford, and I am president of the Committee for Freedom of Choice, and I have submitted to the committee and exhaustive analysis, a 31-page analysis, of what I believe the problem is.

I'd like to address myself to a couple of points I believe which are of major concern to you, and to this committee.

And one of those points is simply, why the controversy, why the divergent results between proponents and exponents of Laetrile, and indeed, why the divergent results between the orthodoxies of one set of tests and another. I think these are all very rational.

First of all, I am an electronics engineer. I am a former member of Stanford University. I've been a consulting engineer in electronics and medical electronics for some of the largest companies in this country, including General Electric, RCA, Varian Associates, and Litton Industries.

I am a quality control consultant for Cyto Pharma de Mexico, which is the only certified Laetrile manufacturing company in North America. I am on the Board of Directors of Cydel Clinic in Mexico, the Onocological-Metabolic Research & Treatment Center, operating under the auspices of the Mexican Government.

Senator CHAFEE. Mr. Bradford, can I ask a quick question?

Mr. BRADFORD. Yes, sir.

Senator CHAFEE. As a former staff member of Stanford University——

Mr. BRADFORD. Yes, sir.

Senator CHAFEE. In what capacity were you there?

Mr. BRADFORD. I was in a research—I was an engineering research staff member. I was part of the development team that built the Stanford linear accelerator.

Senator CHAFEE. What year was that?

Mr. BRADFORD. I was—let me see. It was from 1955—1965, pardon me—up to about 2 years ago, when I resigned from Stanford University.

Senator CHAFEE. 1965 to 1975, something like that?

Mr. BRADFORD. Yes, sir, about 11 years.

Senator CHAFEE. Thank you very much.

Mr. BRADFORD. You're welcome.

Now, first of all, gentlemen, I think that this committee, and many of the speakers here, are extremely naive if one takes a simple premise that all the proponents or all the individuals on one side of this question are honorable, and all the individuals on the other side of the question, are dishonorable.

Let me stress that I believe that for a number of reasons it is quite likely, and not only likely, but has, in fact, happened, that a group of well-credentialed scientists on both sides of this issue have come up with differing results on Laetrile.

Prior to doing that, I would like to state for the record that the Committee for Freedom of Choice, in addition to vigorously pursuing State decriminalization and freedom of choice legislation, at the State and Federal levels, offers—operates a national doctor-patient referral system, we hold lay symposiums, and we hold doctors' workshops throughout the country on Laetrile and metabolic therapies.

We are currently working with State health departments, pharmaceutical concerns, universities, and cancer centers in designing experiments for Laetrile metabolic programs, for cancer control.

We are collaborating with Government offices on labeling requirements, as well as administration. And we are making available to all interested parties the identification criteria, quality control, and manufacturing processes, so that certified Laetrile may be manufactured within the continental limits of the United States by anyone who wishes to do so.

I would like to offer into evidence a letter to Vincent DeVita, M.D., director, Division of Cancer Treatment, National Cancer Institute, Bethesda, Md.

[The letter to Dr. DeVita follows:]

THE COMMITTEE FOR FREEDOM OF CHOICE IN CANCER THERAPY, INC.
148 MAIN STREET • SUITE 408 • LOS ALTOS, CALIFORNIA 94022 • (415) 948-9475

July 7, 1977

Vincent DeVita, M.D.
Director, Division of Cancer Treatment
National Cancer Institute
Bethesda, Maryland

Dear Doctor DeVita:

As the major proponent of Laetrile research and decriminalization efforts in this country, the Committee for Freedom of Choice in Cancer Therapy, Inc., cannot help but be cheered by news that the National Cancer Institute will, at long last, undertake clinical trials of this greatly misunderstood compound.

We are, however, somewhat distressed that what we see as a decisive and fair trial is, apparently, not contemplated by what NCI has in mind. No genuine human trials will resolve the controversy unless; (a) Laetrile is administered as part of an overall metabolic therapy, (b) this program is provided exclusively--that is, not as an adjunctive to chemotherapy and/or radiation and/or surgery; and (c) it is administered by a metabolic physician with experience and training in this admittedly new field.

Nonetheless, we agree that in a testing program in which one group of "terminal" patients is provided with the recommended dosage of certified Laetrile vs. another group which does not receive Laetrile, at least insinuations of possibly significant statistrics might be obtained. And this is at least something.

But we cannot imagine NCI being albe to conduct even this limited-value trials without at least some input, let alone monitoring, by experienced Laetrile experts. It is for that reason that I should like to offer the services of the Committee in providing one or more physicians or researchers to participate in your contemplated program. Our candidates would be persons who by experience and training are competent in cancer therapy and acquainted with Laetrile dose levels, responses and its use with other therapies, or by itself, or--ideally--as the central ingredient in a total metabolic program.

I personally and the Committee in general are at your service in any way at all in which we may be useful in furthering Laetrile trials, and I hope to hear from you at your earliest convenience.

Sincerely,

Robert W. Bradford,
President

Mr. BRADFORD. Now, I charge Senator, that orthodox medicine is not qualified to evaluate Laetrile either by experience or by education. It has been demonstrated right here today that mouse studies, for instance, transplanting human tumors in mice and then attempting to control those tumors with Laetrile, was ineffective. We could have saved the Government thousands upon thousands of dollars if they had just collaborated with the pro-Laetrile people before they started the test, because that isn't the way it works.

Now, if they are going to use any more of the taxpayers' money, the only thing that we're asking them to do is to collaborate with the people who've had 20 years of experience on how to use this compound. Now, I don't think that's too much to ask. We are openly offering our services in this area to anybody, this committee, or any Government agency who wants it, up to our financial capabilities. And I'd like—Senator, I'd like to stress at this point that the Freedom of Choice Committee had a budget last year of slightly over $100,000. Compared to just the ACS alone, which had a budget of nearly $1 million. So if one asks why some of this data is not available now, it is because you're looking at this table at the people who have to do it all. We can't hire secretaries, or computers. And we don't have large banks of people to do the work for us. We need your help. And that's one of the reasons why we're here, not to cause additional fractions between the various groups. We're asking for your cooperation, and we're offering ours.

Senator KENNEDY. You say you're just a small group, yet you're talking about the treatment of various people, thousands of people in this country. All we're asking is that we get at the independent study. We've agreed now in terms that it'll by the Merck definition. We'll get an independent review and a scientific evaluation. And that's the way that it should be done. We don't permit, when the drug companies put forward a particular drug, that they're going to be the ones who are going to decide how a particular drug is going to be evaluated. We use the test and the procedures which were established to do it.

And I would hope if we can get the questions of the ethical consideration, which are very significant, that we'd publish in the Federal Register how that particular model was going to be established, and if we'd invite the scientific community to make comments, and we'd invite your people to make comments.

Mr. BRADFORD. I think that's the only way that it can be done.

Senator KENNEDY. Pardon?

Mr. BRADFORD. I think that's the only way that it can be done, Senator.

Senator KENNEDY. And the only thing that we can agree on, of course, is that we ought to suspend it until we get a final definition. I mean, that's the way it is done in terms of other drugs. You don't continue to use it until you prove it one way or the other.

I think that this is really the appropriate way to proceed on it. We're on the record now in terms of following that profile, or that model, or that test. I think we'll make a lot of progress.

Mr. BRADFORD. I would like to also stress, Senator, and I do not want to leave the impression with this committee or on the Senate record that this information has not been available, and we have not tried to cooperate in the past.

As you may or may not know, at the Kansas City hearings, we offered clinical data to Dr. Young, who is head of the new drug section of NCI, and he made a statement before that committee to the end that he found this data and information extremely interesting, and that he would visit our Cydel Clinic.

There were 14 cases. Last week we presented another 30 cases from the Cydel Clinic to NCI. So we are doing everything within our limited power.

I'd like to also put everything in proper perspective. And when we talk about Dr. Richardson whom—and not only Dr. Richardson, but the some other 1,200 physicians in this country who brought this whole issue to the American people. I'm really proud to be associated with them.

Now, these doctors are not on grants. They have practices. And not only that, they have been harrassed in this country for 4 years. It hasn't been easy for these physicians to generate the type of statistical information that is required to show the efficacy of this drug in this country. That's why the Cydel Clinic exists, because we put up a clinic outside of this country utilizing all orthodox modalities as well as the metabolic approaches to cancer patients, utilizing computer patient workups, utilizing all the facilities including nuclear scanning, diagnostic X-rays, complete laboratory facilities. And this is the information that is now being presented to NCI and to the FDA. So we are doing everything in our power to comply, and to bring this to a head.

Now, I would like—yes, sir.

Senator SCHWEIKER. I want to ask one question on a statement you made earlier. You cited the mouse experiments. You believe those studies were poorly designed—they were a waste of money, because that isn't the way Laetrile is supposed to work.

Mr. BRADFORD. That's right.

Senator SCHWEIKER. Now, in a nutshell, in layman's language, how does Laetrile work?

Mr. BRADFORD. Dr. Krebs, you want to just respond to that very briefly.

Senator SCHWEIKER. I mean, there's no sense in having a whole new set of experiments if they're going to be controversial before we start. That's why I do support the concept of airing the procedures and getting agreement before setting up the studies, so that the results will be acceptable to both sides. Otherwise, the results will be disputed and we'll just be back where we started.

Mr. KREBS. Yes, Senator Schweiker, the one area of honest difference, and of contention, between the Laetrile clinicians, on the one hand, and the standard on the other, is the matter of gross tumefaction, the lump or the bump. We contend that the lump or bump, the tumor, is but a symptom of an underlying systemic dietary deficiency state, a dysmetabolic state. And this is the state that is corrected by the administration of Laetrile or vitamin B–17. The lumps or bumps do not magically disappear.

And all over the country, these people who are indeed the architects of the Laetrile victory, these patients who have been on Laetrile for 4 or 5 years are still carrying these lumps and bumps, and very many of these patients who are examined today by an honest, competent surgeon would be told, my God, if you don't get into surgery and have this cut off within the next month, you're not going to live, you're not going to make it.

96-492 O - 77 - 18

You see, we are faced with a scientific revolution just as profound as the germ theory of disease. It's just as profound as the difference between the Copernican theory and the tables of Ptolemy. This is—we do not necessarily speak the same language. Those in the Laetrile movement, and those out of it.

This is not difficult to understand in view of the fact that 400,000 Americans are dying every year. This is new testimony to the total futility of what we're doing. And as I've urged to Senator Kennedy, and I would repeat, much more important at this juncture than the Laetrile program itself is to bring in men like Professor Hardin P. Jones, put them under oath, bring in experts, and let them dissect this contention that the cancer population, when considered as a population, live for a shorter period of time and suffer more when treated than if left entirely alone.

Hardin Jones' findings have never been raised. They're just been allowed to accumulate dust. We may well be dealing with a situation here in which the retreat to Laetrile represents a retreat from agents that are counterproductive. This may account partially for some of the enthusiasm.

The scientific thing to do is to find out whether or not what we are doing today is, or is not, counterproductive, whether or not the death rate of cancer in America would be lower or higher if we suspended all therapy totally.

Mr. BRADFORD. Let me just summarize for you.

Senator SCHWEIKER. I'm trying to find out how to find out. That's my problem.

Mr. BRADFORD. Pardon?

Senator SCHWEIKER. I'm trying to find out how to find out.

Mr. KREBS. Oh, by review of Dr. Hardin B. Jones' excellent monograph on the demography of the cancer population. And this has never been questioned or challenged. It's just——

Senator SCHWEIKER. Well, how about tests on Laetrile? I'm trying to pin down what kind of tests you folks would——

Mr. KREBS. Before the test, Senator, I would—this may seem a little pedestrian—I would urge a reassessment of these findings that have been ignored. Because there is no economic or social or trade impulsion to investigate these findings of Hardin B. Jones.

Senator SCHWEIKER. But he didn't ever do anything on Laetrile, did he?

Mr. KREBS. No, no, sir. And this is the guide you—this would be the value of this work. His conclusions point to the—this, that when we look at the cancer population as a population, those left entirely untreated suffer a little less and live a little longer than if treated.

Now, that's a terrible, terrible statement for Professor Jones to make, and allow this statement to go unrefuted. But there are thousands of these practitioners in America who accept what Jones says.

Mr. BRADFORD. I think we've got off to the question of whether or not orthodox therapy is effective or not. And just to summarize, the state that we are in, the protocols that exist for orthodox therapy are not applicable for the most part, to metabolic therapy and Laetrile. I don't know whether you caught that or not, Senators. And this is one of the reasons why we're having problems.

The protocols and screening techniques as they exist today are not applicable to Laetrile and metabolic therapy. And this is one of the reasons why collaboration is going to be absolutely necessary if we're going to receive any—or we're going to get any meaningful data, anything that both sides are going to accept. So this is the basic problem.

I have another problem——

Senator KENNEDY. But you're not reneging on our agreement to put a test——

Mr. BRADFORD. Absolutely not. All I'm saying is, it's going to be difficult. Sloan-Kettering a couple of weeks ago said they didn't know how to set up protocols for metabolic therapy. And all I'm saying is, it has to be done. It hasn't been done for 20 years, and we're willing to work on it.

Senator SCHWEIKER. I'm trying to find out how to do it.

Dr. RICHARDSON. Perhaps, Senator, I could give another little bit of an insight into the way I think of this, that normally you have a cancer cell that has a job to do in the normal body, and it is under a surveyant factor, which is a vitamin, vitamin B–17. And if you're taking this vitamin, then you keep this population under control. If you become deficient in that vitamin, then that cell, that potential cancer cell, begins to spread and metastasize. At some particular point, then, the body is going to have an immune reaction, it's going to attempt to surround a collection of these malignant cells. And then you're going to have your tumor.

So the cancer itself started way, way, way back. I mean, the metabolic deficiency disease started way back.

Senator SCHWEIKER. Well, what if we give one group of terminally ill cancer patients Laetrile, and not give Laetrile to a control group? Is that the sort of test you have in mind? Is that what you're talking about?

Dr. RICHARDSON. No, I'm just talking about in the normal person, we have a normal cell——

Senator SCHWEIKER. My question was, how do we have a fair test of Laetrile? How do we set up a study that will be acceptable to you?

Dr. RICHARDSON. I'm getting to the point. It's going to be difficult unless you would say, now, everyone in the country can take vitamin B–17. And the sooner you did that, the sooner the price would plummet, drop to nothing.

Senator SCHWEIKER. Well, what's wrong with a test involving one group that's taking it and one that isn't?

Mr. BRADFORD. As long as you include a complete metabolic program, there wouldn't be anything wrong with it.

Dr. RICHARDSON. We're talking about a preventative; that's the true value. Now, when we got over the bridge to that final phase, that terminal phase, then we're dealing with a tumor that Laetrile isn't going to get rid of. Sometimes it does, and that's great. But the whole thing is, that they will notice this immediately, and they did in the 1953—wasn't it 1953?—California report, when it was used for cancer then, which shows that it's been grandfathered, incidentally.

But at that point, they noticed—did you catch that?—they noticed at that point that a person was relieved of pain, didn't have any pain. This is one of the things we noticed in our clinic.

OK, second thing, their appetite increase, their weight gains, and they have a feeling of well-being. This is what they will notice in that terminal patient. It can be given with all other things, but the other things might be making him sick, and, you know, nauseated, and there might be other side effects. So it wouldn't be a consistent testing of Laetrile by itself. You see what I'm saying? They will notice this, but they're not going to notice tumors going away. They might. Sometimes they do.

Mr. BRADFORD. I think we're getting into the actual protocols now, John.

Senator KENNEDY. You've got just a minute or two left for the——

Mr. BRADFORD. Let me finish then, if I may, in the rather short period of time that we have.

And I'd like to just sum up by saying that I'm very proud of the progress that the committee has made, and some 1,200 doctors using Laetrile have made.

But I'm here among other things to warn this committee of my concern. The longer the FDA continues to treat Laetrile as an illegal substance, the sooner is the time before authentic organized crime gets into the act. You cannot have a market as vast as the Laetrile market is now with a demand so great for a compound so harassed, without driving it into the hands of organized crime, Senator.

And gentlemen, if there are already abuses in Laetrile pricing and distribution, and if organized crime does surface in Laetrile, you can place the blame squarely, inexorbitantly, at the door of the Federal Government.

Rest assured, gentlemen, that the people demand Laetrile. You saw that in your recent Harris poll. And they are going to get it whether Big Brother wants it or not.

So those are the realities of life. Our organization has offered its good offices to work with the establishment in using and testing Laetrile. We repeat that offer now. But we cannot expect that thousands of American cancer sufferers are going to wait for more long years, while the Federal Government fiddle-faddles through animal tests and more redtape.

Senator, gentleman, the hot potato really is in your hands.

Senator KENNEDY. Well, the hot potato has been in our hands here this morning and quite clearly indicates that according to the best scientific information from the Food and Drug Administration, from researchers from every important scientific institution in this country, find contrary to what your own findings are in terms of scientific fact, that there isn't a scintilla of evidence that it provides any sense of hope in terms of curing or preventing cancer.

That's the record to date, that in the instances that there's been wholesale profiteering in terms of this, this substance, that there have been gross malpractices, and a number of the individuals who both appeared here today, in terms of the distribution of it; and the lesson from this hearing ought to go on out very clearly, that it's unwise, certainly, for any American to be willing to experiment or accept this particular drug and believe that they are going to be dealing with the disease of cancer. That's the hot potato.

The one thing that we have indicated on this is that if there is new information, that we would not be responsible if we didn't provide

some opportunity of some vehicle for those to present that information, the same way that any drug company presents its information, to be subject to the same kind of scientific review, the best in terms that this country can provide, and that we'll certainly work, as members of the committee, to insure and insist that we try, given the ethical considerations, that that test be done.

And my commitment is, if that test is done, and it does show that it is meaningful in terms of it, you're going to find that you have no finer champion in terms of legitimatizing this. But if it doesn't, your commitment is to stop, halt, cease raising false hopes among the American people that there is some panacea, and some people whose families have been struck by cancer, and in the most vulnerable times of their lives, are not going to listen to slick salesmen offer a false sense of hope. And that is what the conclusions of this hearing is this morning, and we ought to understand what that conclusion is, at least in terms of my own position.

Mr. BRADFORD. Your insinuations, Senator, are not acceptable, but your plan is acceptable, and we will cooperate on it.

Senator KENNEDY. Fine.

The subcommittee will stand in recess.

Senator CHAFEE. It seems to me you are running around the bend. The IND provides for going through a process that this Government, through scientific evidence, has found the best way to proceed.

Mr. BRADFORD. If you want to give me 3 minutes, I will tell you why we will not use an IND.

Senator CHAFEE. You have made the statement about the black market and crime and all that, but it seems to me from all the allegations that you had that I haven't heard rebutted, that those presently involved are making a good bit of money.

Dr. RICHARDSON. I haven't heard that proved today, or in any court trial I have been in. I have heard it alleged.

Mr. BRADFORD. Let me——

Senator CHAFEE. The statement was made by previous panels.

I would like to address this to you. Who is making the money?

Mr. BRADFORD. I don't think anybody today is making money. Those statements were made in San Diego, and could not be substantiated, and I think it is plain gall that the district attorney would walk up here and use the same figures that he couldn't substantiate before the jury in California.

Senator CHAFEE. What is this being sold for?

Mr. BRADFORD. The Mexican Government has set the price for a vial of amygdalin, that is three grams, at $9. A patient in the United States through a physician would pay $10.50 for that vial. That is a minimum markup.

If you look at other drugs, they go up 10,000 percent. The pharmaceutical people tell us that that same vial could not be sold in this country for less than $30 a vial if we weren't handling it.

Senator KENNEDY. Let me ask Dr. Richardson, was there deposited in a single bank account some $2 million?

Dr. RICHARDSON. Senator Kennedy, I explained it to you once.

Senator KENNEDY. Will you please answer?

Dr. RICHARDSON. I will refer to page 77 of my book. We put into our gross office practice account a certain amount of money.

Senator KENNEDY. What was that amount?

Dr. RICHARDSON. Well——

Senator KENNEDY. Tell us now.

Dr. RICHARDSON. I could explain it to you. I didn't really think I would have to defend myself all over again on this, but I will explain it to you.

There were two accounts. One of them had, we will say, over a 2-year period of time, $1½ million gross.

Senator KENNEDY. $1½ million?

Dr. RICHARDSON. Wait a minute, please. Our lawyer told us, because of the peculiar circumstances, that we should create another checking account.

Senator KENNEDY. Peculiar circumstances?

Dr. RICHARDSON. Every day we take half of the gross amount and put it in the vitamin purchases account. Mr. Hoffman came along and added the two together and said, Dr. Richardson has deposited in bank accounts——

Senator KENNEDY. $1½ would be a closer estimate?

Dr. RICHARDSON. I will give you what that was for any particular year on your written request, anything you want, but it is all in the book.

Again, I am saying that is a gross account. There is no reference to the private account, so I don't see how anybody gets around to computing it.

Mr. BRADFORD. But I think the Senator's question should be answered with regard to——

Senator KENNEDY. It should be answered.

Would you submit it in writing?

Senator CHAFEE. Say it quickly. We have 7½ minutes to vote.

Mr. BRADFORD. Indeed, the compound amygdalin, and Laetrile is really only a brand name for the refined, purified extract of amygdalin, has been isolated and known about and used medically for well over a century. There is no mystery about this compound. Nor is there any mystery about the extraction process. A high school scientist, with a supply of apricot kernals, alcohol, and ether, storage space and some refrigeration equipment, can make Laetrile. The extraction process, just like amygdalin itself, is in the public domain.

Still, it takes 2,000 pages of data, 10 years and, what is more important, about $20 million to do it.

Now, if you don't have a substance that is patentable, you can't generate funds for it.

Now, take Valium for instance.

Senator CHAFEE. Let us just stick with this.

Mr. BRADFORD. That is the reason, Senator.

Senator CHAFEE. At this point we will include in the record the full statements of Dr. Richardson and Mr. Bradford along with some additional statements supplied. However, due to mechanical limitations and in the interest of economy, certain material submitted for the record (too voluminous for reprinting) may be found in the files of the subcommittee.

[The prepared statements of Dr. Richardson and Mr. Bradford, and additional material supplied for the record, follows:]

Prepared Statement of Dr. John A. Richardson, Albany, California

-1-

Let me begin with a short biography. I was in college when our county was attacked and forced into World War II. I quit school and joined the Marine Corps. After successfully completing the Officers Candidate School Training, I served in Guam, Saipan and China as a first lieutenant. Following the war I returned to Hamilton college where I played football and served on the student council and honor court. After being graduated I entered medical school at the University of Rochester and upon completion of my studies received a fellowship for medicine and surgery at Mary Imogene Bassett Hospital in Cooperstown, New York. Continuing to prepare myself for practice I accepted a fellowship in ear, nose and throat at Kaiser Hospital in San Francisco.

Finally, in 1956, I opened a general practice in Albany, California. It grew rapidly and I became both professionally and financially successful.

I first heard of Laetrile in 1969 through Ralph Bowman, who is now my office manager. While traveling and doing promotional work in a non-medical field, Mr. Bowman, quite by chance, met a woman who had been declared a terminal cancer victim. This lady's cancer had been brought under control through the use of Laetrile.

Mr. Bowman, who had been a close personal friend for a number of years, enthusiastically brought me an armload of literature on the subject. I was curious, but dubious, as are all trained physicians about claims concerning mysterious, magic potions which purportedly slay the cancer dragon.

Some weeks later while taking a brief vacation, I began to delve into the literature on Laetrile, or, as it is also known, amygdalin or Vitamin B17. This vitamin is extracted from apricot seeds and contains a substance from a family known as nitrilosides. I discovered that these nitrilosides occurred in nature not only in apricot seeds

but also in peach seeds, bitter almonds, and some 1,200 natural sources. Tonight, if you have lima beans with your dinner, you will be ingesting nitrilosides.

I learned that there are parts of the world where the everyday diet is high in nitrilosides; and I noted that the higher the natural diet is in this substance, the lower the incidence of cancer. It was hypothesized that these nitrilosides are connected to the immunity system which exists in each of our bodies. One noted, for example, that in the last century, millet, which is high in nitrilosides, was a staple in the American diet. Since that time, wheat, which is low in nitrilosides, has replaced millet on our tables even as the incidence of cancer has been steadily increasing.

Such information was fascinating, but strictly academic since I did not treat cancer patients as part of my practice. Then one day my nurse, Charlotte Anderson, came to me almost in tears to announce that her sister had cancer. She wanted to know if I would treat her with Laetrile shots. Whether to do this was a very difficult decision. I told her that the proponents of Laetrile did not claim that it was a cure for cancer, but that it often acted as a control much in the way that insulin, not a cure for diabetes, serves to control that disease. My nurse believed that her sister's chances were better with Laetrile than through the traditional forms of treatment - composed of cutting (surgery), burning (radiation), and poisoning (chemotherapy).

At that time I had no idea of how political the treatment of cancer had become, and how politics and self-interest now so often supersede the search for medical cures. I did know that the treating of cancer with Laetrile was frowned upon by the medical establishment. But my Hippocratic Oath as a physician was and is more important to me than politics, the whims of bureaucrats, the vested interests of drug

companies and research institutions, or even the current fads of those who claim to speak for the medical profession. I knew I could not refuse to treat my nurse's sister without betraying my Hippocratic Oath and becoming a traitor to my conscience. What I did not then realize was that I was about to bring down upon myself and my family the vengeance and hatred of a professional machine that felt its authority threatened.

Kaiser Hospital had biopsied a melanoma on the arm of my nurse's sister and wanted to amputate immediately. Consider what it meant to her and all of us when she responded beautifully to the Laetrile treatment. I saw her recently at a wedding, and gentlemen, she came up to me and grabbed both of my hands . . . with both of her hands.

With such splendid results, I began using Laetrile with other patients as part of an overall nutritional program. The use of Laetrile is legal in the State of California as long as it is not being used specifically and exclusively as a treatment for cancer. But I soon found myself the victim of harassment by armies of state and federal bureaucrats.

Much of the cancer research has been sponsored by the American Cancer Society, established long ago by the Rockefeller family and some of its business friends. Since they were in the petroleum and drug businesses they were interested in looking for a solution to the cancer threat that involved the use of synthetic drugs. Most synthetic drugs have a coaltar base; that is, they are derivatives of petroleum.

Over the past several decades, the American Cancer Society has financed and directed the vast majority of the cancer research in this country through grants. If you wanted money to do cancer research you were most likely to get it by looking in an area which involves

the use of coaltar based chemicals and assorted synthetic medicines.

Maybe they have not been looking in the right place. There is another theory on the prevention and control of cancer. This lies in the field of orthomolecular medicine, a term coined in 1968 by Dr. Linus Pauling, the famous Nobel laureate.

Orthomolecular medicine involves preventing and treating disease through the use of vitamins, minerals and enzymes.

As much as $28 billion is spent each year in the fields of cancer research, detection and treatment. You could put the portion of this $28 billion which goes into orthomolecular research in your eye and it would not blur your vision. The bureaucrats, foundation powers, and medical politicians do not intend to be proved wrong. The answer is going to be found in synthetics come hell or high water. In the opinion of those of us in orthomolecular medicine, this means it may never be found at all while Americans continue to die horribly at the rate of 370,000 a year.

I have treated over 5,000 patients with Laetrile. I used the substance because of the empirical evidence that in many cases the patient is greatly benefited. Keep in mind that most of the patients who came to me did so as a last resort after their doctor has told them that they will die within a few days to a few months. These people have undergone all the traditional therapies which have failed.

Many of these people cannot be helped because the cancer has gone too far and destroyed the vital organs beyond their ability to regenerate themselves. However, a substantial percentage of these people do receive great relief from pain, their appetite returns and they feel much better. We cannot save their lives, but we can allow them to die without being narcotocized, without pain and with dignity.

Many patients, however, do make astounding progress at bringing their cancer under control. I have compiled a book, LAETRILE CASE HISTORIES, a copy of which is submitted herewith. This book documents the case histories of sixty-two of these people. The number of people responding to treatment with Laetrile far exceeds the possibility of "spontaneous remission".

One of the most maddening tricks used by the Medical Establishment to discredit Laetrile is to assert that its proponents make claims which they do not.

I do not know of a single M.D., providing his patients with Laetrile who claims the substance is a cure. At best, it brings the disease under control. But, it does work substantially better than the traditional methods of cut, burn and poison, particularly when used as part of a complete program of nutritional therapy involving a special diet with supplements of minerals and enzymes.

When a better treatment for cancer is developed, I will be among the first to embrace it. In the past, before my license was revoked for using Laetrile in my practice, my conscience and the Hippocratic Oath could not permit me to stand idly by while 370,000 people died agonizing deaths each year when a substantial percentage of them could be helped.

Submitted by:

JOHN A. RICHARDSON, M.D.

July 8, 1977

THE COMMITTEE FOR FREEDOM OF CHOICE IN CANCER THERAPY, INC.
146 MAIN STREET • SUITE 408 • LOS ALTOS, CALIFORNIA 94022 • (415) 948-9475

STATEMENT OF ROBERT W. BRADFORD, PRESIDENT
SENATE SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH
JULY 12, 1977

MR. CHAIRMAN, AND HONORABLE MEMBERS OF THE SENATE SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH:

MY NAME IS ROBERT W. BRADFORD. I AM AN ELECTRONICS ENGINEER, HOLDER OF NUMEROUS PATENTS, AND PRESIDENT OF THE COMMITTEE FOR FREEDOM OF CHOICE IN CANCER THERAPY, INC., A FIVE-YEAR-OLD NON-PROFIT EDUCATIONAL ORGANIZATION WHICH HAS LED THE FIGHT FOR THE DECRIMINALIZATION OF LAETRILE OR VITAMIN B-17 IN CANCER THERAPY ACROSS THE UNITED STATES. THE COMMITTEE, WHICH IS HEADQUARTERED IN LOS ALTOS, CALIFORNIA, HAS APPROXIMATELY 35,000 MEMBERS IN 500 CHAPTERS IN ALL PARTS OF THE UNITED STATES, INCLUDING PUERTO RICO. THE PROFESSION MOST ABUNDANTLY REPRESENTED IN OUR ORGANIZATION IS THAT OF MEDICAL ARTS, WHICH HAS 2,000 REPRESENTATIVES, AND OF THESE APPROXIMATELY 1,200 ARE MEDICAL DOCTORS.

ADDENDUM 1

holder of numerous patents RELATED TO ELECTRONICS AND PHYSICS. I AM A FORMER STAFF MEMBER OF STANFORD UNIVERSITY AND HAVE BEEN A CONSULTING ENGINEER IN ELECTRONICS AND MEDICAL ELECTRONICS TO SOME OF THE LARGEST COMPANIES IN THE COUNTRY, INCLUDING G.E., R.C.A. VARIAN ASSOCIATES AND LITTON INDUSTRIES.

I AM A QUALITY CONTROL CONSULTANT FOR CYTO PHARMA DE MEXICO, THE ONLY CERTIFIED LAETRILE MANUFACTURING COMPANY IN NORTH AMERICA.

I AM ON THE BOARD OF DIRECTORS OF THE CYDEL CLINIC IN MEXICO, THE ONOCOLOGICAL-METABOLIC RESEARCH AND TREATMENT CENTER OPERATING UNDER THE AUSPICES OF THE MEXICAN GOVERNMENT.

I WAS RECENTLY CONVICTED IN SAN DIEGO OF "CONSPIRACY" to smuggle LAETRILE INTO THE UNITED STATES. I WAS FINED $40,000 AND AM NOW ON 3 YEARS PROBATION WITH NO RESTRICTIONS WHATSOEVER ON MY LAETRILE-RELATED ACTIVITES.

ADDENDUM 2

and of these approximately 1,200 are medical doctors. WE NOW HAVE, ACCORDING TO THE RECENT HARRIS POLL, THE SUPPORT OF THE MAJORITY OF THE AMERICAN PEOPLE.

THE COMMITTEE FOR FREEDOM OF CHOICE, IN ADDITION TO VIGOROUSLY PURSUING STATE DECRIMILI ZATION AND FREEDOM OF CHOICE LEGISLATION AT THE STATE AND FEDERAL LEVELS, OPERATES A NATIONAL DOCTOR/PATIENT REFERRAL AND INFORMATION CENTER. WE HOLD LAY SYMPOSIUM AND DOCTOR WORKSHOPS WHROUGHTOUT THE COUNTRY.

WE ARE CURRENTLY WORKING WITH STATE HEALTH DEPARTMENTS, PHARMACEUTICAL CONCERNS, UNIVERSITITES AND CANCER CENTERS IN DESIGNING EXPERIMENTS FOR LAETRILE-METABOLIC PROGRAMS FOR CANCER CONTROL. WE ARE COLLABORATING WITH GOVERNMENT OFFICES ON LABELING REQUIREMENTS AS WELL AS ADMINISTRATION, AND WE ARE MAKING AVAILABLE TO ALL INTERESTED PARTIES THE IDENTIFICATION CRITERIA, QUALITY CONTROL AND MANUFACTURING PROCESSES SO THAT CERTIFIED LAETRILE CAN BE PRODUCED WITHIN THE UNITED STATES BY ANY ONE INTERESTED IN DOING SO.

I AM HERE TODAY TO DENOUNCE, AS FORCEFULLY AND FORTHRIGHTLY AS I CAN, WHAT I BELIEVE TO BE ONE OF THE MOST SCANDALOUS CHAPTERS IN AMERICAN HISTORY. THIS SCANDALOUS CHAPTER CONSISTS OF TWO PARTS — FIRST, AND MOST HORRENDOUS, THE ONGOING EFFORTS OF THE FOOD AND DRUG ADMINISTRATION TO DENY DYING CANCER PATIENTS ACCESS TO LAETRILE OR VITAMIN B-17 AND, IN SO DOING, ACTUALLY FLAUNTING A U.S. DISTRICT COURT ORDER; AND, SECONDLY, THE LONG, EVIL BATTLE OF ENTRENCHED INTERESTS TO DENY THE AMERICAN PEOPLE AND AMERICAN PHYSICIANS ACCESS TO LAETRILE.

LET ME DEAL WITH THE FIRST PART OF THIS SCANDAL FIRST, FOR IT DIRECTLY AFFECTS THE LIVES OF THOUSANDS OF CANCER SUFFERERS, ALL OF WHOM HAVE FOUND AT LEAST SOME RELIEF THROUGH THE USE OF LAETRILE AND THE TOTAL METABOLIC TREATMENT PROGRAM OF WHICH IT FORMS THE CENTRAL PART.

AT THE CURRENT TIME, THE FOOD AND DRUG ADMINISTRATION HAS BEEN ENJOINED BY THE U.S. DISTRICT COURT, WESTERN OKLAHOMA DISTRICT, FROM INTERFERRING WITH THE RIGHT OF AMERICAN CANCER PATIENTS TO IMPORT OR USE FOREIGN LAETRILE. THE INJUNCTION AGAINST THE FDA, RENDERED LAST YEAR, HAS BEEN SUSTAINED BY THE 10TH CIRCUIT COURT OF APPEALS.

THE INJUNCTION, AND A SYSTEM OF COURT ORDERS AND AFFIDAVITS WHICH FOLLOWED IT, BROUGHT AN END TO THENEED FOR AMERICAN CANCER PATIENTS TO HAVE TO BECOME CRIMINALS—THAT IS, SMUGGLERS—IN THE EYES OF THEIR OWN GOVERNMENT WHEN THEY WENT ABROAD FOR A FORM OF TREATMENT DENIED THEM AT HOME. HOWEVER, FOR THE PAST TWO MONTHS, THE FDA HAS GONE OUT OF ITS WAY TO JAM, THWART, AND OBSTRUCT THE COURT ORDER-AFFIDAVIT PROCESS. AGENTS ACTING IN BEHALF OF TERMINAL CANCER PATIENTS—PATIENTS TOO ILL OR OTHERWISE NOT DISPOSED TO MAKE THE TRIP TO TIJUANA, MEXICO, TO BRING IN THEIR OWN SUPPLIES OF LAETRILE OR VITAMIN B-17—ARE NOW BEING PREVENTED FROM ACTING AS INTERVENORS FOR THESE DESPERATELY ILL PATIENTS. IN THE CASE OF MYSELF AND MR. J. FRANKLIN SALAMAN, THE VICE PRESIDENT OF THE COMMITTEE, SOME $80,000 WORTH OF LAETRILE WHICH WE HAVE LEGALLY IMPORTED FROM MEXICO UNDER THE COURT ORDER-AFFIDAVIT PROCESS HAS BEEN HELD UP BY THE FDA FOR MORE THAN SIX WEEKS. THAT IS, WE HAVE BEEN UNABLE TO DISTRIBUTE IT TO HUNDREDS OF PATIENTS WHO BELIEVE THEIR LIVES DEPEND ON IT. THE FDA HAS USED EVERY EXCUSE IN THE WORLD TO TAKE UP TIME, TO STALL, AND TO PREVENT THE SHIPMENT OF THIS MERCHANDISE. QUITE SIMPLY, THE FDA MAY BE GUILTY OF MURDER.

IN THE MEANTIME, THIS REGULATORY AGENCY HAS INVOLVED ITSELF IN SOME OF THE MOST OUTRAGEOUS ACTIONS AGAINST AMERICAN CITIZENS IN THIS CENTURY.

In Tennessee, the FDA impounded more than 40 tons of apricot kernels from Douglas Heinsohn, a Committee regional chairman, apparently on the grounds that the kernels, from which-- it is true—Laetrile may be manufactured, were being shipped through the mails as medicine. This ridiculous, expensive, time-consuming harassment of Mr. Heinsohn was so blatant that a federal court in Tennessee threw the case out of court and returned possession of this natural food to Mr. Heinsohn. In Wisconsin, the FDA caused raids on the only domestic producer of Laetrile in the United States, seized supplies and caused the arrests of the plant's top officers. This case has also failed in a federal court.

Around the country, state and federal agents are photographing members of the Committee, inquiring as to their business practices and, in general, applying all the harassing pressure they can against us.

All of this might be somewhat comprehensible if either the Committee or Laetrile distributors were overtly breaking the law, or if either the Committee or Laetrile distributors were engaged in some dangerous and nefarious activity such as narcotics importation and distribution, or if the Committee or Laetrile distributors were somehow involved in endangering the public.

THE FACT IS, NONE OF THE ABOVE HOLDS. TO BEGIN WITH, EVEN AS WE DEBATE THE ISSUE, A DOZEN STATES HAVE DECRIMINALIZED THE USE OF LAETRILE OR VITAMIN B-17 IN CANCER THERAPY, AND AT LEAST A DOZEN OTHER STATES ARE WELL ON THE WAY TO DOING THE SAME. THE LOUIS HARRIS POLL OF THE LAST WEEK OF JUNE 1977 REVEALED, WITH ONE STATISTIC AFTER ANOTHER, THAT A MAJORITY OF AMERICANS SUPPORT THE DECRIMINALIZATION OF LAETRILE AND THAT AN EVEN GREATER MAJORITY SUPPORT THE CONCEPT THAT THE STATES HAVE THE RIGHT TO DECRIMINALIZE LAETRILE EVEN WHILE THE FDA'S UNWRITTEN BAN ON ITS INTERSTATE SHIPMENT AND SALE CONTINUES.

I SAY "UNWRITTEN BAN" BECAUSE THAT'S WHAT IT IS. CONGRESS HAS PASSED NO LAW AGAINST EITHER LAETRILE OR APRICOT KERNELS. INDEED, ONLY THE STATE OF CALIFORNIA HAS SPECIFIC STATUTES AGAINST LAETRILE, AND THESE HAVE SO FAR BEEN OVERWHELMINGLY DEFEATED IN THE STATE SENATE WITHIN THE LAST 30 DAYS. THE LEGAL OPPOSITION TO LAETRILE HAS COME ALMOST ENTIRELY FROM TH E FDA'S WHIMSICAL TREATMENT OF THE SUBSTANCE AS EITHER AN UNPROVEN NEW DRUG OR AN UNSAFE OR ADULTERATED FOOD PRODUCT. JUDGE LUTHER BOHANON OF THE WESTERN OKLAHOMA U.S. DISTRICT COURT HAS ALREADY RULED THAT THE FDA HAS NEVER, IN 14 YEARS OF DE FACTO BANNING OF LAETRILE, DEVELOPED EVEN A MINIMAL ADMINISTRATIVE RECORD TO SUPPORT ITS CLAIM THAT LAETRILE FALLS INTO EITHER OF THESE TWO CATEGORIES.

96-492 O - 77 - 19

THAT IS WHY JUDGE BOHANON ORDERED THE SPECIAL HEARING ON LAETRILE IN KANSAS CITY LAST MAY DURING WHICH, OVER A 2-DAY PERIOD, THE FDA SOUGHT TO DO WHAT IT HAD NOT DONE IN 14 YEARS—NAMELY, DEVELOP SOME KIND OF RECORD TO SUBSTANTIATE ITS ACTIONS AGAINST LAETRILE. GENTLEMEN, UNTIL JUDGE BOHANON RULED IN FAVOR OF CANCER PATIENTS IN THE CASE OF RUTHERFORD VS. THE U.S.A., FOR THE BETTER PART OF TWO DECADES AMERICAN CANCER SUFFERERS HAVE HAD TO LITERALLY SNEAK OFF TO FOREIGN COUNTRIES FOR TREATMENT WITH THE NON-TOXIC NATURAL FOOD FACTOR LAETRILE OR VITAMIN B-17, AND THEN BE TREATED BY THEIR GOVERNMENT AS SMUGGLERS WHEN THEY TRIED TO BRING THIS HARMLESS SUBSTANCE BACK WITH THEM. THE SCENARIO HAS BEEN ABSOLUTELY OUTRAGEOUS.

EVEN AS MORE AND MORE FEDERAL JUDGES AROUND THE COUNTRY HAVE FOLLOWED JUDGE BOHANON'S LEAD AND HAVE ISSUED COURT ORDERS TO INDIVIDUAL PATIENTS TO ALLOW THEM TO IMPORT LAETRILE, THE FDA HAS, NATURALLY AT TAXPAYER EXPENSE, ACTUALLY SENT ITS OWN ATTORNEYS INTO THE COURTROOM TO ARGUE AGAINST THE RIGHT OF THESE DYING PATIENTS TO HAVE ACCESS TO THIS LAST GASP OF HOPE. IT'S INCREDIBLE, BUT TRUE.

THE FDA HAS BEEN ABSOLUTELY AND UTTERLY DEAF TO THE PLEAS OF DOCTORS AND PATIENTS ALIKE IN THE MATTER OF LAETRILE.

THE SINGLE ARGUMENT ON WHICH THIS REGULATORY MONSTROSITY HAS FALLEN BACK REPEATEDLY IS THE LITANY OF "GO THROUGH THE NEW DRUG LICENSING PROCESS LIKE EVERYONE ELSE AND SHOW US YOUR EVIDENCE." LET ME EXPLAIN WHY WE'RE JUST NOT ABOUT TO GO ALONG WITH THAT.

FIRST OFF, WE FLATLY DON'T TRUST THE FDA. EVEN AFTER LAETRILE WAS DESCRIBED AS A VITAMIN, THE MCNAUGHTON FOUNDATION, STILL TRUSTING THE FEDERAL ESTABLISHMENT AND HAVING WORKED FOR SEVERAL YEARS TO GATHER DATA ON LAETRILE, DID MAKE A THIRD EFFORT, IN 1970, TO LICENSE THE SUBSTANCE THROUGH THE USUAL CHANNELS. I W LL NOT BELABOR THE DETAILS HERE, BUT WHAT HAPPENED IN 1970 WAS AT LEAST ENOUGH TO MAKE YOU WONDER: AN IND—THAT IS, INVESTIGATIONAL NEW DRUG—LICENSE WAS FIRST ISSUED TO TEST LAETRILE, THEN, WITHIN A WEEK, REVOKED, AND THE FOUNDATION GIVEN A BRIEF PERIOD OF TIME TO MAKE UP FOR ALLEGED "DEFICIENCIES" IN ITS EXTENSIVE AND THOROUGH DOCUMENTATION OF THE SAFETY AND EFFICACY OF LAETRILE IN ANIMAL STUDIES AND HUMAN USE. EVEN THOUGH THE MCNAUGHTON FOUNDATION COMPLIED WITH THE REQUEST FOR NEW INFORMATION AND HAD IT EN ROUTE IN THE MAIL IN TIME, THE FDA CAVALIERLY CLOSED ITS DOORS, CLAIMED THE NEW INFORMATION WAS NOW LATE, AND THEREFORE THAT THE FOUNDATION HAD FAILED TO COMPLY.

SECONDLY, EVEN IF WE DID MAKE AN EFFORT, IN 1977 OR ANY OTHER YEAR TO ATTEMPT THE LICENSING OF THIS NATURAL FOOD FACTOR THROUGH THE INCREASINGLY LABYRINTHINE PROCESSES OF THE FDA, IT WOULD MEAN, AS YOU GENTLEMEN MUST SURELY BE AWARE, A TIME PERIOD OF ANYWHERE FROM FIVE TO TEN YEARS OF ANIMAL TESTS, THE FILLING OUT OF UPWARDS OF TWO HUNDRED THOUSAND PIECES OF PAPER, AND AN EXPENDITURE OF ANYWHERE FROM FOURTEEN TO TWENTY MILLION DOLLARS, NONE OF IT RECOVERABLE BECAUSE THERE IS NO PATENT ON THE NATURAL FOOD FACTOR LAETRILE.

BUT THIRDLY, BY NO MEANS DO WE CONSIDER LAETRILE TO BE A DRUG, EITHER OLD OR NEW, LET ALONE AN ADULTERATED FOOD. EVEN IF LAETRILE WERE THOUGHT TO BE A DRUG, IT HAS BEEN GRANDFATHERED BY HAVING BEEN IN EXISTENCE AS A CANCER TREATMENT BEFORE THE FOOD, DRUG AND COSMETIC ACT WAS AMENDED IN 1962.

NOTWITHSTANDING THE BLEATINGS OF THE NATION'S MEDICAL AND PHARMACEUTICAL ESTABLISHMENT, MORE AND MORE BIOCHEMISTS AND SCIENTISTS ARE COMING TO RECOGNIZE THAT THE NATURAL COMPOUNDS WHICH MAY JOINTLY BE CALLED LAETRILE OR LAETRILES AND WHICH ARE SCIENTIFICALLY KNOWN AS CYANOGENETIC GLUCOSIDES AND SIMILAR DESIGNATIONS ARE, INDEED, VITAMIN B-17.

THAT IS, THEY ARE NON-TOXIC, THEY ARE WATER SOLUBLE, THEY ARE UBIQUITOUS IN THE PLANT KINGDOM, AND THEY ARE NECESSARY TO HUMAN METABOLISM. THIS IS BECAUSE CANCER IS A CHRONIC, SYSTEMIC, METABOLIC DISEASE CHARACTERIZED BY AN UNRELIEVED DIETARY DEFICIENCY—A DEFICIENCY OF VITAMIN B-17. SO, WE ARE SAYING, FIRST, THAT THERE IS NO NEED TO GO THROUGH THE FDA RED TAPE TO LICENSE THIS GOD-CREATED NATURAL FOOD IN THE FIRST PLACE, AND THAT EVEN IF WE TRIED ANY SUCH LICENSING WE HAVE NEITHER THE FUNDS NOR THE TIME TO WASTE ON AN EXERCISE WHICH, IF 1970 IS ANY INDICATION, WOULD BE FRUITLESS ANYWAY.

I HAVE SAID WE DON'T HAVE THE TIME. I SHOULD RATHER SAY THE AMERICAN PEOPLE DON'T HAVE THE TIME. EVEN WHILE WE'RE TALKING ABOUT IT, ANOTHER 1,100 CITIZENS WILL HAVE DROPPED DEAD OF CANCER BY MIDNIGHT TONIGHT. YES, THAT'S 1,100 A DAY NOW—OR WELL OVER 400,000 A YEAR, WHICH MAKES THE VIETNAM WAR PALE BY COMPARISON. DESPITE ALL THE PROPAGANDA EMANATING FROM THE AMERICAN CANCER SOCIETY AND THE NATIONAL CANCER INSTITUTE, WE ARE CONTINUING TO LOSE THE SO-CALLED WAR ON CANCER AND THE ESTABLISHMENT WILL NOT FACE UP TO THE FACT, JUST AS WHEN WE WERE LOSING THE WAR IN SOUTHEAST ASIA THE ESTABLISHMENT WOULDN'T TELL US THE TRUTH ABOUT THAT, EITHER.

IT IS ABSOLUTELY INCREDIBLE THAT, WITH A COMBINED PUBLIC-PRIVATE FIVE BILLION DOLLARS DUMPED INTO THIS LATEST PHONY WAR SO FAR, WE ARE NO CLOSER EITHER TO THE CAUSE OR CURE OF CANCER THAN BEFORE THE INVESTMENT WAS MADE. THIS IS IRRESPECTIVE OF THE AMERICAN CANCER SOCIETY'S 122 MILLION DOLLAR PER YEAR TAKE FROM THE AMERICAN PEOPLE. MORE PEOPLE THAN EVER BEFORE ARE GETTING CANCER AND DYING FROM IT THAN AT ANY TIME IN HISTORY. CANCER STRIKES ONE IN EVERY FOUR AMERICANS, KILLS ONE OUT OF EVERY SIX, HITS TWO OUT OF EVERY THREE FAMILIES, IS THE SECOND MAJOR KILLER OF ADULTS AND IS NOW THE PRIMARY CAUSE OF DEATH IN CHILDREN TO AGE 14. YOU CALL THAT PROGRESS? THE ESTABLISHMENT LIKES TO SAY THAT, MY, ISN'T IT NICE THAT IN THE 1930'S WE ONLY SAVED ONE OUT OF 5 CANCER VICTIMS AND NOW WE SAVE 1 OUT OF 3? BUT THE FACTS ARE THAT THE ONLY TINY ADVANCES IN CANCER RECOVERY RATES SINCE 1950 ARE DUE TO THE DEVELOPMENT OF ANTIBIOTICS AND BETTER BLOOD TRANSFUSION TECHNIQUES—THAT IS, PEOPLE TODAY ARE MORE APT TO SURVIVE OPERATIONS FOR CANCER, RATHER THAN CANCER ITSELF. IN FACT, PRESIDENT FORD'S COUNCIL ON ENVIRONMENTAL QUALITY REPORTED LAST YEAR THAT ALTHOUGH THE CANCER INCIDENCE RATE HAD MORE THAN DOUBLED IN THIS CENTURY, THERE HAD BEEN HARDLY ANY IMPROVEMENT IN CANCER TREATMENT STATISTICS.

DON'T BE BEGUILED BY REPORTS OF IMPROVEMENT IN SKIN CANCER, CHORIOCARCIONOMA IN WOMEN, HODGKIN'S DISEASE AND CHILDHOOD LEUKEMIA. FIRST OFF, SKIN CANCER HAS BEEN EMINENTLY CURABLE SINCE THE AGE OF PLATO. USING SKIN CANCER STATISTICS IN THE TOTAL CANCER PICTURE IS A STATISTICAL JUGGLING FEAT USED TO KEEP US AWAY FROM THE CENTRAL REALITY THAT THERE HAS BEEN ESSENTIALLY NO IMPROVEMENT IN THE RATES OF INCIDENCE AND FATALITY FROM THE KILLER CANCERS, AND IN SOME CASES THE RATES ARE EVEN WORSE NOW THAN THEY WERE 20 YEARS AGO. BEAR IN MIND, TOO, THAT HODGKIN'S DISEASE AND THE CHILDHOOD LEUKEMIAS, WHERE IMPROVEMENT HAS BEEN NOTED--IF WE REALLY BELIEVE THAT A DIMINISHING IN SYMPTOMS IS EQUIVALENT TO A CURE— CONSTITUTE SLIGHTLY MORE THAN ONE PERCENT OF ALL CANCER.

CANCER IS, THEN, A RAGING PANDEMIC. SO-CALLED ORTHODOXY HAS NOT ONLY FAILED TO STOP IT, IT CAN'T EVEN FIGURE OUT THE TRUE NATURE OF CANCER. ALL IT CAN COME UP WITH IS MORE VARIATIONS OF WHAT WE CALL CUT, BURN AND POISON—SURGERY, RADIATION AND CHEMOTHERAPY. NOW WE'RE LEARNING THAT SURGERY ITSELF CAN ACTUALLY SPREAD CANCER, THAT X-RAYS AND RADIATION THEMSELVES MAY SPREAD CANCER OR ACTUALLY INDUCE LEUKEMIA IN THE OFFSPRING OF PEOPLE SO TREATED, AND THAT CHEMOTHERAPY, A KIND OF CHEMICAL BLOWTORCH APPLIED TO THE WHOLE SYSTEM, IS UNABLE TO KEEP FROM KILLING THE WHOLE BODY EVEN AS IT OCCASIONALLY KILLS CANCER CELLS.

FURTHER, WE'RE LEARNING OF THE DANGERS INHERENT IN THE MUCH-HERALDED MAMMOGRAPHY OR BREAST X-RAY EXAMINATION OF WOMEN, AND ALSO LEARNING THAT SOME SO-CALLED LEGAL AND ORTHODOX CHEMOTHERAPEUTIC DRUGS MAY BE INVOLVED IN INDUCING SECONDARY CANCER. AGAIN, CAN THIS BE PROGRESS?

ON THE OTHER HAND, LAETRILE HAS BEEN KICKING AROUND FOR THREE DECADES—AWKWARDLY, UNWANTED, THE BLACK SHEEP OF CANCER. BUT IT PERSISTS. I'M NOT GOING TO STAND HERE AND TELL YOU THE WORLD LITERATURE ON LAETRILE IS MASSIVE—IT ISN'T. BUT THERE IS ONE. IT CONSISTS OF MORE THAN TWO DECADES OF WORK BY DR. MANUEL NAVARRO AND HIS COLLABORATORS IN THE PHILIPPINES; EXPERIMENTAL USE IN ITALY; CLINICAL USE IN JAPAN, THE PHILIPPINES, MEXICO, AND A NUMBER OF OTHER COUNTRIES; ANIMAL WORK IN EAST AND WEST GERMANY; CLINICAL EXPERIENCE IN WEST GERMANY; ANIMAL WORK IN FRANCE; AND, MOST IMPORTANTLY, CONTINUING ANIMAL EXPERIMENTATION IN THIS COUNTRY, NOT ONLY AT MEMORIAL SLOAN-KETTERING CANCER INSTITUTE, WHOSE DIRECTORS WISH TO WRITE OFF AT LEAST EIGHT POSITIVE ANIMAL TESTS AS MEANINGLESS WHILE CLINICAL RESEARCHERS AT SLOAN-KETTERING CLAIMS THAT PRESTIGIOUS FACILITY IS COVERING UP THE POSITIVE LAETRILE RESULTS; BUT ALSO EXCITING AND PROMISING ANIMAL WORK CURRENTLY UNDERWAY AT SALSBURY STATE COLLEGE, MARYLAND, AND AT LOYOLA UNIVERSITY, CHICAGO. ASIDE FROM THAT, SOME EXTREMELY IMPORTANT WORK WITH EARLY, EXCITING RESULTS IS BEING CONDUCTED ON TERMINAL CANCER PATIENTS IN ISRAEL.

ASIDE FROM ALL THE ABOVE, GENTLEMEN, ARE THE TESTIMONIES OF ANYWHERE FROM 50,000 TO 75,000 AMERICAN AND CANADIAN CANCER SUFFERERS WHO HAVE USED, OR ARE USING LAETRILE, EITHER BY ITSELF OR AS PART OF AN OVERALL METABOLIC PROGRAM. THE FDA, ACS AND NCI ROUTINELY WRITE OFF ALL OF THIS INFORMATION AS "ANECDOTAL." I ASK YOU, REASONABLE MEN THAT YOU ARE: HOW MANY ANECDOTES DOES IT TAKE TO MAKE A FACT? HAVE ALL THESE PEOPLE BEEN TRICKED INTO THINKING THEY FEEL BETTER, OR ARE GAINING WEIGHT, OR ARE SEEING THEIR CANCERS RETREAT? CAN ALL THESE POSITIVE BENEFITS BE ASCRIBED TO A TARDY RESPONSE TO CHEMOTHERAPY, RADIATION OR SURGERY, OR, MORE OUTRAGEOUSLY, TO A SO-CALLED SPONTANEOUS REGRESSION? I THINK NOT. I THINK THE PEOPLE WILL BE HOODWINKED NO MORE BY THESE EFFORTS TO WRITE OFF OR PUT DOWN THE GROWING, IMPRESSIVE TESTIMONY OF MEN AND WOMEN WHO HAVE EITHER BEEN SAVED OUTRIGHT BY LAETRILE, OR WHO, EVEN THOUGH THEY EVENTUALLY EXPIRED, UNDERWENT LIFE EXTENSION, RELIEF FROM PAIN AND AN IMPROVEMENT IN WELL-BEING BECAUSE THEY USED THE LAETRILE PROGRAM.

WHAT I AM SUGGESTING HERE, GENTLEMEN, IS THAT, CONTRARY TO THE PRESS RELEASES OF THE FDA, THE AMERICAN CANCER SOCIETY, THE NATIONAL CANCER INSTITUTE AND THE AMERICAN MEDICAL ASSOCIATION, THERE IS, TO PARAPHRASE THE ESTABLISHMENT, BOTH A "SHRED OF EVIDENCE" AND A "VALID SIGN OF EFFICACY" IN THE LAETRILE TREATMENT PROGRAM, AND SINCE THIS IS TRUE, FAILURE TO RECOGNIZE OR USE OR TEST OR OFFICIALLY SANCTION LAETRILE USE IN THIS COUNTRY WHILE 1,100 AMERICANS PER DAY DROP DEAD OF THE DISEASE IS A MORAL OUTRAGE AND A NATIONAL SCANDAL FAR IN EXCESS OF ANYTHING UNEARTHED BY WATERGATE.

LET ME REASSERT HERE, ONCE AND FOR ALL, EXACTLY WHAT THE PROPONENTS OF LAETRILE CLAIM FOR THIS SUBSTANCE. AND I HOPE THE MEDIA WILL PAY VERY CLOSE ATTENTION TO THIS, SO WE CAN BURY, ONCE AND FOR ALL, THE MONOTONOUS, PERSISTENT DESCRIPTION OF LAETRILE AS A MIRACLE CANCER DRUG OR AN ILLICIT, APRICOT-PIT CANCER CURE. I WILL SAY ALL OF THIS IN ORDER TO INDICATE HOW MODEST OUR CLAIMS FOR THE LAETRILE TREATMENT PROGRAM REALLY ARE.

FIRST OFF, LAETRILE IS NOT A MIRACLE. THE COMPOUND AMYGDALIN—AND LAETRILE IS REALLY ONLY A BRAND NAME FOR THE REFINED, PURIFIED EXTRACT OF AMYGDALIN--HAS BEEN ISOLATED AND KNOWN ABOUT AND USED MEDICALLY FOR WELL OVER A CENTURY. THERE IS NO MYSTERY ABOUT THIS COMPOUND. NOR IS THERE ANY MYSTERY ABOUT THE EXTRACTION PROCESS. A HIGH SCHOOL SCIENTIST, EQUIPPED WITH A SUPPLY OF APRICOT KERNELS, ALCOHOL AND ETHER, STORAGE SPACE AND SOME REFRIGERATION EQUIPMENT, CAN MAKE LAETRILE. THE EXTRACTION PROCESS, JUST LIKE AMYGDALIN ITSELF, IS IN THE PUBLIC DOMAIN. THAT IS, WE ARE NOT DEALING WITH SOME SUPER-SECRET, ONE-MAN FORMULA CONCOCTED IN THE BASEMENT OF A BOOTLEG FACTORY.

SECONDLY, AND WE SAY THIS OVER AND OVER AGAIN, LAETRILE IS NOT OFFERED AS A CANCER CURE. THERE IS NO CURE FOR CANCER. AT LEAST NOT YET. THE VERY OPTIMUM THING WE SAY ABOUT LAETRILE IS THAT IT IS A NATURAL FOOD FACTOR, A VITAMIN—VITAMIN B-17, TO BE SPECIFIC—AND THAT IN THE VERY BEST OF INSTANCES IT MAY EFFECT A CONTROL—BUT NOT A CURE—OF CANCER, AND THEN ONLY IN A TOTAL METABOLIC SETTING.

IT IS SO IMPORTANT TO REALIZE THAT IN THE LAETRILE MANAGEMENT PROGRAM WE ARE TALKING ABOUT A TOTAL METABOLIC PROGRAM EMPHASIZING A RADICAL CHANGE IN DIET, THE USE OF PROTEIN-DIGESTING ENZYMES, TRACE MINERALS, REST, EXERCISE, PROPER ATTITUDE, VITAMINS A, C, E AND B-15—AND, OF COURSE, VITAMIN B-17 OR LAETRILE. THAT'S WHY ALL THE TALK ABOUT WHAT LAETRILE DOES ON MOUSE TUMORS, PARTICULARLY TRANSPLANTED MOUSE TUMORS, SIMPLY DOESN'T MEAN ANYTHING TO US. THERE HAVE BEEN NO METABOLIC TREATMENT PROGRAMS FOR CANCER-STRICKEN MICE. UNTIL THERE ARE, SINGLE-SHOT, 10-DAY TESTS OF LAETRILE ON MICE SIMPLY DOESN'T MEAN MUCH.

SO, UNDER THE VERY BEST OF CONDITIONS, OUR METABOLIC PHYSICIANS IN THIS COUNTRY AND OTHER PARTS OF THE WORLD TELL US THAT LAETRILE AND THE ENTIRE METABOLIC PROGRAM MAY EFFECT THE CONTROL OF CANCER, JUST AS INSULIN, GIVEN WITH ITS DIETARY PROGRAM, MAY INDEED CONTROL—BUT NOT CURE—DIABETES. LAETRILE, THEN, MAY HELP CONTROL—BUT NEVER CURE—CANCER. WHAT WE SEE, OVERWHELMINGLY, IS THAT PATIENTS ON THE METABOLIC TREATMENT PROGRAM UNDERGO A SERIES OF POSITIVE RESPONSES TO LAETRILE AND ITS ADJUVANT THERAPY.

THESE RESPONSES RANGE SIMPLY FROM SUBJECTIVE FEELINGS OF IMPROVEMENT, TO ACTUAL STIMULATION OF APPETITE AND CONSEQUENT WEIGHT GAIN; THEN, AND MOST DRAMATICALLY, AS THE SINGLY MOST FREQUENTLY REPORTED RESPONSE, WE FIND A SHARP DECREASE, AND VERY FREQUENTLY A COMPLETE ELIMINATION OF, THE PAIN ASSOCIATED WITH CANCER. THIS, GENTLEMEN, IS SUCH A BLESSING THAT, IF FOR NO OTHER REASON, LAETRILE SHOULD BE FULLY LEGAL AS AN ANALGESIC IN CANCER TREATMENT. THEN, WE HAVE MANY CASES OF A REDUCTION IN THE SYMPTOMS OF CANCER—THAT IS, AN END TO THE DEATHLY PALLOR, AN ELIMINATION OF THE BAD ODOR CONNECTED WITH CANCER, AND A VISIBLE DECREASE IN TUMORS. NOW, BEAR IN MIND THAT 95% OF THE AMERICANS WHO TURN TO THE LAETRILE TREATMENT PROGRAM ARE ALREADY TERMINAL—THAT IS, THEY HAVE BEEN ON RADIATION AND CHEMOTHERAPY OR BEEN MUTILATED THROUGH SURGERY, AND THEY HAVE BEEN SENT HOME TO DIE. THAT ANY OF THESE PATIENTS SHOULD SHOW IMPROVEMENT, LET ALONE TOTAL RELIEF, WOULD BE THE MIRACLE; BUT THE FACT IS, AT THE CLINICS IN TIJUANA, WEST GERMANY, THE PHILIPPINES, AND IN THE CASE-LOAD OF AMERICAN PHYSICIANS, WE ARE SEEING LITERALLY THOUSANDS OF CASES OF RELIEF AND EVEN TOTAL CONTROL THROUGH THIS PROGRAM.

IT IS TRUE THAT ONLY FIVE PERCENT OF SUCH PATIENTS EXHIBIT TOTAL CONTROL—THAT IS, COMPLETE REMISSION OF ALL SYMPTOMS AND SURVIVAL BEYOND FIVE YEARS. BUT SOME 65 TO 70 PERCENT OF ALL PATIENTS, ALMOST ALL OF WHOM, AGAIN, ARE TERMINAL, ARE RECEIVING A DIRECT RESPONSE TO THE THERAPY.

BUT INSTEAD OF SETTING FOOT IN THE TIJUANA CLINIC TO SEE FOR THEMSELVES, INSTEAD OF CAREFULLY EXAMINING THE CASE-LOAD OF AMERICAN LAETRILE-USING PHYSICIANS, MEMBERS OF THE ESTABLISHMENT CONTINUE TO VILLIFY LAETRILE, CHARACTER-ASSASSINATE ITS PROPONENTS, AND DISMISS OUR HUMAN EVIDENCE AS ANECDOTAL AND THE ADMITTEDLY SLIM BUT EXISTING ANIMAL EVIDENCE AS UNPROVEN.

YOU HEAR THE OPPOSITION NOTING THAT LAETRILE IS NOT DANGEROUS IN AND OF ITSELF—WHICH IS FINE—BUT WHAT'S WRONG WITH FREEDOM OF CHOICE IN LAETRILE IS THAT IT KEEPS PEOPLE FROM ORTHODOX THERAPY. WE HAVE ALREADY INDICATED HOW UNSUCCESSFUL ORTHODOX THERAPY REALLY IS, BUT PERHAPS THE STRONGEST INDICTMENT ABOUT ORTHODOXY COMES FROM A VETERAN RESEARCHER OF CANCER STATISTICS, A PHYSIOLOGIST WHO HAS TESTIFIED FOR THE AMERICAN CANCER SOCIETY AND ALSO IN OUR SO-CALLED "CONSPIRACY TO SMUGGLE" TRIAL.

To paraphrase Dr. Hardin Jones of the University of California, if you show up in a clinic with lumps and bumps and are diagnosed with cancer, you STATISTICALLY will have a better chance of living longer and feeling better if you just go home and forget about the cancer. That is, forget about ANY treatment, including Laetrile. Now, gentlemen, this indictment against orthodoxy is serious. It shows utter failure in the War on Cancer. I am not saying that so-called orthodoxy has NEVER worked. I am not saying that you should ban surgery, radiation and chemotherapy. Our proponents are not suggesting that people be rounded up at bayonet point to get and use Laetrile. If we extrapolate correctly the statements of the former head of the NCI, Dr. Frank Rauscher, it is correct to assume that, viewing cancer in gross statistics, there is ONLY a 7-1/2 percent opportunity for a cancer patient treated by orthodoxy to survive for 5 years. The other way to say that is that there is a 92.5% chance that he will NOT survive for 5 years. Yes, admittedly, some cancers have a much higher so-called cure rate, as we have noted, but in the BIG killers, such as lung cancer, there has been practically no progress at all.

NOW, OUR METABOLIC PHYSICIANS ARE SAYING THAT THE TOTAL METABOLIC PROGRAM FOR CANCER IN WHICH LAETRILE MAY BE SEEN AS THE CROWN JEWEL IN A TOTAL TREATMENT DIADEM REPRESENTS THE BEST TREATMENT FOR CANCER. BUT WE KNOW THAT THE VAST MAJORITY OF AMERICAN MEDICINE IS STILL HOOKED TO THE SCHOOL OF ALLOPATHY—THAT IS, THE VIEW THAT CANCER IS MANY DISEASES, NOT ONE, AND THAT TOXIC CHEMICALS AND RADIATION MAY BE ADDED TO SURGERY TO DEAL WITH THE MALIGNANCY. THE FACT IS, MANY LAETRILE-USING PHYSICIANS ARE GIVING LAETRILE RIGHT ALONG WITH THE SO-CALLED ORTHODOX THERAPY AND ALSO ACHIEVING REMARKABLE RESULTS. ONE OF THEM IS DR. MARIO SOTO DE LEON, MEDICAL DIRECTOR AT THE CYDEL CLINIC, TIJUANA, A MAN TRAINED AS AN ONCOLOGIST, OR CANCER SPECIALIST, NOT AS A METABOLIC PHYSICIAN. DR. SOTO NOW HAS HUNDREDS OF CASE HISTORIES IN WHICH SO-CALLED ORTHODOXY WAS MIXED WITH LAETRILE TREATMENT WITH DRAMATIC RESPONSES.

GENTLEMEN, WE ARE READY TO DEMONSTRATE EVERYTHING WE HAVE SAID HERE TODAY. WE HAVE PHYSICIANS, PATIENTS AND CASE HISTORIES. WE PLEAD FOR AMERICAN ORTHODOXY TO VIEW THEM, TO RESEARCH ALL WE HAVE SAID, AND THEN DARE TO RENDER A SWEEPING DENUNCIATION OF LAETRILE AS A HOAX OR A FRAUD UPON THE PUBLIC.

LET ME DEAL WITH OTHER ARGUMENTS USED AGAINST THE LAETRILE MOVEMENT.

WE ARE SAID TO BE PROFITEERS LEECHING OFF THE CONFUSION OF CANCER VICTIMS. I WANT TO PUT THIS VICIOUS ATTACK TO REST ONCE AND FOR ALL. FIRST OFF, THE ENTIRE LAETRILE TREATMENT PROGRAM, BE IT IN TIJUANA OR ON THE SO-CALLED AMERICAN BLACK MARKET, ROUTINELY COSTS 10 PERCENT OR LESS THAN THE COST OF ORTHODOX TREATMENT IN THIS COUNTRY. AMERICAN ORTHODOXY HAS SET THE COST OF CANCER PER VICTIM IN THIS COUNTRY AT ABOUT $19,000, AND WE ALL KNOW OF MEDICAL BILLS FOR CANCER FAR IN EXCESS OF $50,000. THE STANDARD LAETRILE TREATMENT BILL IS AROUND $1,500 TO $2,500—PERHAPS $3,000 OR MORE IF YOU THROW IN THE ROUNDTRIP TICKET TO TIJUANA, FOOD AND LODGING. YES, THERE IS A MARKUP IN U.S. LAETRILE THAT HAS BEEN IMPORTED—BUT EVEN WITH THAT MARKUP, THE FACT IS THAT THE COST OF A GRAM OF LAETRILE OR AMYGDALIN ON THE SO-CALLED BLACK MARKET IS ACTUALLY CHEAPER THAN THE COST OF A GRAM OF AMYGDALIN THAT YOU COULD LEGALLY BUY FROM A CHEMICAL COMPANY IF IT WERE BEING USED EXPERIMENTALLY.

AS TO PROFITEERING, NOW LET'S BE LOGICAL: IF I OR THE OTHER MAJOR LAETRILE PROPONENTS ARE ACTUALLY PROFITEERS AND SMUGGLERS, WHY ON EARTH DO WE WANT TO LEGALIZE, OR DECRIMINALIZE, LAETRILE? IT WOULD SURELY FIT OUR FIENDISH PURPOSES MUCH, MUCH MORE TO KEEP THE STUFF DE FACTO ILLEGAL AND JACK UP THE PRICE, JUST AS THE PURVEYORS OF BOOTLEG BOOZE DID IN THE 1920'S AND THE DISTRIBUTORS OF HEROIN DO TODAY.

96-492 O - 77 - 20

PROFITEERS? CRIMINALS? NOT REALLY. MOST OF THE PROFITEERING IN THIS COUNTRY GOES ON IN THE NAME OF ORTHODOXY.

IT IS SAID THAT PEOPLE WHO FEEL BETTER ON LAETRILE ARE SIMPLY RESPONDING TO A SO-CALLED PLACEBO EFFECT. WELL, IF THAT'S TRUE, THEN LAETRILE SHOULD BE IMMEDIATELY LICENSED AS A PLACEBO, FOR CERTAINLY IT IS A SUCCESSFUL PLACEBO—BUT, OF COURSE, RESPONSES IN BABIES AND ANIMALS TO LAETRILE TREATMENT RATHER UNDERCUT THE PLACEBO ARGUMENT, UNLESS BOTH BABIES AND ANIMALS UNDERSTAND ENGLISH.

ARE THE PROPONENTS OF LAETRILE ACTUALLY FOISTING OFF LAETRILE ON THE AMERICAN PEOPLE? NO REALLY, SINCE LAETRILE IS AMERICAN IN ORIGIN. BUT WHAT WE ARE ARGUING FOR, AND WHAT SEEMS TO BE DISTRESSING THE POWERS THAT BE ALMOST AS MUCH AS LAETRILE, IS THE CONCEPT OF FREEDOM OF CHOICE IN CANCER THERAPY. NOW, WHAT DOES THAT MEAN? I WILL STATE IT AS SUCCINCTLY AS I CAN:

THE MOVEMENT FOR FREEDOM OF CHOICE IN CANCER THERAPY, WHICH IS BECOMING THE POLITICAL SUCCESS STORY OF THIS CENTURY, MEANS THAT PHYSICIANS AND PATIENTS, WITH THE INFORMED CONSENT OF BOTH, SHOULD HAVE ACCESS TO LAETRILE OR ANY OTHER NON-TOXIC ALTERNATIVE THERAPY WITHOUT BEING HARASSED OR ARRESTED.

THAT'S ALL WE'RE SAYING. OUR MOVEMENT IS NOT OUT TO OVERTHROW MEDICINE, IS NOT ILLEGALIZING RADIATION OR CHEMOTHERAPY, IS NOT FORCING PEOPLE TO USE LAETRILE. AND INFORMED CONSENT MEANS JUST THAT. CONTRARY TO WHAT THE OPPOSITION IS SAYING, WE ARE NOT BRINGING BACK THE PATENT MEDICINE ERA. WE ARE SUGGESTING THAT ALL CANCER PATIENTS MUST BE IN THE HANDS OF PHYSICIANS—HOPEFULLY, PHYSICIANS WHO KNOW HOW TO USE LAETRILE. WE OPPOSE SELF-TREATMENT, AND WE OPPOSE THE AVAILABILITY OF THERAPEUTIC LAETRILE—NOT, OF COURSE, APRICOT OR ANY OTHER FRUIT SEEDS OF EVEN LOW-DOSE LAETRILE TABLETS—OVER THE COUNTER (NON-QUALIFIED PHYSICIANS).

OUR ARGUMENTS ARE LOGICAL, AND THE FREEDOM OF CHOICE ISSUE IS BEING OVERWHELMINGLY APPROVED IN EVERY STATE WHERE ADEQUATE TIME AND ENERGY ARE ALLOWED FOR THE AIRING OF THIS UTTERLY LOGICAL, HUMANE ARGUMENT.

LET'S FACE IT: THE ESTABLISHMENT CAN NO LONGER DEAL EITHER WITH THE MATTER OF LAETRILE EFFICACY, OR WITH THE FREEDOM OF CHOICE ISSUE. THEY ARE LOSING HANDS DOWN ON BOTH. IT IS FOR THAT REASON THAT YOU ARE BEING TREATED NOT TO ATTACKS ON THE SUBSTANTIVE ISSUES—LAETRILE EFFICACY AND FREEDOM OF CHOICE—BUT TO CHARACTER ATTACKS ON SOME OF THE PRINCIPALS IN THE LAETRILE MOVEMENT, MYSELF VERY MUCH INCLUDED. I WOULD LIKE YOU TO KEEP THIS IN MIND.

The New York Times, for example, has engaged in gutter journalism of the foulest variety by selectively reporting, at times incorrectly, on the academic careers of myself and of Ernst T. Krebs, as if—gentlemen—our academic backgrounds had ANYTHING to do with the substantive issues of Laetrile efficacy and freedom of choice. I am here to reject as vehemently as I can the outrageous lie that I am making hundreds of thousands of dollars of profit per month off Laetrile. If I were the criminal described by the Times, my obvious LOGICAL course would be to take these millions of dollars of illicit profit I allegedly have made and split for Brazil. I really don't need a three-month-long trial in San Diego costing me many thousands of dollars, or continual attacks on my character, or even this presentation, in order to live. Call me an idealist; call me a fanatic; call me insane; call me anything—but not criminal.

The cheap-shot attacks on Doctor Krebs are even more atrocious. We have never hidden the fact that this man, with many patents to his name and many years of advanced education, has only an honorary doctorate, as if that means something. Are you aware, gentlemen, that Christopher Columbus never went to nautical school? Can we recall the shoddy credentials of Thomas Edison? Was Albert Einstein all that bright a student in school? Do any of these things MEAN anything? Of course not.

YOU KNOW AS WELL AS I THAT AD-HOMINEM ATTACKS ARE THE LAST REDOUBT OF THE DESPERATE. IF YOU CANNOT DEAL WITH THE ISSUES, IF YOU CANNOT FACE THE ACCUSATIONS, THEN YOU DESTROY THE ACCUSER, EVEN AS THE ESTABLISHMENT IS TRYING TO DESTROY US ACCUSERS RIGHT NOW.

I MENTIONED THAT THE SCANDALOUS CHAPTER IS IN TWO PARTS. THE OTHER PART IS ONE ON WHICH I SIMPLY DON'T HAVE TOO MUCH TIME TO DWELL, BUT IT HAS TO DO WITH THE EVOLUTION IN THIS COUNTRY OF A VAST, CLUBBY, INTERLOCKING AMERICAN CANCER INDUSTRY, ONE NOW WORTH AN ESTIMATED TWENTY-FIVE BILLION DOLLARS A YEAR. WHILE I WILL NOT IMPUTE EVIL MOTIVES TO ALL THE PEOPLE WHO CONSTITUTE THIS INDUSTRY, WE CANNOT DENY THE SIREN LURES OF VESTED INTERESTS BOTH AT THE LEVEL OF EGO AND AT THE LEVEL OF ECONOMIC GAIN. NOBODY WANTS HIS RESEARCH GRANTS CUT OFF, AND NOBODY RATTLES THE CAGE OR SHAKES THE RESEARCH BOAT IF HE WANTS TO CONTINUE TO PLAY ON THE TEAM. BECAUSE OF THIS CLUB OF INTERLOCKING INTERESTS, WOE BETIDE ANY SUBSTANCE OR INDIVIDUAL WHICH DEVELOPED, AS IT WERE, OUTSIDE THE PALE. THE AMERICAN CANCER ESTABLISHMENT DID NOT WISH TO HEAR DR. MAX GERSON EXPOUND 30 AND 40 YEARS AGO ON THE NUTRITIONAL ASPECTS OF CANCER AND THE FACT THAT CANCER COULD BE PREVENTED, LET ALONE TREATED, BY DIETARY FACTORS ALONE.

NOW, DECADES LATER, AT LEAST A FEW VOICES FROM WITHIN THE HALLOWED HALLS OF THE NCI ARE BEGINNING TO DISCOVER THE DIETARY ASPECTS OF CANCER. BETTER LATE THAN NEVER. AND, WHEN SUCH UNWANTED OR ALLEGEDLY UNPROVEN REMEDIES AS THE HOXSEY HERBAL FORMULAS, KREBIOZEN AND GLYOXYLIDE CAME ALONG, THE CANCER ESTABLISHMENT WENT TO ENORMOUS LENGTHS TO SMASH THEM OUT OF EXISTENCE AND TO RUIN THE CAREERS AND REPUTATIONS OF THEIR DEFENDERS--JUST AS THE ESTABLISHMENT IS NOT TRYING TO DO WITH LAETRILE.

LUCKILY, A HINT OF SUCH CORRUPTION WORKED ITS WAY INTO THE CONGRESSIONAL RECORD. NOW, I'M NOT HERE BEATING THE DRUMS FOR THE HOXSEY OR KREBIOZEN TREATMENTS, BUT A QUARTER-CENTURY AGO THEY WERE THE OBJECT OF A CONGRESSIONAL INVESTIGATION, JUST AS LAETRILE SHOULD BE NOW.

BENEDICT F. FITZGERALD, JR. WAS SPECIAL COUNSEL TO THE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE, ONE OF WHOSE PANELS WAS THEN PROBING THE WHOLE PICTURE OF CANCER TREATMENT IN THIS COUNTRY AND, INCIDENTALLY, RUFFLING THE FEATHERS OF THE AMERICAN MEDICAL ASSOCIATION AND THE AMERICAN CANCER SOCIETY. IN A REPORT TO THE SENATE INTERSTATE COMMERCE COMMITTEE ON THE NEED FOR INVESTIGATION OF CANCER RESEARCH ORGANIZATIONS, SPECIAL COUNSEL FITZGERALD WROTE OF THE KREBIOZEN CONTROVERSY, AND I AM QUOTING FROM THE CONGRESSIONAL RECORD OF AUGUST 28, 1953:

"I HAVE CONCLUDED THAT IN THE VALUE OF PRESENT CANCER RESEARCH, THIS SUBSTANCE"—MEANING KREBIOZEN-- "AND THE THEORY BEHIND IT DESERVE THE MOST FULL AND COMPLETE AND SCIENTIFIC STUDY. ITS VALUE IN THE MANAGEMENT OF THE CANCER PATIENT HAS BEEN DEMONSTRATED IN A SUFFICIENT NUMBER AND PERCENTAGE OF CASES TO DEMAND FURTHER WORK. BEHIND AND OVER ALL THIS IS THE WEIRDEST CONGLOMERATION OF CORRUPT MOTIVES, INTRIGUE, SELFISHNESS, JEALOUSY, OBSTRUCTION AND CONSPIRACY THAT I HAVE EVER SEEN."

UNQUOTE. GENTLEMEN, I WOULD ARGUE THAT THAT SAME WEIRD CONGLOMERATION OF CORRUPT MOTIVES, INTRIGUE, SELFISHNESS, JEALOUSY, OBSTRUCTION AND CONSPIRACY CONTINUE TO THIS VERY DAY, AND LIES AT THE ROOT OF THE ESTABLISHMENT OPPOSITION TO NON-TOXIC, NON-PATENTABLE LAETRILE, AND TO THE WHOLE SCHOOL OF PREVENTIVE MEDICINE AND HOLISTIC OR METABOLIC THERAPY, WHICH POSES SUCH A CLEAR AND PRESENT DANGER TO DRUG-BASED ALLOPATHIC MEDICINE, THE PHARMACEUTICAL CARTEL AND THIS COUNTRY'S OBSCENE ONE HUNDRED AND FORTY BILLION DOLLAR PER YEAR SO-CALLED HEALTH CARE DELIVERY INDUSTRY—THAT IS, THE SICK BUSINESS, WITH ITS 200 TO 300 DOLLAR A DAY HOSPITAL ROOMS, ITS SKYROCKETING MEDICAL INSURANCE, ITS AWESOMELY SALARIED SURGEONS, DIAGNOSTICIANS, INTERNISTS AND OTHER MEDICAL SPECIALISTS.

WE BELIEVE THAT CONGLOMERATION CONTINUES WHEN WE READ THE UNDERGROUND NEWSLETTERS AT MEMORIAL SLOAN-KETTERING CANCER CENTER, WHOSE VERY EMPLOYEES ARE ALLEGING A COVERUP OF POSITIVE TEST RESULTS OF LAETRILE ON MICE.

WE BELIEVE THAT CONGLOMERATION CONTINUES WHEN WE NOTE THAT AT ROSWELL PARK IN BUFFALO, NEW YORK, A RESEARCHER WHO DARED LINK X-RAYS IN MOTHERS TO LEUKEMIA IN CHILDREN HAS SEEN HIS ONE-POINT-FIVE MILLION-DOLLAR RESEARCH GRANT CANCELLED BY THE NATIONAL CANCER INSTITUTE.

WE BELIEVE THAT CONGLOMERATION CONTINUES WHEN WE REALIZE, AS ONLY A CONVICTED SO-CALLED CONSPIRATORIAL SMUGGLER CAN REALIZE, THAT THE FEDERAL GOVERNMENT SPENT MILLIONS OF DOLLARS IN A THREE-MONTH-LONG PROSECUTION IN CALIFORNIA TO CLAMP DOWN ON WHAT TURNED OUT TO BE POSSIBLY $130,000 WORTH OF ALLEGEDLY ILLICIT PROFITS IN MEXICAN LAETRILE SHARED OVER A 30-MONTH PERIOD BY 50 SO-CALLED CONSPIRATORS.

WE BELIEVE THAT CONGLOMERATION CONTINUES WHEN WE SEE PHYSICIANS STRIPPED OF THEIR LICENSES FOR DARING TO BE FAITHFUL TO THEIR HIPPOCRATIC OATHS AND OBEYING THE HIPPOCRATIC INJUNCTION TO "FIRST, DO NO HARM," AS THEY PROVIDE LAETRILE FOR CANCER PATIENTS.

WE BELIEVE THAT CONGLOMERATION CONTINUES WHEN PHYSICIANS AND PHARMACISTS ARE ROUTINELY ARRESTED AND HARASSED BY SEVERAL BRANCHES OF GOVERNMENT ALL AT ONCE BECUASE OF THEIR INVOLVEMENT WITH LAETRILE OR VITAMIN B-17.

AS I SAID, WE DON'T HAVE YEARS TO WAIT FOR THE ELEPHANTINE FOOD AND DRUG ADMINISTRATION TO CEASE AND DESIST IN SQUANDERING TAXPAYER FUNDS ON THE HARASSMENT OF HONEST MEN AND WOMEN WHO USE OR DISTRIBUTE LAETRILE.

I COME BEFORE YOU NOT ONLY TO DENOUNCE ALL OF THE ABOVE, AND TO EXPRESS AS MUCH RAGE AS I, AS A SINGLE AMERICAN CITIZEN, CAN, BUT TO ASK YOU TO DO SOMETHING ABOUT IT.

I AM HERE, AMONG OTHER THINGS, TO WARN YOU THAT, THE LONGER THE FDA CONTINUES TO TREAT LAETRILE AS AN ILLEGAL SUBSTANCE, THE SHORTER IS THE TIME BEFORE AUTHENTIC ORGANIZED CRIME GETS INTO THE ACT. YOU CANNOT HAVE A MARKET AS VAST AS THE LAETRILE MARKET NOW IS, WITH A DEMAND SO GREAT FOR A COMPOUND SO HARASSED WITHOUT DRIVING IT INTO THE HANDS OR ORGANIZED CRIME. AND, GENTLEMEN, IF THERE ALREADY ARE ABUSES IN LAETRILE PRICING AND DISTRIBUTION, AND IF ORGANIZED CRIME DOES SURFACE IN LAETRILE, YOU CAN PLACE THE BLAME SQUARELY AND INEXORABLY AT THE DOOR OF THE FEDERAL GOVERNMENT.

I AM ASKING YOU FOR URGENT, EMERGENCY MEASURES:

THE FDA MUST GET OFF THE BACKS OF PHYSICIANS, CANCER PATIENTS, AND OURSELVES. WHAT, IN THE NAME OF HUMANITY, IS THIS AGENCY DOING? WHOM DOES IT REPRESENT? SURELY, NOT THE PEOPLE. THE HARRIS POLL HAS ALREADY INDICATED THAT. HOW IS IT POSSIBLE THAT AT A TIME WHEN OUR NATION IS FLOODED WITH HEROIN, COCAINE, UPPERS AND DOWNERS AND IS LITERALLY AWASH IN MARIJUANA, THE FEDERAL GOVERNMENT SEES FIT TO EXPEND MILLIONS AND MILLIONS OF TAXPAYER FUNDS TO SUPPRESS THE EXTRACT OF APRICOT KERNELS? WHERE IS THE LOGIC? WHERE IS THE MORALITY?

WE NEED ACTION FROM THE CONGRESS, FROM THE ELECTED REPRESENTATIVES OF THE PEOPLE, TO CALL OFF THE DOGS OF THE FDA AND TO LIFT THE UNWRITTEN BAN OF THE FDA AGAINST LAETRILE. THAT BAN IS, AFTER ALL, INCREASINGLY MOOT AS THE STATES THEMSELVES DECRIMINALIZE LAETRILE. DO WE REALLY WANT ANOTHER AMERICAN CIVIL WAR? DO WE REALLY NEED A CONFRONTATION BETWEEN STATES' RIGHTS AND THE FEDERAL BEHEMOTH ON THE ISSUE OF LAETRILE? MUST WE PLAY THIS GREEK DRAMA OUT TO ITS DISASTROUS BUREAUCRATIC CONCLUSION? HOW MANY THOUSANDS OF AMERICANS MUST BE TREATED AS CRIMINALS OR NEEDLESSLY DIE BECAUSE OF FDA RED TAPE?

-30--

REST ASSURED, GENTLEMEN, THAT THE PEOPLE DEMAND LAETRILE, AND THEY ARE GOING TO HAVE IT, WHETHER BIG BROTH R LIKES IT OR NOT.

OUR ORGANIZATION HAS OFFERED ITS GOOD OFFICES TO WORK WITH THE ESTABLISHMENT IN USING AND TESTING LAETRILE. WE REPEAT THAT OFFER NOW. BUT WE CANNOT EXPECT THAT THOUSANDS OF AMERICAN CANCER SUFFERERS ARE GOING TO WAIT FOR MORE LONG YEARS WHILE THE FEDERAL GOVERNMENT FIDDLE-FADDLES THROUGH ANIMAL TESTS AND MORE RED TAPE.

GENTLEMEN, THE HOT POTATO IS IN YOUR LAP.

An Objective Refutation of David M. Greenberg, Ph.D. –
and his article entitled
"The Vitamin Fraud in Cancer Quackery"*
by: John A. Richardson, M.D.

There is no doubt that the article in reference is professional - not scientific but a professional hatchet job, thus giving credence to the conspiratorial facts presented in Ed Griffin's book, World Without Cancer. What a crown for an 83 year old man with a reputation as an expert in cancer. We must admit that we have even questioned whether such an article could be written by a Greenberg; more likely a Ross whose smear editorial was more to the point and less protected by the pseudo-scientific verbiage of the Greenberg article.

Author Greenberg makes no attempt to compare the characteristics of vitamin B-17 with the generally accepted characteristics of a vitamin. What follows immediately, therefore, is a compilation of the known and observed characteristics of vitamin B-17 matched carefully with the known and generally accepted characteristics of a vitamin. The reader will observe that vitamin B-17 is similar to a vitamin in every respect and dissimilar in none.

*Western Medical Journal; April, 1975 p. 345

Characteristics of a Vitamin	Characteristics of Vitamin B-17 (Nitrilosides)
1) Organic (as contrasted with the inorganic trace minerals), fat or water soluble.	1) Vitamin B-17 is organic and water soluble.
2) Present in small amounts in food or the organism for which the compound is a vitamin (milligram or microgram amounts).	2) Vitamin B-17 as a nitriloside is present ubiquitously in seeds of fruits and grains and grain fed animals.
3) Essential for normal metabolism and physiological activities (perhaps not essential to life itself in all cases).	3) Vitamin B-17 will increase appetite, cause weight gain, reduce pain and produce a feeling of well-being.
4) Absence or deficiency of the vitamin results in a characteristic deficiency syndrome which is apparent clinically (pellegra, scurvy, etc. - some fatal, some only near fatal).	4) Absence of vitamin B-17 may produce headaches, anorexia, bizarre muscular pains, skin changes, anemia, sense of impending doom, loss of weight, bowel changes, nitrite-nitrate imbalance, high blood pressure, sickle cell anemia and finally, tumefaction.
5) A vitamin is used catalytically in the body to aid in metabolism, but is not metabolized itself to produce energy (such as occurs with carbohydrates, fats or proteins).	5) The degradation products of vitamin B-17 are excreted as thiocyanate and benzoic acid. Vitamin B-17 does not produce energy by itself.
6) Generally of low molecular weight (small molecule).	6) All forms of vitamin B-17 are of low molecular weight or small molecules.
7) If of "B" complex must be water soluble.	7) Vitamin B-17 is water soluble.

We would not even bother to reply with a point by point refutation except for the fact that there are still among us individuals "on our side" who don't and probably never will realize that the press, radio and T.V. are owned and controlled by the same conspiracy that is opposing vitamin B-17; by the same conspiracy that issued the F.D.A. secret memorandum of June 14, 1974 under the signature of Robert A. Tucker for Glenn Kilpatrick, and of the same conspiracy which now orchestrates the harassment of good citizens by various branches of government and quasi-governmental institutions. Under the so-called Freedom of Information Act everyone should write for the F.D.A. secret memorandum mentioned above (copy furnished from the F.D.A. on request). It will show how this special report fills a very important objective in the conspiracy's effort to do away with the private sector's use of vitamin B-17 in our time.

But first let's take care of the Sloan-Kettering Bug-a-boo. It is hardly scientific technique to refer to personal correspondence in the Greenberg list of references since it does not offer the reader an opportunity to check out the accuracy. We have on record, telephone conversations (but I'm not going to add them to our references) with Dr. Sugiura who performed two successful experiments with tumor systems treated with amygdalin in mice, and with doctors high up who acknowledge the amygdalin efficacy which is deliberately being kept under cloak by politics. They know the truth, and even if their pay checks were not a powerful carrot stick, they would be powerless by themselves to announce the efficacy of the preparation simply because the kept press wouldn't allow it. Realizing, as does the conspiracy, that a statement of the known facts will fall on deaf ears even among our supporters, nevertheless it must be

stated again and again and again before proceeding with the painfully tedious, point by point, sentence by sentence refutation of the Greenberg travesty, editorial or letter. Again, before proceeding, let it be known that it is hardly scientific for the author to quote himself to the exclusion of four or five more recent articles which refute or contradict his 1952 findings.

The author deliberately throws sand in the reader's eyes by, in the 2nd paragraph, alluding to the Laetriles as including amygdalin and prunasin. Laetrile is a patented name which can only be applied to L-mandelonitrile-beta-glucuroniside which is cleaved only be beta-glucuronidase. Amygdalin and prunasin are both cleaved by glucosidase. Vitamin B-17 or nitriloside, meaning cyanide bearing, would be best applied. The author is insisting that we cannot call a nitriloside a vitamin because he says it isn't a vitamin and for no other explained reason.

Laetrile has never been promoted as an anti-cancer agent by E.T. Krebs, Jr.; it may have been thought so by the senior Krebs when he first developed it and didn't realize its vitamin characteristics. In the 6th paragraph the author states amygdalin is illegal in California. This is a lie because the Business and Professions code gives the physician a vested right to use anything he thinks will help the patient. No subsequent legislation has attempted to repeal this vested right.

In 1953 the Cancer Commission of the California Medical Association alleged that they made an investigation, but later evaluation of the report that followed proved that they merely went through the motions of an investigation with "group dynamics". This was done contrary to the Business and Professions code

which states that there shall be no discrimination against any different point of view. This report also led to the passage of the so-called anti-quackery laws in California, contrary to the Federal and State Constitutions' admonitions against "Bills of Attainder".

The 7th paragraph states a few facts which are to prepare the reader for a coup. But the hypothesis he has stated is not correct since it is presumed that cancer tissue is rich in beta-glucosidase not beta-glucuronidase. Why the misstatement, unless to create a strawman which can be destroyed with fallacious material presented to a "grateful world" by the author in 1952. Greenberg, the presumed author, states that there is no differential between the rhodenase content of comparable normal and cancerous tissue. How these can be "comparable" with tumor tissue containing both malignant and somatic tissue, we do not know. But he refers to his own work in 1952 and does not include the more updated work of Giordano, Violante, Lerenzetti and Sapio (1957).

We fail to see why E.T. Krebs, Jr., in postulating a theory on how vitamin B-17 might work, would be shifting ground. Certainly anyone who attempts to explain how B-12 or penicillin works wouldn't be so attacked. Nor do we find patience with the author's attempt to use this weak argument against Krebs as another weight with which to sink the theory that vitamin B-17 is a vitamin.

In the following paragraph the author again erroneously lumps all nitrilosides as Laetriles and all the unlinking enzymes as beta-glucosidase - again the error of the author's ways is only more pronounced when he says that Laetriles are unlinked by beta-glucosidase. Laetrile is a specific name for L-mandelonitrile-beta-glucuronside which is unlinked by beta-glucuronidase, while amygdalin and

prunasin are unlinked by beta-glucosidase. But what is all the author's persiflage of knowledgeable error attempting to do? It becomes more and more apparent as we proceed with his ludicrous discourse and we still haven't reached the part which explains why vitamin B-17 is not a vitamin. Evidently the author is attempting to fix in our minds that it is a "non-thing". In fact, after getting to the point where the author mentions some of the characteristics of vitamins and without even bothering to attempt to match some of the characteristics of vitamin B-17 with those of a vitamin, he concludes that vitamin B-17 is not a vitamin because there is no evidence that it is a vitamin, that there is no evidence of physiological function, (even though earlier he described some physiological function) and that no specific disease has been associated with a lack of Laetrile in any animal.

Now the casements have been thrown open and the oracle has spoken. End of argument, over and out. But just in case someone still has a question, the author continues mixing us up by lumping amygdalin, prunasin and Laetrile as all being Laetrile and then mixing us up with his oft repeated error that beta-glucosidase splits Laetrile. It doesn't, but beta-glucuronidase does, and it is present in malignant cells in large quantities. There is another little point to which the author might pay attention: Laetrile is hydrolyzed in the stomach while amygdalin is not. That is why Laetrile is not given by mouth. Perhaps the author would himself like to try that little experiment, thus providing a socratic exit from this veil of tears and thus save his reputation from being that of an ignominious hatchet man. But certainly we would not suggest such an erroneous experiment.

96-492 O - 77 - 21

But let's not tarry. Moving on then, we come to the observation that each vitamin has a unique physiological function that cannot be performed by any other class of compounds. And the author dismesses this too, merely by saying, "No evidence has been adduced that laetriles have any such physiological function." So it seems timely for us to ask, is there any other vitamin that destroys fruit flies in the presence of beta-glucuronidase? Or more precisely, is there any other vitamin that visibly knocks off malignant cells under the microscope? It has been asserted that Laetrile will do just that. For the benefit of those still too obtuse to grasp just how vitamin B-17 is used in the treatment of the metabolic disease entity of cancer, it should be thoroughly understood that the tumor is the final immune reaction of the organism as it "recognizes" the microscopic "cancer" cells to be noxious. This reaction is made up of 80% to 90% normal somatic components in an attempt to surround or dilute the offending cancer cells. The B-17 has its effect on the microscopic cancer cell but not upon the somatic component of the tumor. Furthermore, since the somatic reaction is comparable to that of an abscess formation, a Ghon tubercle, or a foreign body reaction, the tumor itself should not be attacked as its destruction would merely contribute to the further spread of the malignant cells.

It was probably not planned that way by those who defined "cancer" as the tumefaction itself, as the disease's final and most outstanding symptom. But there is poetic justice in that no rational approach to the deficiency disease should include an attack upon the tumor, unless of course its presence by obstruction is incompatible with life itself. At that point surgery would be recommended.

The author sets up a strawman in terms of the revolt against processed food and again in a pseudo-scientific manner, presumes to identify the popular support of vitamin B-17 as a reaction of the herd against its master's forced feeding of processed foods.

Gratuitously the author sets down the requirements and definitions of a vitamin. He lumps animal and man together saying that a vitamin cannot be synthesized by the cells of the organism, and then with much authority, says that man has lost his ability to form vitamin C, which he said couldn't be formed in the first place. I suppose that we should be grateful to the author for another pseudo-scientific observation that man lost his ability. Presumably the author has had some contact with scientific work done before the flood. Or perhaps some acquaintance over the years did research upon Adam and Eve. We probably should be grateful for the real disclosure that vitamins are produced from bacteria present in the rumen. Now, has man lost this rumen, or is the author yet to arrange this gift? Probably not, since mutations are in fact always a regression or throwback. But since the bacteria accomplish this, then probably the animals themselves have also lost their ability. Well, it's probably of no importance, but it's difficult to patiently accept the author's mental ruminations as even pseudo-science.

Now, however, we find that the weight of all this tremendous scientific knowledge comes to a crushing thud with the "proof" that "No evidence has ever been adduced that laetriles are essential nutritional components." Where in the definition of a vitamin did the author mention that it must be an essential nutritional compound? He might have arranged it, but then it would have been

wrong, and so evidently this man with knowledge extending back prior to the flood was setting up a little semantic trap. Then we have the author stating that, "Laetriles (evidently persisting in his new nomenclature) have never been shown to promote any physiological process vital to the continued existence of any living organism." There again we have a semantic trap since this is not generally accepted as part of the definition of a vitamin.

The author breaks for home base with the pitch coming fast past his ears into the catcher's mit when he says, "No specific disease entity has been associated with a lack of a laetrile in any animal." (There's that attempt at distorting the nomenclature again.) We're not sure whether he is including man in this category as he has before. But that's just the point; there are those of us who have compiled strong evidence that a deficiency of vitamin B-17, the extrinsic factor and chymotrypsin, the intrinsic factor, results in the metabolic disease entity known as cancer.

We might even state that since the disease entity, cancer, is known as a metabolic disease, why should it be an exception to the axiom that there is no metabolic disease that does not have its prevention and control in the food which is available to us from nature? Can the author name one? No, he cannot, because there is none. Then we might ask the reader, why should the disease entity of cancer be an exception?

Again the author continues to mix up the enzyme systems presumably because he's more of a hatchet man than a scientist and just too anxious to deal the adversary a death blow. He says, "these compounds probably are not extensively broken down..." Certainly no one will accept "probably" as scientific proof.

Again we must remind the author that Laetrile is the name of a specific patented nitriloside. No student of biochemistry can correctly use the name of one chemical to cover all similar chemicals and expect to be other than a big puffed-up political animal, undoubtedly unfamiliar with even the index of the textbook ghosted for him.

At any rate, beta-glucosidase does not split Laetrile but it does affect amygdalin. Again, Laetrile cannot be taken orally because it hydrolyzes in the stomach. Amygdalin can be taken orally because it is not hydrolyzed in the stomach. Approximately 5% is hydrolyzed by the beta-glucosidase present in the apricot seed and occasionally in the pathological bacteria which causes the putrefaction of protein. Several weeks of the oral ingestion of the seed frequently clears up the offensive odor of fecal material which Americans have come to accept as normal. Now there is a physiological process readily apparent to anyone wishing to ingest five to seven uncooked apricot seeds over a two to three week period, on a daily basis. The author evidently doesn't realize that Laetrile cannot be taken orally while amygdalin can. It would seem as if his attempt to lump all nitrilosides into Laetrile has created this confusion for him. Someone ought to stop him before he creates chaos.

Again, he states that one of the unique properties of a vitamin is that its physiological function cannot be performed by any other class of compounds. All right, then can the author demonstrate any other vitamin capable of preventing the metabolic disease entity known as cancer? No, he cannot. So the author is still no closer to proving that vitamin B-17 is not a vitamin.

Then we have; "The claim that laetriles have the property of a vitamin (so called vitamin B-17) there fore is not supported by any valid scientific evidence." The author has not dared mention the vitamin characteristics of vitamin B-17, either assuming that the reader is not familiar with the characteristics or hoping that no one will ask.

We go on with Greenberg's other statements of "dubious validity" such as the part about thiocyanate which we remember Dr. Harper wasn't too sure about in the Richardson trial. Greenberg says there are other sources of cyanide which will produce thiocyanate, (thus sharing the spotlight with Greenberg's previously mentioned "statements of dubious validity"). Greenberg's next little gem about cyanocobalamin being an artifact doesn't contribute anything of value to the "dubious value" thesis. So much for author Greenberg's irrelevant and toxic persiflage. If all of this sounds confusing, it's not our fault. Read Greenberg's article.

In the paragraph directly below the heading Vitamins and Cancer, author Greenberg asks, "Is there some special relationship between vitamins and cancer?" He then answers by saying, "There are no valid grounds to believe there is and after many years search for a unique difference in metabolism between normal and neoplastic cells, none has been found - except for quantitative differences in rates of certain metabolic reactions." The exception should prove the rule along with the concluding sentence of the paragraph which states that cells with a high rate of turnover are more susceptible to a nutritional deficiency than nonproliferating or slowly proliferating cells.

What is this, double talk? Author Greenberg says it's not so and attempts to prove it with a statement that says it is so.

The next paragraph refers to authors Greenstein and Tannenbaum in 1954 and 1953 respectively reviewing earlier nutritional studies. But this is 1975 and there's a lot that has been written in the past twenty years. Nothing seems to be added to author Greenberg's special article in this paragraph or in the next three paragraphs except for a delightful trip through the "tules" regarding some useless information that author Greenberg throws in just so the reader will know that he's aware of even esoteric peripheral theories (don't ask us, we're in the dark as to the importance of isoriboflavin, deoxpyridoxine and pyrithiamin not having been found useful in cancer treatment).

Now then, as we near the close of provocateur Greenberg's article we have the question, "Could cyanide be a useful agent for the eradication of cancer?" He answers it succinctly enough. "No," he says. So with another side trip through the "tules", author Greenberg explains how hydrogen cyanide itself kills other things. So we won't try that. Brown tried it and it didn't work for him either. Finally, in the paragraph before the summary, we learn that, "In experiments that have been carried out with amygdalin, this compound has been administered along with beta-glucosidase. The results have been an increased toxicity with no evidence of improvement of anti-cancer activity." Now it's worth going over that paragraph to really absorb what Greenberg is trying to say. First, he doesn't name the experiment, the dosages, whether used on animals or humans, the amount of beta-glucosidase, where or how admin-

istered, and who suggested using beta-glucosidase anyway? The results he says have been increased toxicity (how measured? and by whom?) and "no evidence of improvement of anti-cancer activity." Now here we have a paucity in definitions of terms, certainly no references cited. All we may ask is what would the reasonable man think of author Greenberg's final effort?

We have not enjoyed discrediting "le Grand Homme" Greenberg. Nor would we have done so had not our accusers themselves been the perpetrators of one of the most incredible hoaxes known in recent history; that radiation and chemotherapy had anything at all beneficial to add to the vitamin deficiency syndrome known as cancer. Nor would we have wanted to be responsible for jeopardizing what must be a fantastic backlog of chemotherapeutic and radiation inventory. Perhaps, however, in some future war some Greenberg or Ross will figure a way to reconvert 5FU back to nitrogen mustard gas from whence the idea came, thereby reingratiating them with their masters.

We are not unaware that this monograph will find its way to but a small number of interested people, and by comparison the Greenberg article will be referenced and cross referenced as a new bulwark of the anti-vitamin B-17 faction in order to replace the now thoroughly discredited "California report of 1963". We think though, that our little effort will go a long way towards exposing the legacy of error which still sustains a 20th century arrogance of ignorance, thought previously to be the sole possession of bygone and more bigoted generations.

1) Burk, D., McNaughton, A.R.L. and Von Ardenne, M. Hyperthermy of cancer cells with amygdalin - glucosidase and synergistic action of derived cyanide and benzaldehyde. Minerva Chir. 24:1144 (1969).

2) Cerami, A. Cyanate as an inhibitor of red cell sickling. New Engl. J. Med. 287:807 (1972).

3) Cerami, A. and Peterson, C.M. Cyanate and sickle cell disease. Sci. Am. April, 1975, p. 45.

4) Fishman, W.H. and Anlyan, A.J. A comparison of the beta-glucuronidase activity of normal, tumor and lymph node tissues of surgical patients. Science 106:66 (1947).

5) Fishman, W.H. and Anlyan, A.J. Beta-glucuronidase activity in human tissues. Some correlations with the processes of malignant growth and with the physiology of reproduction. Fourth Int. Cancer Research Congress 6:1034 (1950).

6) Fishman, W.H. and Anlyan, A.J. The presence of high beta-glucuronidase activity in cancer tissue. F. Biol. Chem. 169:449 (1947).

7) Fishman, W.H. Beta-glucuronidase activity of blood and tissue of obstetrical and surgical patients. Science 105:646 (1947).

8) Funderburk, C.F. and Van Middlesworth, L. Effect of thiocyanate concentration on thiocyanate distribution and excretion. Proc. Soc. Exptl. Biol. Med. 136:149 (1971).

9) Giordano, G., Violante, A., Lerenzetti, G. and Sapio, U. Rhodanese activity of the neoplastic and hematopoietic tissue of rats with myeloma in leukemic phase. Biochemie Appl. 3:284 (1957).

10) Harper, H.A. Review of Physiological Chemistry. Lange Medical Publishers, Los Altos, California (1973).

11) Homberger, I. and Fishman, W.H. The Physiopathology of Cancer. Paul B. Hoeber, Inc., New York (1955).

12) Houston, Robert G. Sickle cell anemia and dietary precursors of cyanate. Am. J. Clin. Nutrition 26:1261 (1973).

13) Kittler, Glenn D. Laetril: Control for Cancer. Warner, New York (1963).

14) Krebs, E.T. Jr. The nitrilosides (B-17), their nature, occurrence, and significance. Antineoplastic vitamin B-17. J. Appl. Nutr. 22:75 (1970).

15) Lang, K. Die Rhodanbildung im Tierkoerper. Biochem. Zeitschrift 259:243 (1933).

16) Mendel, B., Rodney, H. and Bowman, M.C. Rhodanese and the Pasteur effect. Cancer Research 6:495 (1946).

17) Morrow, A.G., Greenspan, E.M. and Carrol, D.M. Comparative studies of liver glucuronidase activity in inbred mice. J. Nat. Cancer Inst. 10:1199 (1950).

18) Oke, O.L. The role of hydrocyanic acid in nutrition. World Rev. Nutr. Dietet. 11:170 (1969).

19) Osuntakun, B.O. Cassava diet and cyanide metabolism in rats. Brit. J. Nutr. 24:797 (1970).

20) Rosenthel, O. Distribution of rhodanses. Fed. Proc. 7:181 (1948).

21) Sanchez, F. and Bertran, E. Castella Variations in the rhodanese activity induced by injection of chorionic gonadotropin. An. Facul. Vet. Univ. Madrid y Inst. Invest. Vet. 3:78 (1951).

22) Stefansson, V. Cancer: Disease of Civilization? An Anthropological and Historical Study. Hill and Wang, New York (1960).

23) Stern, K. and Wilheim, R. The Biochemistry of Malignant Tumors. Reference Press, Brooklyn, New York (1943).

24) Summer and Somers Chemistry and Methods of Enzymes. Academic Press, New York (1947).

AMERICAN MEDICAL ASSOCIATION
535 NORTH DEARBORN STREET • CHICAGO, ILLINOIS 60610 • PHONE (312) 751-6000 • TWX 910-221-0300

JAMES H. SAMMONS, M.D.
Executive Vice President
(751-6200)

July 8, 1977

Honorable Edward M. Kennedy
Chairman
Subcommittee on Health and Scientific Research
Committee on Human Resources
United States Senate
4230 Dirksen Senate Office Building
Washington, D. C. 20510

Re: Laetrile

Dear Senator Kennedy:

The American Medical Association is pleased to take this opportunity to submit its comments on laetrile to the Subcommittee.

We believe the issues surrounding the laetrile controversy could have wide impact on the provision of quality care to the public.

We request these comments be made a part of the official hearing record in this matter.

Very truly yours,

James H. Sammons, M. D.

Enclosure

STATEMENT

of the

AMERICAN MEDICAL ASSOCIATION

before the

Subcommittee on Health and Scientific Research
Committee on Human Resources
United States Senate

Re: Laetrile

July 12, 1977

The American Medical Association takes this opportunity to speak to issues surrounding laetrile, a nostrum for the cure, treatment, palliation and prevention of cancer.

These issues are gaining major significance as state legislatures across the country are considering and passing laws to legitimize its use. To date, 12 state legislatures have passed such laws and 9 governors have either signed legislation legalizing laetrile or have allowed such legislation to become law without their signatures. This action by the States jeopardizes the uniform system of federal regulation of drugs based upon evidence of safety, efficacy, quality and proper labeling.

This legislative activity is based upon arguments advanced by laetrile advocates that laetrile has some affect on cancer, or even if it does not have any effect, it is a harmless substance and therefore persons should be allowed the freedom of choice in selecting the treatment for cancer which they feel is appropriate.

These laetrile advocates also allege that the medical establishment has a vested financial interest in treating cancer victims and therefore has been

preventing the marketing of laetrile. This allegation is simply not true.

Whether laetrile is toxic or not does not avoid the fact that when people who are afflicted with cancer turn away from recognized treatment in order to use a purported "miracle cure", which is in fact ineffective, they are giving up any chance they have for the cure or mitigation of their disease. The recognized treatments for cancer can be radical and frightening and people are justifiably concerned about the risks often involved in surgery and in the side effects from radiation treatments and established chemotherapy. It must also be acknowledged, though that these treatments have been proven to be effective in the cure or mitigation of cancer in many cases.

Furthermore, the allegation that the medical profession is trying to "cover up" and to suppress material and research which would prove laetrile's effectiveness is baseless. This is one of the techniques used by those who advocate the marketing of laetrile.

The advocates of laetrile have offered a number of theories on why laetrile works, how it works and why it should be allowed on the market. The mere fact that there is a constantly changing set of theories as to why laetrile should be used or how it does work is sufficient to lead objective persons to question the validity of any of the theories put forth. However, these inconsistencies alone do not lead to the belief that laetrile should not be approved for marketing. Laetrile has never been shown to be effective for the treatment or prevention of cancer in any well documented or controlled scientific test performed to date.

For example, as early as 1953, the Cancer Commission of the California Medical Association investigated laetrile as a treatment for cancer in human beings. The Commission found that "in two independent studies by experienced research workers, laetrile has been completely ineffective when used in large

doses on cancer in laboratory animals, in lesions which are readily influenced in useful chemotherapy."

In May of 1975, a report in the Canadian Medical Association Journal concluded that laetrile could not be considered as a palliative in cancer therapy on the basis of the biological rationale advance by the manufacturer.

In April of 1970, the U. S. Food and Drug Administration approved an investigative new drug application submitted to test and perform experiements using laetrile. Twenty-one days after receipt of the application, the FDA withdrew its approval because a subsequent review of the application disclosed a large number of serious pre-clinical deficiencies. The applicant did not proceed to correct the defects found in the application identified by FDA when offered the opportunity to do so. The application was therefore terminated in May of 1970.

Further investigations as to the effectiveness of laetrile were then conducted by the National Cancer Institute beginning in 1973. While certain animal tests carried out by a single investigator at the Sloan-Kettering Institute for Cancer Research indicated that laetrile had the effect of reducing metastases from mammary tumors in experimental animals, the results of this set of tests could never be reproduced under similar conditions and is considered by Sloan-Kettering to be "innocent observer error".

The Sloan-Kettering Institute has released the results of approximately 32 animal studies that were carried out that confirm the fact that laetrile has no anti-tumor activity. This latest series of experiments adds to the already large body of scientific evidence that indicates that laetrile is not effective in the prevention or treatment of cancer. The report also points out a certain risk of toxic reactions from laetrile when ingested in high doses contrary to

the claims of laetrile advocates as to laetrile's safety.

The American Cancer Society has long pointed out, through its continuous review of scientific literature, that laetrile is not a proven or generally recognized treatment for cancer.

While the weight of scientific evidence indicates the ineffectiveness of laetrile in the treatment or palliation of cancer, the proponents of laetrile rely upon undocumented testimonials as to cures and remissions. These reports are anecdotal and testimonial in nature. Such reports do not in fact establish the effectiveness of laetrile. These reports provide no evidence as to whether the "cured" individual had cancer in the first place or whether the person was simultaneously receiving proven treatment for cancer while participating in a laetrile regimen. The type of evidence offered by the proponents of laetrile is of a type which is wholly unacceptable to medical science since it provides no documentation as to the conditions under which these so-called treatments took place.

The American Medical Association likewise views laetrile as ineffective in the treatment of cancer. In 1976, the AMA at its Annual Meeting adopted the following resolution pertaining to the profession's view of laetrile:

> RESOLVED, That the American Medical Association continue to inform the public of the danger of delay in the diagnosis and treatment of malignancies by methods not generally recognized by the medical profession as beneficial and effective; and be it further
>
> RESOLVED, That the American Medical Association inform the public that the safety and efficacy of amygdalin for the treatment or palliation of malignancies is unproved and that the use of amygdalin in such cases exploits the victims of malignancies and their families by preying upon the emotions of the hopelessly ill, in some cases for the profit of the unscrupulous.

At its just completed 1977 Annual Meeting, the Association reviewed its

earlier policy and adopted an additional resolution stating:

> RESOLVED, That it is the position of the American Medical Association that laetrile is a substance which has no proven value as a drug.

The AMA wholeheartedly supports the efforts of the Food and Drug Administration in preventing the distribution of laetrile in interstate commerce until such time as it is shown to be safe and effective as required by law. Quality patient care would suffer if laetrile were made available without such compliance. We believe that the promoters of laetrile who are charging exorbitant fees for its use and who prey upon the emotions of the hopelessly ill are the unscrupulous. These are the persons who seek to prey upon, and profit from, those whom they cannot help, thus often causing immeasurable harm.

John C. Ballin, Ph.D.
Executive Director
Marilyn A. Krause
Executive Assistant

NATIONAL COUNCIL ON DRUGS
P.O. Box 7969
Chicago, Illinois 60680
(312) 751-6321

Ray W. Gifford, Jr., M.D.
Chairman
Frederick Shideman, M.D.
Vice-Chairman
Walter M. Booker, Ph.D.
Alvira B. Brands, R.N., D.N.Sc.
Donald O. Fedder, Pharm.B.S.
Edward G. Feldmann, Ph.D.
Mrs. Alice Fordyce
Benjamin M. Kagan, M.D.
John H. Marsden, M.D.
F. Gilbert McMahon, M.D.
John A. Owen, Jr., M.D.
Gordon H. Schrotenboer, Ph.D.
Alan B. Varley, M.D.
W. Clarke Wescoe, M.D.

July 8, 1977

Honorable Edward M. Kennedy
United States Senate
431 Russell Senate Office Building
Washington, D.C. 20510

Dear Senator Kennedy:

I was disappointed to learn that time did not permit presentation of oral testimony on laetrile by the National Council on Drugs at your Subcommittee hearings on July 12, 1977. I am enclosing copy of testimony that I had intended to present.

On behalf of the National Council on Drugs, I would appreciate your making this statement part of the record of your hearings on laetrile.

Sincerely,

John A. Owen, Jr.

John A. Owen, Jr., M.D.

Enclosure

96 492 311

Participating Organizations
American Dental Association
American Medical Association
American Nurses Association
American Pharmaceutical Association
American Society for Clinical Pharmacology and Therapeutics
American Society for Pharmacology and Experimental Therapeutics
National Medical Association
Pharmaceutical Manufacturers Association

Liaison Organizations
American Society of Hospital Pharmacists
American Veterinary Medical Association
U.S. Food and Drug Administration

John C. Ballin, Ph.D.
Executive Director
Marilyn A. Krause
Executive Assistant

NATIONAL
COUNCIL
ON DRUGS

P.O. Box 7969
Chicago, Illinois 60680
(312) 751-6321

Ray W. Gifford, Jr., M.D.
Chairman
Frederick Shideman, M.D.
Vice-Chairman
Walter M. Booker, Ph.D.
Alvira B. Brands, R.N., D.N.Sc.
Donald O. Fedder, Pharm.B.S.
Edward G. Feldmann, Ph.D.
Mrs. Alice Fordyce
Benjamin M. Kagan, M.D.
John H. Marsden, M.D.
F. Gilbert McMahon, M.D.
John A. Owen, Jr., M.D.
Gordon H. Schrotenboer, Ph.D.
Alan B. Varley, M.D.
W. Clarke Wescoe, M.D.

STATEMENT

by

National Council on Drugs

on

Laetrile

for

Hearings, July 12, 1977

Subcommittee on Health

Committee on Human Resources

U.S. Senate

by

John A. Owen, Jr., M.D.

96 492 312

Participating Organizations
American Dental Association
American Medical Association
American Nurses Association
American Pharmaceutical Association
American Society for Clinical Pharmacology and Therapeutics
American Society for Pharmacology and Experimental Therapeutics
National Medical Association
Pharmaceutical Manufacturers Association

Liaison Organizations
American Society of Hospital Pharmacists
American Veterinary Medical Association
U.S. Food and Drug Administration

I am John A. Owen, Jr., M.D., Chairman of the Task Force on Laetrile of the National Council on Drugs. I am Professor of Internal Medicine, in the Division of Clinical Pharmacology, at the University of Virginia School of Medicine in Charlottesville, Virginia, where I live and practice medicine.

The National Council on Drugs is a relatively new organization, made up of representatives of the professional organizations most concerned with drugs and drug therapy. We have previously considered the question of laetrile and on May 9, 1977, issued a statement that strongly supported the attempts of the Food and Drug Administration to consider this substance a drug and to require proof of both efficacy and safety prior to release.

Since no such proof has appeared, our position remains unchanged. We still insist that these conditions be fulfilled. Indeed, to disregard them is to disregard all that the FDA stands for and to return to the pre-1906 era, when any quack could produce any nostrum he wished and foist it off on the public.

But the increasing momentum of the movement to legalize laetrile on a state-by-state basis has concerned the Council and has led to the appointment of a Task Force on Laetrile of which I am Chairman. We have met and agreed on the following objectives, toward which we strive.

First, the Food and Drug Administration should earn recognition as an agency whose decisions are based on a scientific methodology and the accumulation of valid and convincing evidence. This country

is better served by an FDA that is always right in the long run, though beset with difficulties, rather than by an agency so all-powerful that it can immediately enforce all its edicts, right or wrong.

Second, the medical profession as a whole should demonstrate that delicate balance of scientific knowledge and humane concern that characterizes not only a wise doctor but a good doctor. While monolithic condemnation of a worthless cure is correct, it must be coupled with a sensitive concern for the agony of the hopeless to be truly right.

Third, we should all try to defuse emotional confrontations which accomplish nothing and are detrimental to any sincere effort to obtain the truth. The very appreciable advances that have occurred in conventional cancer therapy have been deliberately downgraded and denied and, therefore, a comprehensive, factual, and ongoing public education program on cancer is desperately needed.

To achieve these objectives, we have come to the conclusion that the time is ripe, in 1977, for a controlled clinical trial of laetrile. This should be done under rigorous scientific conditions, in a variety of selected cancer treatment centers, under the auspices of the National Cancer Institute in cooperation with the Food and Drug Administration.

Such a decision would guarantee for the cancer patient a completely legitimate opportunity to obtain laetrile of known strength and purity in a setting that would permit precise diagnosis of the disease and

study of the treatment, and where any problem that arose could receive the best medical care available.

Such a study might explore the possibilities of therapeutic effects of laetrile not easily tested in animal studies, e.g., 1) a pain-relieving or mood-elevating effect, 2) an effect on immune processes, 3) an amelioration of some of the side-effects of conventional cancer therapy, or 4) other as yet unknown effects.

Such a planned and organized approach to an answer would give us all an opportunity to lower our voices, to reconsider our infallibility, and to get on with the business of caring for the sick.

If such a study produced evidence of any beneficial therapeutic effect of laetrile, we would all have cause to rejoice. If laetrile proved totally and unequivocally worthless, the lesson for our hard-pressed legislators, both at the state and federal level, would be highly salutary.

A former resident of my community, Mr. Thomas Jefferson, characterized the University of Virginia as follows: "For here we are not afraid to follow truth wherever it may lead, nor to tolerate any error so long as reason is left free to combat it." I recommend this philosophy to you, not as the dead words of a dead historical figure, but as a living and exciting rule of thumb for all of us.

LAETRILE TOXICITY: A REPORT OF TWO CASES

Frederick P. Smith, MD
Thomas P. Butler, MD
Stanley Cohan, MD
Philip S. Schein, MD

Division of Medical Oncology, Department of Medicine and, Department of Neurology, Georgetown University School of Medicine, Washington, D.C. 20007

Running Title: Laetrile Toxicity

Synopsis

Laetrile is an unproven remedy for cancer which has been assumed to be nontoxic by both the public and a wide segment of the medical profession. We describe two cases with serious adverse reactions associated with Laetrile administration. One patient developed a syndrome of fever, dermatitis, and gastrointestinal symptoms which promptly disappeared after discontinuation of Laetrile, only to recur after she resumed taking the compound. The second patient developed a neuromuscular disorder that reversed following withdrawal of Laetrile.

It behooves the advocates of Laetrile to provide detailed toxicologic information which is regularly required of any experimental therapy.

Laetrile (amygdalin), a cyanogenic glycoside found in seeds of apricots, peaches and bitter almonds, is an unproven remedy for cancer (1) that has received recent widespread attention in the lay press. The use of Laetrile has been legalized in several states even though antineoplastic activity has not been demonstrated for a broad range of predictive animal tumor systems (2,3,4,), and there is no clear evidence of clinical effectiveness in man.

One of the strongest arguments for approval voiced by the proponents of Laetrile, has been the assertion that this material is void of the usual toxicities associated with conventional cancer therapy. Both the public and medical profession have accepted this claim of safety on faith and it has been assumed that Laetrile is, at worst, a nontoxic placebo. However there are no published reports of systematic evaluations of this compound's potential for producing adverse reactions.

We report here two cases of toxic reactions that occurred in association with Laetrile administration and challenge the present claims of its safety.

Case 1

This 48 year old white female was diagnosed as having a well-differentiated lymphoproliferative disorder in 1965 at which time she was treated with cobalt radiation. For the past 8 years she had been treated with Prednisone 20 mg daily, and intermittently had received various forms of unconventional therapy, but not Laetrile. In July, 1976 the patient was referred to the Division of Medical Oncology at Georgetown University Hospital after she first evidenced progression of disease with marked hepatosplenomegaly. Following an initial evaluation, it was recommended that she begin a course of Leukeran (Chlorambucil) but she failed to return for followup.

In January, 1977 she returned after having spent three months in a nutritional clinic in Germany where she received Wobe-Mugos and pyrogenic intravenous medication but not Laetrile. She was found to have widespread lymphadenopathy, a liver span of 17 cms and the spleen was palpable 12 cm below the left costal margin. Her Hgb was 8.5 g/dl, white blood count 72,000/cu mm with 80% well differentiated lymphocytes and her platelet count was 63,000/cu mm. Bone marrow aspirates were unsuccessful, bone biopsies demonstrated complete replacement with well differentiated lymphocytes. She was treated with Leukeran (Chlorambucil) 0.12 mg/kg for 7 days and Prednisone was maintained. The white blood count improved to 15,000/cu mm while her hemoglobin and platelet count were not appreciably changed. The lymphadenopathy and hepatosplenomegaly did not change significantly. She again failed to appear for followup.

On April 25, 1977 she returned with complaints of malaise, nausea, backache, headache, abdominal cramps and fever without chills. She was found to be febrile to 38.8°C (102°F) with a diffuse, nonpruritic, erythematous macular rash which was most pronounced over the trunk but spared the face. The abdominal examination demonstrated diffuse tenderness, but bowel sounds were audible

and there were no signs of peritoneal inflammation. The lymphadenopathy had not changed, the liver span was 18 cms, and the spleen remained palpable 11 cms below the left costal margin. Her hemoglobin was 8 g/dl, white blood count 7,000/cu mm with 89% lymphocytes, 6% polymorphonuclear cells, 5% bands, platelet count was 69,000/cu mm. The patient had spent three weeks in Mexico (from February 23 through mid-March) receiving intravenous Laetrile (Amygdalina, Cytopharma de Mexico, Reg. #84954SSA) 6 gm daily. She continued receiving intravenous Laetrile 6 gm each week in addition to oral Laetrile 500 mg three times a day following her return to the United States. She had not taken Leukeran since January but had continued Prednisone.

In view of her relative neutropenia and fever, she was hospitalized. Blood, urine, stool and throat cultures were taken and she was treated symptomatically with intravenous fluids. Laetrile was discontinued, but the daily oral Prednisone was maintained. All cultures proved negative for pathogenic bacterial growth and within 24^{0} of admission, her temperature was normal and her rash and abdominal cramps rapidly resolved within two days. She signed herself out against medical advice.

On June 5, she resumed Laetrile against our advice and again received 6 gm intravenously on a weekly basis and 500 mg three times a day orally. She was readmitted to the hospital on June 20 with headache, nausea, abdominal cramps, rash and fever to 38^{o}C (102^{o}F), the exact syndrome leading to her admission of April 25. Again cultures were negative for pathogenic bacterial growth, blood cyanide level was 1 ugm/dl, and skin biopsy was consistent with a drug eruption with perivascular infiltration with lymphocytes. Laetrile was discontinued on admission and the fever, rash, and abdominal discomfort cleared within 48 hours.

Case 2

In June, 1976 this 46 year old man was found to have large cell anaplastic carcinoma of the lung metastatic to the left parieto-temporal region of the cerebrum. He was treated with radiation therapy, 3000 rads, to the whole brain and to the mediastinum followed by chemotherapy with chlorozotocin, a Phase I investigational drug. In September, 1976 he experienced a generalized major motor seizure and was placed on Dilantin (Diphenylhydantoin). Neurologic examination at that time demonstrated an isolated left medial rectus paresis, with moderate dilation and reduced light reflex of the left eye, normal skeletal muscle strength, normal deep tendon reflexes, but a positive snout reflex.

He was admitted to the hospital in March, 1977 with a one-week history of progressive neuromuscular symptoms. On examination there was bilateral lid ptosis, complete on the left and 75% on the right. Bilateral medial rectus paresis was present, but the other cranial nerves were intact. He had bilateral upper and lower extremity proximal muscle weakness to three-fifths of expected strength with normoactive reflexes, a right Babinski reflex, and a snout reflex. The blood glucose was 91 mg/dl, serum electrolytes, calcium and CPK were normal. It was learned from the patient that he had been taking a 500 mg Laetrile tablet daily since September, 1976 in addition to the prescribed Dilantin. Laetrile was discontinued, and within 48 hours his ptosis and proximal muscle weakness improved dramatically, and resolved completely in 6 days. Computerized axial tomogram (CAT) of the brain showed a new lesion in the techtum and he was started on Decadron (Dexamethasone) and given additional CNS radiation.

The patient has remained off Laetrile and continued on chlorozotocin and on followup visits, has not had recurrence of either ptosis or proximal muscle weakness.

Discussion

The initial rationale for the use of Laetrile as an anticancer agent was based on the assumption that the compound would be taken up by cancer cells and then hydrolyzed by β-glucosidases to liberate cyanide. It was subsequently demonstrated that animal tissues have only trace β-glycosidase activity and tumor cells even less (5). To our knowledge, there are no reports of adverse reaction associated with 'therapeutic' doses of Laetrile, but this compound has never been subjected to a systematic toxicologic evaluation. Cyanide poisoning and death have been reported in young children ingesting apricot and other fruit seeds containing cyanogenic glycosides (6,7). Acute cyanide poisoning is manifest by giddiness, hyperpnea, headache, palpitation, cyanosis, unconsciousness and death. A chronic neurologic toxicity has been described in natives ingesting cassava which contains cyanogenic glycosides. At the present time it is not possible to determine whether the observed toxicities were directly related to cyanide, an intermediate metabolite of amygdalin, or perhaps an adulterant in the specific batch of compound.

Our first patient presented with a rash, gastrointestinal symptoms and fever requiring hospitalization. These symptoms and signs improved dramatically after discontinuation of Laetrile, only to return within 3 weeks after resumption of this material. This patient had a form of malignancy readily recognized to be responsive to conventional chemotherapy, but nevertheless she sought an ineffective, and toxic, treatment.

Our second case developed a potentially more serious reaction. This patient presented with ptosis and weakness of the extremities that cleared rapidly after stopping Laetrile. Although the location of the metastasis might have contributed to the ptosis, this abnormality cleared before either radiotherapy or dexamethasone were initiated. It is probable that the

reduction in muscular strength was mediated either by direct toxicity to muscle or by interference with neuromuscular transmission. Unfortunately we did not have the opportunity to perform the appropriate neuromuscular tests to elucidate the exact mechanism.

We feel that these cases represent definite toxicities resulting from the administration of Laetrile. The syndromes could have been misdiagnosed as a manifestation of disease in patients with malignant diseases. The measures taken to insure quality control of Laetrile, and the concentration of 'active agent' as well as that of potentially toxic contaminants are not known. It cannot be assumed that Laetrile is nontoxic or that this compound has not already contributed to the death of patients with malignant diseases. Therefore it behooves the advocates making claims of effectiveness of Laetrile, not only to provide data which demonstrate objective benefits from this material, but also to furnish detailed toxicologic information which is regularly required for any experimental therapy.

References

1. Jukes, TH: Laetrile for cancer. JAMA 236:1284-1286, 1976.

2. Laster, WR, Schabel, FM: Experimental studies of the antitumor activity of amygdalin MF (NSC-15780) alone and in combination with β-glucosidase (NSC-128056). Cancer Chemother. Rep. 59:951-965, 1975.

3. Wodinsky, I, Swiniarski, K: Antitumor activity of amygdalin MF (NSC-15780) as a single agent and with β-glucosidase (NSC-128056) on a spectrum of transplantable rodent tumors. Cancer Chemother. Rep. 59:939-950, 1975.

4. Martin, DS: Laetrile testing a Cover-up that Wasn't. Medical World News 21-23, October 6, 1975.

5. Greenberg, DM: The vitamin fraud in cancer quackery. Western Jour. Med. 122:345-348, 1975.

6. Townsend, WA, Boni, B: Cyanide poisoning from ingestion of apricot kernels. Morbid Mortal Weekly Report 24:427, 1975.

7. Sayre, JW, Kaymakcalan, S: Cyanide poisoning from apricot seeds among children in central Turkey. NEJM 270:1113-1115, 1964.

STATE OF CALIFORNIA—AGRICULTURE AND SERVICES AGENCY EDMUND G. BROWN JR., Governor

DEPARTMENT OF Consumer Affairs

BOARD OF MEDICAL QUALITY ASSURANCE
1430 HOWE AVENUE, SACRAMENTO, CALIFORNIA 95825
ALLIED HEALTH PROFESSIONS (916) 322-5043
APPLICATIONS AND EXAMINATIONS (916) 322-5040
COMPLAINTS (916) 322-5030
DISCIPLINARY INFORMATION (916) 322-2341
FICTITIOUS NAMES AND CORPORATIONS (916) 322-5040
VERIFICATIONS OF LICENSES (916) 322-2831

July 14, 1977

Mrs. Kathleen Henderson
Staff Person
Senate Subcommittee on Health & Scientific Research
Room 4220, Dirksen Office Building
First & C Streets, N.W.
Washington, D.C.

Dear Mrs. Henderson:

Thank you for the courtesy extended to me and Mr. Castro on our recent trip to Washington where we testified before Senator Edward M. Kennedy's subcommittee on health and scientific research.

I am enclosing some additional material that may be of value, and which you may wish to include in the record, which was the type of literature that was disseminated by Dr. Richardson to members of the Board, to Mr. Castro, and other individuals in the Richardson hearing.

Sincerely,

Joseph P. Cosentino

JOSEPH P. COSENTINO, M.D.
Medical Consultant

JPC:my

Enclosure

AUGUST 20th, 1975

SENT BY CERTIFIED MAIL.

JOHN A. RICHARDSON, M.D.
514 KAINS AVENUE
ALBANY, CALIFORNIA 94706

TO: RAYMOND REID
SERVANT & EXECUTIVE SECRETARY
BOARD OF MEDICAL EXAMINERS
1020 NORTH STREET, ROOM 434
SACRAMENTO, CALIFORNIA 95814

CC: V.O.O.C. (VIOLATORS OATH of OFFICE COMMITTEE)
SHERIFF'S POSSE COMITATUS (VARIOUS UNITS ALERTED)
SOME NEWSPAPERS
OTHER INTERESTED PARTIES
ATTORNEY GENERAL E. YOUNGER

SUBJECT: POOR GOVERNMENT COMES ABOUT WHEN GOOD CITIZENS SIT ON THEIR HANDS INSTEAD OF STANDING ON THEIR FEET .

SUB-TOPIC: COPY OF ACCUSATION TO RESPONDENT; NUMBER: D-1605

SERVANT, RAYMOND REID, IT IS IMPORTANT TO UNDERSTAND WHATEVER MAY BE MENTIONED. FOR AN EXAMPLE, FOODS, POISONS, DRUGS, WORDS, AND LAWS. LET IT BE UNDERSTOOD FROM THE BEGINNING, THAT WRITER IS INTERESTED IN OBEYING THE LAWFUL LAWS, LAWFULLY PRESENTED. THERE IS OF COURSE "TWO" SETS OF LAWS; (1) LAWFUL LAWS OF THE LAND, & (2) ULTRA-VIRES, PERTAINING TO OFFICIALS AND SO-CALLED LAWS. I HAVE PERSONALLY VOWED TO UPHOLD THE CA. & UNITED STATES CONSTITUTIONS WITHOUT ANY MENTAL RESERVATIONS WHATSOEVER. IT IS HOPED THAT YOU FEEL THE SAME WAY. HOWEVER, REGARDLESS OF HOW YOU MAY FEEL, THERE ARE LAWS THAT MUST BE CONFORMED TO. LET M E CITE SOME, WHICH FOLLOW:

TITLE 18, SECTIONS, #241, #242, #1017, #1018, #1001, & #2381. TITLE 42, SECTIONS, #1983 & #1988. CA. PENAL CODE, SECTIONS, #115, #118, #98, #100, #158, #129, #132, #134, #121, #125, & #126.

IF THE ABOVE LAWS PERTAIN TO YOU, AND THOSE LAWS ARE VIOLATED, THEN IT SHALL BE DECIDED IN A CONSTITUTIONAL COURT OF LAW. THAT IS WHAT COURTS ARE FOR. ADMINISTRATION HEARINGS CANNOT SERVE THE FUNCTION OF A COURT .

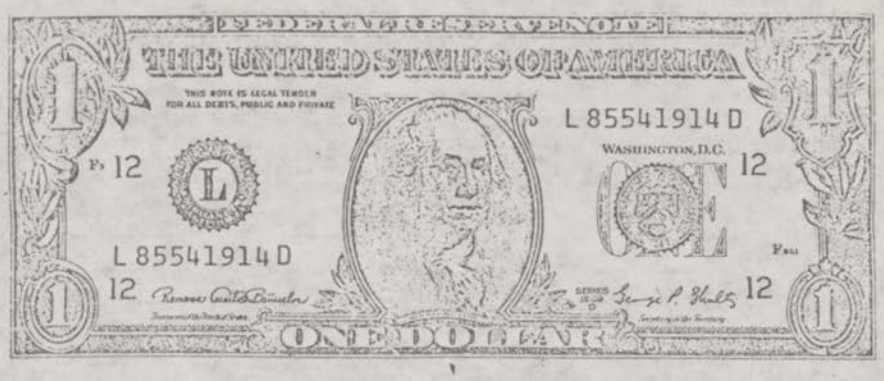
THERE ARE LAWS OF RIGHTS FOUND IN THE CA. CONSTITUTION WHICH FOLLOW: SECTIONS, #1, #2,#7, #9, #11, #13, #14, #16, #18, #19, #23; ARTICLE 1. SECTIONS, #1 & #3; ARTICLE 3. SECTION, 3, ARTICLE 20.

THE CONSTITUTION CONTAINS RIGHTS FOR THE CITIZENS OF THE UNITED STATES. THEY ARE: ARTICLE 1, SECTIONS, #8 & #10. ARTICLE 3, SECTION 1. AMEND - MENTS, #1, #4, #5, #7, #10, #13, #14, & #15.

WRITER WISHES GUARANTEE AGAINST ENCROACHMENT OF RIGHTS IN THE FORM OF AN AFFIDAVIT WHICH FOLLOWS, TO BE COMPLETED, SIGNED, WITNESSED, NOTARIZED , AND THEN RETURNED TO WRIT ER WITHIN TEN DAYS FROM THE DATE OF THE DOCUMENT. "REFUSAL" TO DO SO WILL BE ACCPETED AS POSITIVE PROOF, THAT YOU , RAYMOND REID, SERVANT AND EXECUTIVE SECRETARY OF THE BOARD OF MEDICAL EXAMINERS, ARE IN FACT CONTRIBUTING TO THE OBSTRUCTION OF JUSTICE, FAILING TO UPHOLD THE CA. & UNITED STATES CONSTITUTIONS, THE CRIMINAL LAWS, THEREFORE, ABIDING BY THE ULTRA-VIRES SO-CALLED LAWS. SUCH "REFUSAL" TO COMPLY WILL CONSTITUTE "PRIMA-FACIE" EVIDENCE THAT YOU, RAYMOND REID, HAVE AND/OR WILL WILLFULLY AND KNOWINGLY, WITH MALICIOUS INTENT, SOUGHT OR SEEK TO CONSPIRE AGAINST JOHN A. RICHARDSON, M.D., THROUGH EX-PARTE HEARINGS,.. AND NOT THROUGH THE JUDICIAL PROCESS GUARANTEED TO WRITER, FORCED TO SUBMIT TO THE KIND OF ILLEGAL PRESSURES WHICH IS CRUEL AND UNUSUAL PUNISHMENT.

WITH CONSTITUTIONAL REGARDS
AND MASTER IN GOVERNMENT

JOHN A. RICHARDSON, M.D.



PHONY MONEY

This is a Federal Reserve Note that people use in lieu of lawful U.S. Currency due to its close physical resemblence to lawful money. It is the only available money that can be obtained at a bank. The unit of issue shall be termed the "Dollar" but should not be interpreted as being lawful U.S. Money as definied by the U.S. Constitution and the U.S. Coinage Acts of 1783 and 1900.

These notes are printed in several denominations among which are one, five, ten, twenty, fifty and one hundred "Dollars".

The notes are printed in black and green ink on a special paper so that they closely resemble lawful money that could be redeemed for Gold or Silver.

The seal is printed in green ink to minimize the probability of people accidentally mistaking it for lawful U.S. Currency, such as United States Notes or Silver Certificates.

Its value is not stable like lawful money but more like a Yo Yo, up and down, up and down.

COPYRIGHT 1974 by LAURENCE G. PORTER

96-492 O - 77 - 23

AUGUST 29TH, 1975

SOVEREIGN-CITIZEN-DEFENDANT'S PROTECTION OF RIGHTS A F F I D A V I T

FOR RAYMOND REID, SERVANT & EXECUTIVE SECRETARY, BOARD OF MEDICAL EXAMINERS, SACRAMENTO, CALIFORNIA

I,_____ __ _____, RESIDING AT:_____CITY OF:_____ STATE OF:_____, EMPLOYED BY:_____, CITY OF:_____ STATE OF:_____, HOLDING POSITION OF:_____, FOR_____YRS. &_____MONTHS, DO OF MY OWN FREE WILL AND ACCORD, SWEARING AS ACCORDED BY LAWFUL LAW, UNDER PENALTIES OF PERJURY, SERVING WITH THE HONESTY AND INTEGRITY, AS ACCORDED BY THE CRIMINAL LAWS SET FORTH TO PROTECT SOVERIGN-CITIZEN-DEPENDANT'S RIGHTS AGAINST CONSPIRACY IN ANY FORM; ALSO, "I" AM NOT IN THE PROCESS, NOR HAVE I BEEN IN THE PROCESS OF CIRCUMVENTING JOHN A. RICHARDSON'S CONSTITUTIONAL RIGHTS AFFORDED HIM, AND, "I" AM FULLY AWARE OF THE PENALTIES FOR VIOLATING CRIMINAL LAWS THAT CAN BE USED AGAINST ME FOR CONSPIRING IN ANY MANNER OR FORM. I AM COGNIZANT OF THE CA. & UNITED STATES CONSTITUTIONS THAT GIVES "RIGHTS OF PROTECTION" AND THAT "I" HAVE NOT, NOR WILL "I" CONSPIRE, ALONE OR WITH OTHER PARTIES TO DEPRIVE SAID DEFENDANT OF HIS CONSTITUTIONAL RIGHTS. I FULLY UNDERSTAND THE DUE PROCESS OF LAW, AND THAT ANY ADMINISTRATION HEARING IS IN FACT, NOT A COURT OF LAW, THEREFORE, NOTWITHSTANDING, DUE TO HIGHER LAW RIGHTS, AND IT IS FULLY REALIZED THAT THE ONLY LEGITIMATE FUNCTION OF GOVERNMENT IS TO PROTECT JOHN A. RICHARDSON'S LIFE, LIBERTY AND PROPERTY, AND THAT TO DEPRIVE HIM OF SAME, IS COMMITTING UNLAWFUL ACTS, AND VIOLATING CRIMINAL LAW THUS PLACING SAID DEFENDANT IN JEOPARDY, AND ALSO PLACING ME, RAYMOND REID IN A POSITION TO BE SUED IN A FEDERAL COURT. I AM FULLY AWARE OF ART. 1, SECTION 10, IN THE U.S. CONSTITUTION AND THE TWO MONETARY SYSTEMS; (1) THE FED NOTE FIASCO; (2) & CONSTITUTIONAL MONIES WITH REPRESENTATIVE VALUE. I AM AWARE OF THE ULTRA-VIRES FORM OF STATUTE LAW ON THE BOOKS, NOTWITHSTANDING. "I" AM RESPONSIBLE FOR MY ACTIONS AND AM SERVING WITH INTEGRITY IN MY POSITION, OR ELSE, I WOULD NOT BE IN THIS POSITION, SO HELP ME GOD.

SIGNATURE:_____SIGNATURE:_____
RAYMOND REID NOTARY PUBLIC

SUBSCRIBED AND SWORN TO BEFORE ME THIS___DAY OF_____1975.

WITNESSED:_____

MY COMMISSION EXPIRES ON:_____

96 193 328

PAGE ONE:

AUGUST 21st, 1975

SENT BY CERTIFIED MAIL.

JOHN A. RICHARDSON, M.D.
514 KAINS AVENUE
ALBANY, CALIFORNIA 94706

TOPIC: ACCUSATION NUMBER: D-1605

TO: LOUIS C. CASTRO
PUBLIC SERVANT
DEPUTY ATTORNEY GENERAL, CA.
6000 STATE BUILDING
SAN FRANCISCO, CALIF. 94102

CC: V.O.O.C. (VIOLATORS OATH of OFFICE COMMITTEE)
SHERIFF'S POSSE COMITATUS (VARIOUS UNIT ALERTED)
SOME NEWSPAPERS
OTHER INTERESTED PARTIES

SUBJECT: EVERY CHILD COMES WITH THE MESSAGE THAT GOD IS NOT YET DISCOURAGED OF MAN.

PUBLIC SERVANT CASTRO, BEING A LAWYER, A MAN OF COURT ROOM EXPERIENCE, HAVE IN FACT, KNOWLEDGE OF ALL KINDS OF LAWS. ANYONE THAT HAS DONE SOME STUDYING OF LAWS, KNOWS FULLY WELL THAT IT BREASK DOWN INTO TWO KNOWN FACTORS: A. LAWFUL LAWS, & B. ULTRA-VIRES VARIETY OF SO CALLED LAWS, NOTWITHSTANDING. WRITER IS PERSONALLY INTERESTED IN OBEYING THE LAWFUL LAWS FOUND IN THE CA. & UNITED STATES CONSTITUTIONS, LAWS THAT ARE NOT REPUGNANT IN ANY WAY SHAPE OR FORM. YOU ARE BOUND BY OATH OF OFFICE TO UPHOLD THE CA. & UNITED STATES CONSTITUTIONS. PERJURY IS A VERY SERIOUS OFFENCE. CITIZENS ARE EXPECTED TO OBEY THE LAWFUL LAWS, THAT IS WHY WE HAVE LAW ENFORCEMENT BODIES. THE ONLY LEGITIMATE FUNCTION OF GOVERNMENT IS TO PROTECT MY LIFE, LIBERTY, AND PROPERTY. IT IS IMPORTANT TO WRITER THAT RIGHTS ARE PROTECTED...ALL THE WAY. THERE ARE SEVERAL LAWS FOUND IN TITLE 18, SECTIONS, 241, 242, 1017, 1018, 1001, 2381, 2382 & 1621. ALSO, TITLE 42, SECTIONS 1983 & 1988. THESE LAWS APPLY TO OATH-BREAKING PUBLIC SERVANTS.

WRITER INSISTS UPON A GUARANTEE WHICH IS IN THE FORM OF AN AFFIDAVIT WHICH FOLLOWS. IT IS TO BE COMPLETED, SIGNED, WITNESSED, NOTARIZED AND THEN RETURNED TO WRITER WITHIN TEN DAYS FROM THE DATE OF THE AFFIDAVIT "REPUSAL" TO DO SO, WILL PROVE BEYOND ALL DOUBTS THAT YOU, LOUIS C. CASTRO ARE OR HAVE BEEN WILLING TO CONSPIRE AGAINST SOVERIGN-CITIZEN-DEPENDANT, DONE SO WITH MALICIOUS INTENT. SUCH "REPUSAL"TO DO SO, WILL CONSTITUTE "PRIMA-FACIE" EVIDENCE THAT YOU HAVE WILFULLY AND KNOWINGLY CONSPIRED AGAINST JOHN A. RICHARDSON, M.D. TO DESTROY HIS REPUTATION , AND TO DEPRIVE HIM OF HIS LIVELIHOOD. THE DATE OF THE AFFIDAVIT=8/29/75.

WITH CONSTITUTIONAL REGARDS
AND MASTER IN GOVERNMENT

JOHN A. RICHARDSON, M.D.
IN PRO PER

"I",_____ __ _____, EMPLOYED BY:_____CITY OF:_____, STATE OF:_____, HOLDING POSITION OF:_____FOR:_____YEARS, &_____MONTHS, DO OF MY OWN FREE WILL AND ACCORD, SWEARING AS ACCORDED BY LAWFUL LAW, UNDER PENALTIES OF PERJURY, SERVING THE PEOPLE OF CA. WITH INTEGRITY, AS ACCORDED BY THE CRIMINAL LAWS SET FORTH TO PROTECT SOVERIGN-CITIZEN-DEPENDANT'S RIGHTS AGAINST CONSPIRACY IN ANY FORM FROM THE CITY, COUNTY, STATE AND FEDERAL LEVEL. "I" AM WELL AWARE OF THE CRIMINAL LAWS, TITLE 18, SEC. 241, 242, 1018, 1017, 1001, 2381, 2382, & 1621; AND ALSO, TITLE 42, SEC. 1983 & 1988, as well as THE CA. & U.S. CONSTITUTIONAL SAFEGUARDS AFFORDED JOHN A. RICHARDSON, M.D. IT IS FULLY REALIZED THAT ANY AND ALL ULTRA-VIRES LAWS THAT ARE IN FACT REPUGNANT TO THE LAWS OF THE LAND, NOTWITHSTANDING, THAT THE DEPENDANT IS NOT BOUND TO OBEY THEM (16th AMERICAN JUR., 2nd SEC., P. 177), SO HELP ME GOD.

SIGNATURE:_____LOUIS C. CASTRO:SIGNATURE:_____
PUBLIC SERVANT

SUBSCRIBED AND SWORN TO BEFORE ME THIS___DAY OF_____1975.

PHONY MONEY

This is a Federal Reserve Note that people use in lieu of lawful U.S. Currency due to its close physical resemblence to lawful money. It is the only available money that can be obtained at a bank. The unit of issue shall be termed the "Dollar" but should not be interpreted as being lawful U.S. Money as defined by the U.S. Constitution and the U.S. Coinage Acts of 1783 and 1900.

These notes are printed in several denominations among which are one, five, ten, twenty, fifty and one hundred "Dollars".

The notes are printed in black and green ink on a special paper so that they closely resemble lawful money that could be redeemed for Gold or Silver.

The seal is printed in green ink to minimize the probability of people accidentally mistaking it for lawful U.S. Currency, such as United States Notes or Silver Certificates.

Its value is not stable like lawful money but more like a Yo Yo, up and down, up and down.

COPYRIGHT 1974 by LAURENCE G. PORTER

JANUARY 5th, 1976

JOHN A. RICHARDSON, M.D.
514 KAINS AV.
ALBANY, CA. 94706

SENT BY CERTIFIED MAIL WITH A RETURN RECEIPT REQUESTED.

TO: LOUIS C. CASTRO
PUBLIC SERVANT
DEPUTY ATTORNEY GENERAL
6000 STATE BUILDING
SAN FRANCISCO, CA. 94102

CC: V.O.O.C. (VIOLATORS OATH of OFFICE COMMITTEE)
F.D.A.W.D.C. (FOOD & DRUG ADMINISTRATION WATCH DOG
I.T.G. (IRRITABLE TAXPAYERS GROUP) COMMITTEE)
SHERIFF'S POSSE COMITATUS (VARIOUS UNITS ALERTED)
SOME NEWSPAPERS (SAN FRANCISCO/LOS ANGELES/FRESNO)
K.G.O. (SAN FRANCISCO)

$$$$$$ ART. 1, SEC. 10; U.S. CONSTITITION $$$$$$$$$$$$$$$$$$$$$$$$$

SUBJECT: LUKE 11: VERSE 52: WOE UNTO YOU, LAWYERS! FOR YE HAVE TAKEN AWAY THE KEY OF KNOWLEDGE: YE ENTERED NOT IN YOURSELVES, AND THEM THAT WERE ENTERING IN YE HINDERED .

$$$$ vs. WORTHLESS PHONEY FED NOTES $$$$$$$$$$$$$$$$$$$$$$$$$$$$$$$

PUBLIC SERVANT CASTRO, YOU FAILED TO REBUT THE AFFIDAVIT, DATED, AUGUST 21st, 1975. IT WAS A DISAPPOINTMENT NOT TO HAVE IT RETURNED TO WRITER WITHIN THE REQUIRED TIME LIMIT BUT YOU MUST HAVE HAD A REASON FOR NOT RETURNING IT.

THIS CORRESPONDENCE INCLUDES A DOUBLE JEOPARDY AFFIDAVIT. BEING A LAWYER, YOU SURELY KNOW WHAT "PRIMA-FACIE" EVID - ENCE IS ALL ABOUT.

KINDLY COMPLETE THE AFFIDAVIT, TO BE WITNESSED, SIGNED, NOTARIZED, AND THEN RETURNED ON OR BEFORE J A N U A R Y 16th, 1976. THIS ONE, AS WELL AS THE OTHER IS A FORM OF GUARANTEE FOR WRITER TO AVOID UNSCRUPLOUS PUBLIC SERVANTS DURING THEIR DUTIFUL HOURS WHILE IN PUBLIC SERVICE. "RE- FUSAL" TO DO SO, WILL PROVE BEYOND ANY AND ALL DOUBTS , THAT LOUIS C. CASTRO HAVE BEEN WILLING TO CONSPIRE, AND/ OR CO-CONSPIRE AGAINST JOHN A. RICHARDSON, M.D. WITH MAL- ICIOUS INTENT, WILFULLY AND KNOWINGLY DONE. "SUCH REFUSAL" TO DO SO WILL CONSTITUTE "prima-facie" EVIDENCE FOR THE SECOND TIME IN JUST OVER FOUR MONTHS, IN THE ATTEMPT TO OVERTHROW WRITER'S LIVELIHOOD, FREEDOMS, RIGHTS FOUND IN THE UNITED STATES CONSTITUTION.

WITH CONSTITUTIONAL REGARDS

AND MASTER IN GOVERNMENT

JOHN A. RICHARDSON, M.D.

EXHIBIT "55 ATTACHED:

THE DOUBLE AFFIDAVIT FOLLOWS FOR LOUIS C. CASTRO, PUBLIC SERVANT TO COMPLETE AND RETURN TO WRITER ON OR BEFORE JANUARY 16th, 1976.

"I"_____ __ _____EMPLOYED BY_____FOR_____YEARS AND_____MONTHS, SERVING WITH_____(initial) WITHOUT_____ (initial) INTEGRITY AND HONOR, DO OF MY OWN FREE WILL AND ACCORD, SWEARING AS ACCORDED BY LAWFUL LAW, UNDER PENALTIES OF PERJURY, SERVING THE PEOPLE OF CALIFORNIA, AS WELL AS THE REST OF THE NATION, I HEREBY ATTEST TO THE FACT THAT "I" HAVE IN FACT TAKEN THE OATH OF OFFICE TO UPHOLD THE CALIFORNIA AND UNITED STATES CONSTITUTIONS WITHOUT ANY MENTAL RESERVATIONS OR PURPOSE OF EVASION. "I" HAVE_____(initial) HAVE NOT_____ (initial) ALWAYS MAINTAINED A SPOTLESS RECORD AS I WAS HIRED IN TO DO, THAT I HAVE_____(initial) HAVE NOT_____(initial) COMMITTED FRAUD, BROKEN MY OATH OF OFFICE, NOR HAVE "I" GONE CONTRARY TO THE U.S. CONSTITUTION. "I" BEING A _____ adj.-fill in LAWYER, FULLY REALIZE THE IMPORTANCE OF KNOWING WHAT THE CRIMINAL LAWS ARE AND THE PENALTIES CONNECTED WITH THEM FOR WRONGDOING. "I" HAVE_____(initial) HAVE NOT_____(initial) AT SOME TIME OR OTHER, CONSPIRED "OR" CO-CONSPIRED WITH OTHERS TO "frame" JOHN A. RICHARDSON, M.D. I REALIZE SO WELL THAT IN WORKING FOR GOVERNMENT AS A PUBLIC SERVANT, IT IS EXTREMELY IMPORTANT TO BE HONEST AT ALL TIMES, TO SERVE THE COMMUNITY, AND TO ABIDE BY THE U.S. CONSTITUTION, AND NOT BY THE ULTRA - VIRES SO CALLED LAWS. ONE MUST BE SUSTAINED, AND THAT NO LAW CAN SUPERCEDE THE CONSTITUTION. "I" AM_____(initial) AM NOT _____(initial) GUILTY OF ACCEPTING WORTHLESS, PHONEY FED NOTES WHICH ARE CLEARLY AGAINST ART. 1, SEC. 10, U.S. CONSTITUTION, SO HELP ME GOD. ********** SUBSCRIBED ABD SWORN TO BEFORE ME THIS_____DAY OF_____19_____.

SIGNATURE:_____ LOUIS C. CASTRO

SIGNATURE:_____ WITNESSED

SIGNATURE:_____ NOTARY PUBLIC

COUNTY OF_____

STATE OF _____

FOOD, DRUGS

Food and Drug Administration regulates safety and packaging of drugs, medical supplies, cosmetics, most foods.

MEDICINE - Hyperactive Children

The use of amphetamines to calm hyperactive children is one of medicine's most controversial therapies. Proponents say it slows such youngsters down so that they can pay attention in school and function more normally within their families. Opponents argue that many children put on amphetamines have been incorrectly diagnosed as hyperactive, and are jeopardized because they are "doped up" all the time.

Now one of the pioneer proponents of amphetamine therapy, Dr. Mark Stewart of St. Louis, has changed his mind. He says his follow-up studies show that the drug hides the child's real personality. This often leads to an adolescent identity crisis. "By the time the child reaches puberty, he does not know what his undrugged personality is," Dr. Stewart says. "Worse, the child's family does not know how to accept his undrugged personality." Dr. Stewart says he now uses amphetamines only as "a last resort".

U.S. Beef Is Poisonous, Say Foreign Officials

BY FRED CARTER

It's a fact that Italy and Sweden refuse to let United States meatpackers ship beef to their countries. The authorities in those countries claim that American meat contains residues of DES...diethylstilbestrol...a cancer-inducing hormone used by American farmers to fatten their cattle. At least ten nations, among them Argentina, Australia, Poland, South Africa and Germany prohibit the feeling [illegible] IN THE CAMPAIGN

of DES to their cattle. Research has proven that when DES was given pregnant women to prevent miscarriage, the women produced children who had cancer. Official spokesmen for the FDA claim there is no evidence that any person got cancer from eating DES-fed beef, but Senator Proxmire (Wis.) who is trying sponsor legislation to ba project, wants to kne ten nations have banned it if this is '

Food Dye Linked to Genetic Damage

Washington

A congressional study yesterday revealed for the first time that the country's most widely used food coloring — Red Dye No. 2 — [illegible] genetic damage in test [illegible] possible carcinogen.

It was the first time that [illegible] chromosomal damage has been raised [illegible] dye which [illegible] an admitted [illegible] cancer [illegible] potential factor [illegible]

The report from the General Accounting [illegible] said continued use of the dye — which is [illegible] everything from strawberry ice cream to [illegible] — without resolution of the safety questions is [illegible] "the public by unnecessary risk."

The FDA last week announced the [illegible] a panel of experts who will meet [illegible] make a new examination on the matter.

MAY 21st, 1976

JOHN A. RICHARDSON, M.D.
514 KAINS AV.
ALBANY, CALIF. 94706

SENT BY CERTIFIED MAIL WITH
A RETURN RECEIPT REQUESTED.

TO: STEWART A. JUDSON
PUBLIC SERVANT
ADMINISTRATIVE LAW JUDGE
100 VAN NESS AV.
SAN FRANCISCO, CALIFORNIA

CC: NEWSPAPERS (SAN FRANCISCO-LOS ANGELES-FRESNO-WN., D.C.)
V.O.O.C. (VIOLATORS OATH of OFFICE COMMITTEE)
OFFICIALS (LOCAL----STATE------FEDERAL LEVELS)
C.C.C.C. (CONCERNED CITIZEN'S CONSPIRACY COMMITTEE)
I.T.G. (IRRITATED TAXPAYERS GROUP)

EMPLOYEES FOR AND IN THE STATE OF CALIFORNIA

MANPOWER STATUS

	(CONSTITUTIONAL) DOUBT	(UNCONSTITUTIONAL)	(PRIMA-FACIE CASE)	(CRIMINAL LAW VIOLATIONS)
JULIAN O. STANDEN	DOUBT			
JOANNE RABIN		X	YES	C.P.C. 118/T.18/1621
LOUIS C. CASTRO		X	YES	" " " "
EVELLE J. YOUNGER	DOUBT			
JOHN J. ROUSE		X	YES	" " " "
GERALD P. McCLELLAN		X	YES	" " " "
JOHN W. BLANCHARD		X	YES	" " " "
GEORGE L. KNOTT		X	YES	" " " "
ROBERT WIENS		X	YES	" " " "
LEWIS E. DUNCAN		X	YES	" " " "
HERB SILVIUS		X	YES	" " " "
TAKETSUGU TAKEI		X	YES	" " " "
KRISTIE SMITH		X	YES	" " " "
JIM D. EDDINGTON		X	YES	" " " "
W. SHERWOOD LAWRENCE	DOUBT			
JEFF B. MARSCHNER	DOUBT			
FRANK DALE	DOUBT			

SUBJECT: CALIFORNIA EMPLOYEES (PUBLIC SERVANTS) SUBJECT TO DISPLINARY ACTION BY THE ATTORNEY GENERAL OF THE STATE OF CALIFORNIA FOR ACTS CONTRARY TO REGULATIONS.....

PUBLIC SERVANT, STEWART A. JUDSON, YOUR CORRESPONDENCE, DATED, MAY 13th, 1976, WAS RECEIVED. THANK YOU. CORRESPONDENCE OVER THE SIGNATURE OF THE PUBLIC SERVANT IS PREFERRED OVER "HERESAY" FORM OF CONTACT.

FIRST OF ALL, WHAT IS THE NUMBER N 6369? ANSWER IS HEREBY REQUESTED. YOU HAVE PLANNED FOR A "PREHEARING CONFERENCE." ARE YOU AN ADMINISTRATIVE LAW JUDGE? WHAT DOES THAT MEAN EXACTLY? SUCH HEARING WILL BE FROM AUGUST 3rd THROUGH AUGUST 13th, 1976. YOU CALL THIS A "PRE-HEARING" CONFERENCE PROGRAM. TO ELIMINATE LITIGATION BY STIPULATION AND SETTLEMENT. YOU GO ON TO SAY, THE PROGRAM IS A VOLUNTARY ONE, DESIGNED TO:

A. SIMPLIFY FACUAL LEGAL ISSUES; B. OBTAIN ADMISSIONS OF FACTS AND DOCUMENTS TO AVOID UNNECESSARY PROOF (?) C.REESTIMATING TIME FOR HEARING; D. POSSIBLE SETTLEMENT; & E. DETERMINE "IF" MEMORANDUM OF POINTS AND AUTHORITIES BE REQUIRED.

FINALLY, YOU STATE THAT A PRE-HEARING CONFERENCE WOULD BE APPROPRIATE, HOPING THAT WRITER WILL AGREE. TO AGREE WITH THIS IS SHOWING TOTAL IGNORANCE OF THE LAWFUL LAW PROCEDURE SET FORTH UNDER THE U.S. CONSTITUTION, YET YOU ARE SETTING YOURSELF UP AS A JUDGE OF SORTS. THIS APPEARS THAT THIS AN ENTIRE WASTE OF TAXPAYER'S MONIES. DO YOU DISAGREE? DO YOU KNOW THE CA. & U.S. CONSTITUTIONS? YOU TOOK AN OATH OF OFFICE TO UPHOLD THE CONSTITUTIONS. WHAT HAPPENS IF YOU HAVE, AND/OR ARE VIOLATING YOUR OATH? YOU WILL HAVE TO FACE CRIMINAL LAWS, SO DESIGNED TO PROTECT CITIZENS FROM OATH-BREAKING RASCALS.

WRITER HAS A SUGGESTION, WHICH IS; WRITER WOULD ENJOY A CONFERENCE WITH YOU REGARDING THE CONSTITUTIONAL MERITS OF YOUR REQUESTS TO, DETERMINE WHETHER YOU ARE RIGHT, OR, INCORRECT. WITH ME, WILL BE MY COUNSEL AND APPROPRIATE WITNESS WITH TAPE RECORDERS, ALL, "SOVERIGN-FREE-CITIZENS." HOPING YOU AGREE WITH THIS PROPOSAL, BY LETTING ME BY KNOW BY CORRESPONDENCE. FROM THIS POINT IN TIME, A DATE CAN BE SET, FOR A "SOVERIGN CITIZEN vs. PUBLIC SERVANT" CONFERENCE.

KINDLY TAKE NOTE OF THE FOLLOWING AFFIDAVIT, WHICH IS EASY TO COMPLETE, SIGN, HAVE WITNESSED, NOTARIZED, THEN RETURN TO WRITER ON OR BEFORE JUNE 1st, 1976. FAILING THIS CONSTITUTIONAL EXCERCIZE, WILL LEND BELIEF THAT YOU ARE IN FACT CONSPIRING, OR, CO-CONSPIRING AGAINST JOHN A. RICHARDSON, M.D. DONE SO WITH MALICIOUS INTENT TO AID IN THE DESTRUCTION OF PERSONAL FREEDOMS AND RIGHTS GOVERNED BY THE CA. &. U.S. CONTRACTS, THE CONSTITUTIONS. "SUCH REFUSAL" TO COMPLY WILL CONSTITUTE "PRIMA-FACIE" EVIDENCE GOING HEAVILY AGAINST YOU FOR VIOLATING YOUR OATH OF OFFICE, AND/OR AIDING AND ABETTING CRIMES THROUGH COLLUSION, AND ACTING AS JUDGE DE FACTO ONE WHO HOLDS AND EXCERCISES THE OFFICE OF A JUDGE UNDER COLOR OF LAWFUL AUTHORITY AND BY A TITLE VALID ON ITS FACE, THOUGH HE HAS NOT THE FULL RIGHT TO THE OFFICE, AS WHERE HE WAS APPOINTED UNDER AN UNCONSTITUTIONAL STATUTE, OR BY AN USURPER OF THE APPOINTING POWER, OR HAS NOT TAKEN THE OATH OF OFFICE. STATE vs. MILLER, 111 MO. 542, 20 S.W. 243; WALCOTT vs. WELLS, 21 NEV. 47, 24 P. 367, 9 L.R.A. 59, 37 AM. ST. REP. 478.

```
########################################
#                                      #
#     WITH CONSTITUTIONAL REGARDS      #
#                                      #
#        MASTER IN GOVERNMENT          #
#                                      #
#        JOHN A. RICHARDSON, M.D.      #
#                                      #
########################################
```

"I", STEWART A. JUDSON, PUBLIC SERVANT, EARNING A SALARY PAID BY THE WARY TAXPAYERS , DO HEREBY ATTEST TO THE FOLLOWING ANSWERS OF MY CHOICE, TO SATISFY JOHN A. RICHARDSON, M.D., PROVING MY

WORTH AS A TRUSTWORTHY EMPLOYEE-PUBLIC SERVANT, SATISFYING THE REQUIREMENTS OF THE CA. &. U.S. CONSTITUTIONS, DOING SO UNDER MY OWN FREE WILL AND ACCORD, UNDER PENALTIES OF PERJURY, LAWFULLY COMMITTED (ORALLY), SO HELP ME GOD.

"I", HAVE____(initial) HAVE NOT____(initial) TAKEN THE OATH OF OFFICE, TO UPHOLD THE CA. &. U.S. CONSTITUTIONS, SO HELP ME GOD, TAKEN WITH____(initial) WITHOUT____(initial) MENTAL RESERVATIONS, AND WITH____(initial) WITHOUT____(initial) PURPOSE OF EVASION, SO HELP ME GOD.

"I", STEWART A. JUDSON AM____(initial) AM NOT____(initial) GUILTY OF BREAKING ANY CRIMINAL LAWS, FALLING UNDER THE AUTHORITY OF THE CA. PENAL CODE, AND U.S.C. TITLE 18, VARIOUS SECTIONS APPLYING TO THE CRIME(S). "I" AM____(initial) AM NOT____(initial) BOUND TO OBEY ANY ORDER-COMMAND HANDED DOWN FROM JULIAN O. STANDEN JOANNE RABIN, LOUIS C. CASTRO, JOHN J. ROUSE, GERALD P. McCLELLAN, GEORGE L. KNOTT, ROBERT WIENS, TAKETSUGU TAKEI, KRISTIE SMITH, JIM D. EDDINGTON, HERB SILVIUS, LEWIS E. DUNCAN, JOHN W. BLANCHARD, ALL OF WHOM ARE IN FACT, "PRIMA-FACIE CASES". "I" AGREE _____(initial) DISAGREE_____(initial) THAT THEY ARE NOT FIT FOR GOVERNMENT SERVICE, AND SHOULD BE INDICTED BY A GRAND JURY TO BE TRIED FOR CRIMES AGAINST THE CITIZENRY. "I" AM____(initial) AM NOT_____(initial) A JUDICIAL JUDGE, AND, THAT "I" AM____(initial) AM NOT _____(initial) A PUBLIC SERVANT-WASTE OF TAXPAYERS MONIES, BEING ____(initial) NOT BEING____(initial) A DEPARTMENT SET UP TO DUPLICATE THE JUDICIAL AUTHORITY, SO HELP ME GOD. "I" AGREE_____(initial) DISAGREE____(initial) THAT MORE THAN TWENTY PUBLIC SERVANTS ORDERED TO "GET AT ALL COSTS, WITH TAXPAYERS MONIES," JOHN A. RICHARDSON, M.D., BECAUSE HE IS____(initial) IS NOT_____(initial) A THORNE IN THE SIDES OF THE STATE OF CA. HEALTH DEPT. AND NELSON ROCKEFELLER, WHO HEADS THE DRUG CARTEL OF THE U.S. SET FORTH TO HAVE COMPLETE CONTROL OVER THE RIGHTS OF CITIZENS. "I" DO____(initial) DO NOT____(initial) REQUEST THAT JOHN A. RICHARDSON, M.D. SHOW ME, STEWART A. JUDSON, PROOF THAT NELSON ROCKEFELLER CONTROLS VAST INDUSTRY, PUTTING A STRANGLEHOLD OVER THE MILLIONS OF AMERICANS, AND PROOF THAT THE ABOVE MENTIONED PUBLIC SERVANTS ARE IN FACT, "PRIMA-FACIE" CASES, NOT FIT FOR GOVERNMENT SERVICE. AND THAT "I" AS A HONEST____(initial) DISHONEST PUBLIC SERVANT_____(initial) AM RESPONSIBLE TO REPORT ANY CRIMINAL ACTIVITY ON THE PART OF "ANY" PUBLIC SERVANT, INCLUDING EVELLE J. YOUNGER, TO HIGHER AUTHORITY, REPORTING "OUT-OF-LINE" ACTIVITY ALIEN TO OUR FORM OF GOVERNMENT, AS A REPUBLIC. AND THAT "I" WOULD____(initial) WOULD NOT____(initial) BE AIDING AND ABETTING CRIMES, ACTING IN COLLUSION WITH OTHER PUBLIC SERVANTS WHO

ARE VIOLATING THEIR OATH OF OFFICE TO UPHOLD THE CA. &. U.S. CONSTITUTIONS.

"I" AM____(initial) AM NOT____(initial) FAMILIAR WITH THE ACTIVITIES OF J.E. FEELEY (A PRIMA-FACIE CASE), MGR., CUSTOMER SERVICE, U.S. POST OFFICE, THE OPENING OF U.S. MAIL BELONGING TO JOHN A. RICHARDSON, M.D. WITHOUT A COURT ORDER, SO HELP ME GOD.

"I" AGREE____(initial) DISAGREE____(initial) THAT THE STATE OF CA. HAS A SORRY LOT OF PUBLIC SERVANTS, THAT HAVE_____(initial) HAVE NOT____(initial) CONCOCTED CASES ALONG LINES OF CONSPIRACY USING REPUGNANT LAWS TO THE U.S. CONSTITUTIONS, WHICH IS_____ (initial) IS NOT____(initial) CONSIDERED TREASON, FALLING UNDER THE CRIMINAL CODE, SEC. 1621, 2381, 2382, 241, & 242,TITLE 18. I, STEWART A. JUDSON, AGREE____(initial) DISAGREE____(initial) THAT A DOCTOR'S PRESCRIPTION IS NOT NEEDED TO TAKE POISON, SUCH AS FLOURIDATION, SMOKE TAR & NICOTINE, SO HELP ME GOD.

##########

SUBSCRIBED TO AND SWORN TO BEFORE ME THIS____DAY OF_____, 1976, MR. STEWART A. JUDSON, DID INITIAL THE ANSWERS OF HIS CHOICE, AND HE DID SIGN THE FOREGOING INSTRUMENT IN MY PRESENCE.

SIGNATURE:_____(STEWART A. JUDSON)

SIGNATURE:_____(WITNESSED)

SIGNATURE:_____(NOTARY PUBLIC)

COUNTY OF:_____)

STATE OF :_____)

MAY 18th, 1976

SENT BY CERTIFIED MAIL WITH A RETURN RECEIPT REQUESTED.

JOHN A. RICHARDSON, M.D.
514 KAINS AV.
ALBANY, CALIF. 94706

TO: EVELLE J. YOUNGER
PUBLIC SERVANT
ATTY. GENERAL FOR THE STATE OF CA.
555 CAPITOL MALL
SACRAMENTO, CALIFORNIA 95814

CC: JUDICIAL COUNSEL, CALIFORNIA
NEWSPAPERS (SAN FRANCISCO-LOS ANGELES-FRESNO)
V.O.O.C. (VIOLATORS OATH of OFFICE COMMITTEE)
C.C.C.C. (CONCERNED CITIZEN'S CONSPIRACY COMM.)
OFFICIALS (LOUIS C. CASTRO; JOANNE RABIN; GERALD P. McCLELLAN; ROBERT WIENS; TAKETSUGU TAKEI; JIM D. EDDINGTON; JULIAN O. STANDEN; & GOVERNOR BROWN.)

TOPIC MATTER: FORMAL COMPLAINT AGAINST GERALD P. McCLELLAN FOR CONDUCT UNBECOMING A PUBLIC SERVANT.

DEAR MR. YOUNGER:

WRITER MAKES "FORMAL COMPLAINT" AGAINST PUBLIC SERVANT, GERALD P. McCLELLAN FOR CONDUCT UNBECOMING A TAX-PAID SERVANT OF THE GOVERNMENT OF THE STATE OF CALIFORNIA.

ALLEGED ARE THE FOLLOWING CHARGES, WHICH YOU ARE HEREBY REQUEST-TO FILE AT THE EARLIEST POSSIBLE DATE:

THAT THE SAID GERALD P. McCLELLAN, ON MAY 11th, 1976, IN THE SAID COUNTY OF ALAMEDA, IN THE SAID STATE OF CALIFORNIA, AND BEFORE THE FILING OF THIS INFORMATION, DID THEN AND THERE WILLFULLY AND UNLAWFULLY AND FELONIOUSLY:

COUNT ONE:

ENTERED PRIVATE PROPERTY WITHOUT A WARRANT ISSUED FROM A JUDICIAL BODY, IN VIOLATION OF THE 4th, 5th, 13th, & 10th AMENDMENTS TO THE U.S. CONSTITUTION, TAKING AWAY LIBERTY AND FREEDOMS AND RIGHTS, BY FORCING JOHN A. RICHARDSON, M.D. TO BE SUBJECTED TO AN IMMORAL APPROACH, AND FORCIBLY ATTACKING HIS PERSON IN A UNORTHADOX MANNER, UNBECOMING A PUBLIC SERVANT, DONE SO BEFORE APPROPRIATE WITNESSES, AIDED WITH CAMERAS, AND TAPE RECORDERS, AND AFFIDAVITS-DECLARATIONS TO SUPPORT THE ALLEGATIONS AGAINST, GERALD P. McCLELLAN.

COUNT TWO:

FOR A FURTHER AND SEPARATE CAUSE OF ACTION, BEING A DIFFERENT

96 492 338

OFFENSE OF THE SAME CLASS OF CRIMES AND OFFENSES AS THE CHARGES SET FORTH IN COUNT ONE, GERLAD P. McCLELLAN IS ACCUSED BY THIS INFORMATION OF THE CRIME OF VIOLATION OF THE CA. PENAL CODE, SECTIONS, 118 (PERJURY DEFINED); 98 (FORFEITURE OF AND DISQUALIFICATION FROM HOLDING OFFICE); 15 (CRIME AND PUBLIC OFFENSE DEFINED); 31 (PRINCIPALS DEFINED) 32 (ASSESSORIES DEFINED); 37 (TREASON; DEFINATION; PERSONS CAPABLE OF COMMITTING; PUNISHMENT) & 38 (MISPRISION OF TREASON; DEFINATION; PUNISHMENT). THAT THIS PRINCIPAL IS A "PRIMA-FACIE" CASE, WITH SUPPORTING DOCUMENTS TO THE ALLEGED CRIMES AGAINST THE CITIZNERY AND THE STATE OF CALIFORNIA.

COUNT THREE:

FOR A FURTHER AND SEPARATE CAUSE OF ACTION, BEING A DIFFERENT OFFENSE FROM, BUT CONNECTED IN ITS COMMISSION WITH THE CHARGES SET FORTH IN ALL OF THE PROCEEDING COUNTS HEREOF, GERALD P. McCLELLAN IS ACCUSED BY THIS INFORMATION OF THE CRIME OF VIOLATION OF AIDING AND ABETTING A CRIME WITH CO-CONSPIRATOR, JOHN J. ROUSE, PRESENTLY A DEPUTY CHIEF OF THE DIVISION OF INVESTIGATION, DEPT. OF CONSUMER AFFAIRS, WILLINGLY ORDERED GERALD P. McCLELLAN, WHO IN TURN WILLINGLY AND KNOWINGLY OBEYED ORDERS TO COMMAND JOHN A. RICHARDSON, M.D. TO TESTIFY, TO ANSWER QUESTIONS PROPOUNDED BY STATE EMPLOYEES, AND DID ORDER HIM TO BRING AND PRODUCE ALL AND ANY BOOKS--RECORDS, CLEARLY AGAINST THE OATH OF OFFICE TO UPHOLD THE CA. &. U.S. CONSTITUTIONS, DEPRIVING HIM OF HIS CIVIL RIGHTS, UNDER THE AUTHORITY OF TITLE 42, VARIOUS SECTIONS APPLYING TO THE CRIMES; SAID ACT AND COMMAND BY GERALD P. McCLELLAN, SO ORDERED BY JOHN J. ROUSE. THEN GERALD P. McCLELLAN AND CO-CONSPIRATOR, JOHN J. ROUSE DID THREATEN JOHN A. RICHARDSON, M.D. THAT IF THE NON-COURT ORDERED SUBPOENA WAS NOT OBEYED, THAT HE WOULD LIABLE TO PROCEEDING AND PENALTIES, AS PROVIDED BY ULTRA-VIRES SO CALLED LAWS, REPUGNANT TO THE U.S. CONSTITUTION, 4th, 5th, 13th, 10th, ART. 1, SEC. 8 & 10. THE CRIMINAL LAWS FALLING UNDER THE AUTHORITY OF THE CA. PENAL CODE SEC., 118, 98, AND ALSO, UNDER TITLE 18, SEC. 1621, 241, 242, 2381, & 2382. AFFIDAVIT SUPPORTING THE ALLEGATIONS ATTACHED WITH THIS COMPLAINT.

COUNT FOUR:

FOR A FURTHER AND SEPARATE CAUSE OF ACTION, IT IS HEREBY REQUESTED THAT THE PRINCIPAL, GERALD P. McCLELLAN BE ARRESTED IMMEDIATELY FOR THE FOREMENTIONED COMPLAINTS AGAINST HIM, TO FORMALLY CHARGE HIM CONFORMING TO THE ALLEGED CRIMES MENTIONED HEREIN, AND THAT JOHN A. RICHARDSON, M.D. WILL SIGN SAID

COMPLAINT AT A TIME AND PLACE, THAT IS APPROPRIATE AND BECOMING, SO DESIGNATED BY YOU.

SUBSCRIBED TO AND SWORN TO BEFORE ME, JOHN A. RICHARDSON, M.D. DID SIGN THE FOREGOING INSTRUMENT IN MY PRESENCE.

SIGNATURE: _____ (JOHN A. RICHARDSON, M.D.)

SIGNATURE: _____ (WITNESSED)

SIGNATURE: _____ (NOTARY PUBLIC)

Linda M. Weissflog

COUNTY OF: Alameda)
)
STATE OF : California)

OFFICIAL SEAL
LINDA M. WEISSFLOG
NOTARY PUBLIC - CALIFORNIA
ALAMEDA COUNTY
My Comm. Expires [illegible]

JULY 13th, 1976

MISS DOROTHY J. SOSOKA
1501 RANCHO VIEW DRIVE
LaFAYETTE, CALIFORNIA

SENT BY CERTIFIED MAIL WITH
A RETURN RECEIPT REQUESTED.

EXHIBIT "A" ATTACHED

TO: LOUIS C. CASTRO (PRIMA-FACIE CASE)
TEMPORARY PUBLIC SERVANT
DEPUTY ATTY. GENERAL
6000 STATE BUILDING
SAN FRANCISCO, CALIFORNIA 94102

CC: MR. JERRY FORD
PRESIDENT OF THE UNITED STATES
WASHINGTON, D.C.

EVELLE YOUNGER, ATTY. GEN., CA.
NEWSPAPERS
OTHER INTERESTED PARTIES

DEAR MR. CASTRO:

IT HAS BEEN LEARNED THAT YOU ARE A "PRIMA-FACIE" CASE AND THEREFORE, NOT FIT FOR PUBLIC SERVICE. ON AUGUST 21st, 1975, AN AFFIDAVIT WAS SENT TO YOU, BUT YOU FAILED TO RESPOND TO IT. THEN, AGAIN ON JANUARY 5th, 1976 YOU WERE SENT A SECOND AFFIDAVIT, BUT UTTERLY FAILING TO RETURN YOUR QUERIES, WHICH MAKES YOU FOR THE SECOND TIME, A "PRIMA-FACIE" CASE. ACCORDING TO LAW, THERE IS NO LAW THAT ALLOWS A DISHONEST-DISLOYAL-DISHONORABLE PUBLIC SERVANT TO STAY ON THE PUBLIC DOLE! WHY THEN ARE YOU STILL ALLOWED TO REMAIN ON THE JOB?

YOU HAVE INVOLVED YOURSELF INTO MY AFFAIRS WHICH IS NONE OF YOUR BUSINESS! I AM AN AMERICAN! WHAT ARE YOU, BEING A PRIMA-FACIE CASE?....THERE IS A DIFFERENCE BETWEEN US. IF YOU WERE HONEST, YOU WOULD RESPOND WITH HONOR! SHOW ME THE LAW IN WRITING OVER YOUR SIGNATURE, THE NON-REPUGNANAT LAW THAT ALLOWS YOU A "THERE" PUBLIC SERVANT TO CONSPIRE AGAINST A SOVERIGN CITIZEN AND/OR USE PEOPLE AGAINST PEOPLE?

TAKE CREEPY LAWYERS....AS MOST ARE, AS THE RECORD SHOWS, LIKE TRICKY-DICK NIXON, MITCHELL, CASTRO, AND MANY-MANY OTHERS AS WELL SHOULD READ LUKE 11; VERSE 52, "WOE UNTO YOU, LAWYERS! FOR YE HAVE TAKEN AWAY THE KEY OF KNOWLEDGE; YE ENTERED NOT IN YOURSELVES, AND THEM THAT WERE ENTERING IN YE HINDERED. LAW IS VERY INTERESTING, AND IT CAN BE USED IN THE PROPER WAY.

IT IS PLANNED FOR YOUR REMOVAL FROM OFFICE AS A NOW KNOWN OATH OF OFFICE VIOLATOR, VIOLATING BOTH THE CA. PENAL CODE, SECTION 118 (PERJURY); & 126 (PUNISHMENT--2 TO 14 YEARS IN PRISON), AS WELL AS THE U.S.C., TITLE 18, SECTIONS, 1621 (PERJURY); 2381; 2382; & 241. ONE MIGHT CALL THIS CALIFORNIA JUSTICE SYSTEM "LITTLE WATERGATE." WHEN THE PRESIDENT OF THE UNITED STATES CAN BE REMOVED FROM OFFICE, MITCHELL, AND MANY OTHERS IN A MUCH HIGHER POSITION THAN YOURSELF, THEN IT SHOULD NOT BE TOO DIFFICULT TO REMOVE YOU FROM THE OFFICE OF DEPUTY ATTY. GEN. (CA.)! PERHAPS EVELLE YOUNGER IS A BIT STRANGE, ALLOWING YOU TO STAY IN OFFICE AS A NOW KNOWN "PERJURER, WITH "PRIMA-FACIE" EVIDENCE BACKING THIS UP!

LET IT BE UNDERSTOOD FROM THIS POINT IN TIME, THAT WRITER DOES NOT WANT YOUR PRESENCE ON THE PROPERTY ON JULY 19th, 1976, AT 1:30PM TO TAKE A "DEPOSITION." WRITER IS NOT IN GOOD HEALTH. IF YOU PERSIST IN COMING, THE POLICE WILL BE CALLED FOR MY PROTECTION, DUE TO YOUR THREATENING ADVANCE, AND THREATS STATING THAT A DEPOSITION WAS MANDATORY, GOING AGAINST MY OWN DOCTOR, WHICH "I" REFUSE TO GO AGAINST HIM IN ANY MANNER, OR METHOD! AND TO HAVE AN OATH VIOLATOR IN MY PRESENCE IS SCARRY. IT WOULD BE HARD TELLING WHAT YOU MAY DO. SO ONCE AGAIN, "STAY AWAY FROM ME" AND THE

PROPERTY, MR. CASTRO THE PERJURER! IT MIGHT BE WELL FOR YOU TO PROVE THAT YOU ARE NOT A KNOWN "PERJURER" JUST FOR THE RECORD. IT WOULD CERTAINLY MAKE ME FEEL BETTER. RENDER A STATEMENT, SWORN AND ATTESTED TO, NOTARIZED, AND THEN RETURN TO ME NOT IATER THAN JULY 23rd, 1976. IF NOT, THEN IT WILL PROVE SEVERAL THINGS REGARDING YOUR INFAMOUS METHODS TO "ENTRAP" SOVERIGN AND FREE CITIZENS. BY THE WAY, WRITER HAS READ AND REREAD THE AFFIDAVITS REFERRED TO EARLIER.

THE FOLLOWING IS AN AFFIDAVIT, A "LOW IQ ASSIGNMENT" FOR YOU TO COMPLETE, SIGN, HAVE WITNESSED, NOTARIZED, AND THEN RETURN T O WRITER ON OR BEFORE JULY 23rd, 1976. FAILING THIS "LOW IQ ASSIGNMENT" WILL PROVE BEYOND ALL DOUBTS, THAT YOU ARE NOTHING MORE THAN A SLEEZY, SNOOPING, entrapment artist, AGAINST CERTAIN INDIVIDUALS, WHICH IS CLEARLY AGAINST YOUR OATH of OFFICE, BY DOWNGRADING THE CALIFORNIA AND UNITED STATES CONSTITUTIONS. "SUCH REFUSAL" TO ABIDE BY SUCH REQUEST WILL PROVE YOUR MALICIOUS INTENTS DONE SO, WILLFULLY AND KNOWINGLY, WITH FULL KNOWLEDGE TO OPENLY "BREAK" CRIMINAL LAWS, FALLING UNDER THE AUTHORITY OF THE CA. PENAL CODE, SECTION #118 (PERJURY) AND SECTION #126 (PUNISHMENT--2 TO 14 YEARS IN THE CAN-CAN) AND ALSO, UNDER THE AUTHORITY O F THE U.S.C., TITLE 18, SECTIONS, #1621 (PERJURY), #2381, 2382, #241 & #242.

****

WITH REGARDS TO SANE AND LAWFUL LAW GOVERNMENT
I REMAIN AS A SOVERIGN AND FREE CITIZEN
MISS DORTHY J. SOROKA

****

MY NAME IS KNOWN AS, LOUIS C. CASTRO, AND/OR, MY TRUE NAME IS____ _____, AND "I" DO WITH MY OWN FREE WILL AND ACCORD, UNDER PENALTIES OF PERJURY, LAWFULLY COMMITTED (ORALLY SWORN), RENDER ANSWERS OF MY CHOICE, TO SATISFY MISS DORTHY J. SOROKA QUERIES ABOUT MY ABILITY TO EXECUTE DUTIFUL DUTIES, UNDER THR AUTHORITY OF THE CA. & U.S. CONSTITUTIONS, THAT I WAS HIRED T O SERVE AS A LOYAL AMERICAN, WITHOUT ACTS OF PERJURY, WITHOUT BREAKING ANY CRIMINAL LAWS, SO HELP ME GOD.

"I", LOUIS C. CASTRO, HAVE____(imitial) HAVE NOT____(initial) TAKEN THE OATH of OFFICE TO UPHOLD THE CA. & U.S. CONSTITUTIONS WITH____(initial) WITHOUT____(initial) MENTAL RESERVATION, AND WITH____(initial) WITHOUT____(initial) PURPOSE OF EVASION; AND "I" HAVE____(initial) HAVE NOT____(initial) BROKEN CRIMINAL LAWS, FALLING UNDER THE AUTHORITY OF THE CA. & U.S. CONSTITUTIONS; U.S.C. TITLE 18, SEC. 1621 (PERJURY), 2381, 2382, 241, 242; AND, CA. PENAL C., SECTIONS 98, 118 (PERJURY), AND 126 (PUNISHMENT). "I" HAVE____(initial) HAVE NOT____(initial) BEEN AN ACCESSORY AFTER THE FACTS--AIDED AND ABETTED CRIMES, SO HELP ME GOD. "I" DO___(initial) DO NOT___(initial) UNDERSTAND WHAT IS MEANT BY ART. 1, SEC. 8 & 10 (U.S. CONST.); AND FURTHER, THAT IT IS OKAY

TO USE THE CURRENT MEDIUM OF EXCHANGE, THE WORTHLESS-PHONEY FED NOTES, COSTING 13.70 PER 1M NOTES, REGARDLESS OF DENOMINATIONS, WHICH "I" HAVE AND USE._____(SIGNATURE). IT IS__
LOUIS C. CASTRO
___(initial) IS NOT____(initial) CONSIDERED AN ACT OF PERJURY TO USE, ACCEPT, OR OTHERWISE, USE FED NOTES AS "I" PLEASE, RE - GARDING ART. 1, SEC. 8 & 10 (U.S. CONST.). "I" AM____(initial) AM NOT____(initial) ONE OF THOSE PHONEY lawyers THAT WOULD DARE TO GO AGAINST AN AMERICAN CITIZEN THE WAY CASTRO OF CUBA WOULD, USING CZARIST POWERS TO OVER-RULE CERTAIN PEOPLE, DISREGARDING ETHICS, MORALS, HONESTY, INTEGRITY AND SINCERITY.

"I", L.C. CASTRO HAVE____(initial) HAVE NOT____(initial) ALWAYS BEEN HONEST, SERVING THE PUBLIC WITH HONOR; AND, "I" HAVE_____ (initial) HAVE NOT____(initial) CONSPIRED, OR, CO-CONSPIRED AGAINST "ANY" INDIVIDUAL, SO HELP ME GOD.

FINALLY , BEING A lawyer, "I" AM____(initial) AM NOT___(initial) FULLY AWARE OF THE CRIMINAL LAWS SET FORTH UNDER THE AUTHORITY OF THE C.P.C., AND U.S.C. THAT AFFECTS MY BEHAVIOR, FOR ACTS THAT ARE CONTRARY TO MY OATH OF OFFICE TO UPHOLD THE CA. & U.S. CONSTITUTIONS, WITH____(initial) WITHOUT____(initial), AND THAT "I" CAN___(initial) CANNOT____(initial) BE HELD RESPONSIBLE FOR ANY ACTS--DEEDS, ORDERS COMING DOWN FROM HIGHER UP, REGARDLESS OF THE NATURE OF THE ORDERS, BEING REPUGNANT OR OTHERWISE, SO HELP ME GOD.

##########

SUBSCRIBED TO AND SWORN TO, LOUIS C. CASTRO (OR OTHER NAME)_____ _____, DID INITIAL THE ANSWERS OF HIS CHOICE, AND DID SIGN THE FOREGOING INSTRUMENT IN MY PRESENCE, ON THIS_____ DAY OF_____, 1976.

SIGNATURE:_____(LOUIS C. CASTRO/OTHER NAME)

SIGNATURE:_____(WITNESSED)

SIGNATURE:_____(NOTARY PUBLIC)

COUNTY OF:_____)
)
STATE OF :_____)

96-492 O - 77 - 24

JULY 20th, 1976

JOHN A. RICHARDSON, M.D.
514 KAINS AVENUE
ALBANY, CALIF. 94706

SENT BY CERTIFIED MAIL WITH A RETURN RECEIPT REQUESTED.

MAILING ADDRESS:

1020 CHARLESTON CIRCLE
ROSEVILLE, CA. 95678

TO: PAUL J. DUGAN, M.D.
PUBLIC SERVANT--CHAIRMAN
BOARD of MEDICAL QUALITY ASSURANCE
PHYSICIAN'S ASSISTANT EXAMINING COMMITTEE
DEPARTMENT OF CONSUMER AFFAIRS
1430 HOWE AVENUE
SACRAMENTO, CALIFORNIA 95825

CC: V.O.O.C. (VIOLATORS OATH of OFFICE COMM.)
I.T.P.C. (IRRITATED TAXPAYERS PLUNDER COM.)
NEWSPAPERS (EAST---WEST----NORTH----SOUTH)
OFFICIALS (LOCAL--STATE----FEDERAL LEVELS)
SHERIFF'S POSSE COMITATUS (NATIONAL---INFORMATION ALERT)
C.W.C.O.C.A. (CITIZEN'S WATCHDOG COMMITTEE OVER CONSUMER AFFAIRS)

$$$$$ ART. 1, SEC. 8 & 10; AMENDMENT 9 & 10; U.S. CONSTITUTION $

SUBJECT: WHAT PUBLIC SERVANT THAT HAS SWORN TO UPHOLD THE CA. & U.S. CONSTITUTIONS BEEN RELIEVED OF THAT RESPONSIBILITY?.....

$$$ vs. WORTHLESS-PHONEY FED NOTES=COST 13.70 PER 1M NOTES $$$$$

DR. DUGAN, THE ISSUES CENTERING AROUND WRITER AND THE CONSPIRACY TO "GET HIM" WOULD COVER VOLUMES. THERE ARE TODAY NUMBERS O F KNOWN PERJURERS, PUBLIC SERVANTS, FOR AND IN THE STATE OF CALIF. TAKING MONIES IN THE FORM OF A PAYCHECK. TAKING THIS MONEY IS A CRIME, DR. DUGAN. IT WILL BE INTERESTING TO SEE JUST HOW FAR YOU ARE WILLING TO GO AGAINST WRITER---LEGALLY. IT WILL BE INTERESTING TO SEE "IF" YOU BECOME A "PRIMA-FACIE" CASE. IT IS VITALLY IMPORTANT TO DETERMINE YOUR HONEST OR, DISHONEST WAYS. LET IT BE SAID FOR THE RECORD, WRITER WILL OBEY THE CA. & U.S. CONSTITUT - IONS WITHOUT ANY MENTAL RESERVATIONS, WHATSOEVER, NOR, WITH PURPOSE OF EVASION! WHEN A PUBLIC SERVANT HAS TAKEN THE SWORN OATH TO UPHOLD THE CONSTITUTIONS, IT MEANS TO UPHOLD, AND NOT TO DOWNGRADE THE CONSTITUTIONS---LAWS OF THE LAND. EACH MAN TO HIMSELF AS TO WHAT HE WILL HIMSELF DO, WHETHER IT IS AN ACT OF TREASON , OR, CONSTITUTIONAL ACTS. ATTACKS UPON GOOD AND LOYAL AMERICANS HAS GONE ON FOR YEARS. SURE IT IS A FIGHT! THE BIG QUESTION IS, "ARE YOU A LOYAL--GOOD AMERICAN, ABIDING BY THE CONSTITUTIONS?" IF YOU ARE, FINE, CONGRATULATIONS ARE IN ORDER. If you are not, God help your soul . CONSPIRACY IS UGLY, WHEN IT COMES TO ONE'S FREEDOMS AND RIGHTS AUTHORIZED UNDER THE CONSTITUTIONS. CRIMINAL LAWS ARE SET FORTH FOR THE PROTECTION AGAINST RASCALS IN OFFICE, TO ROUT THEM OUT OF SINECURISM, OUT OF DISLOYALTY, OUT OF FRAUD, AWAY FROM CITY, STATE AND FEDERAL GOVERNMENT LEVELS THUS SAVING

OUR REPUBLIC. KINDLY TAKE NOTE OF THE "PERJURY-DOCUMENT" WHICH FOLLOWS, FOR YOU TO COMPLETE, SIGN, HAVE WITNESSED, NOTARIZED, AND RETURN TO WRITER ON OR BEFORE AUGUST 2nd, 1976. FAILING THIS "LOW IQ ASSIGNMENT" WHICH IS SO EASY TO COMPLETE FOR AN HONEST MAN IN GOVERNMENT SERVICE, WILL INDICATE BEYOND ANY DOUBT YOUR VERY INTENTIONS TO CO-CONSPIRE, OR, CONSPIRE AGAINST JOHN A . RICHARDSON, M.D., DONE SO IN A MALICIOUS MANNER, WILLFULLY AND KNOWINGLY COMMITTED. "SUCH REFUSAL" TO COMPLY WILL CONSTITUTE "PRIMA-FACIE" EVIDENCE GOING HEAVILY AGAINST YOU THREATENING A PRIVATE, FREE, INDEPENDENT CITIZEN---STRIPPING HIM OF HIS RIGHTS AND FREEDOMS, AUTHORIZED UNDER THE CA. &. U.S. CONSTITUTIONS!

WITH CONSTITUTIONAL REGARDS
MASTER IN GOVERNMENT

JOHN A. RICHARDSON, M. D.

"I", PAUL J. DUGAN, M.D., DO OF MY OWN FREE WILL AND ACCORD, UNDER PENALTIES, LAWFULLY COMMITTED (ORALLY SWORN), DO HEREBY ATTEST TO THE ANSWERS OF MY CHOICE, TO SATISFY JOHN A. RICHARDSON M.D., TO PROVE THAT "I", PAUL J. DUGAN AM OR AM NOT A DISHONEST, CROOKED, SCHEMING RASCAL, TAKING ADVANTAGE OF FREE AND INDEPEN - DENT CITIZENS,.....CO-CONSPIRING, OR, CONSPIRING, BREAKING DOWN THE CA. &. U.S. CONSTITUTIONS.

"I", HAVE_____(initial) HAVE NOT_____(initial) TAKEN THE OATH OF OFFICE TO UPHOLD THE CA. & U.S. CONSTITUTIONS, WITH___(initial) WITHOUT____(initial) MENTAL RESERVATIONS, AND WITH____(initial) WITHOUT____(initial) PURPOSE OF EVASION, SO HELP ME GOD. "I", AM ____(initial) AM NOT____(initial) PRESENTLY ENGAGED TO PLOT AGAINST JOHN A. RICHARDSON, M.D., SO HELP ME GOD. MY REASONS FOR GOING AGAINST JOHN A. RICHARDSON, M.D. ARE AS FOLLOWS, IN OWN WORDS:_____

please use your own words, then sign your name.

_____

_____. SIGNATURE:_____

"I", PAUL J. DUGAN, M.D. AM____(initial) AM NOT____(initial) ACQUAINTED WITH THE CRIMINAL CODES, FALLING UNDER THE AUTHORITY OF THE C.P.C., SEC. 118 (PERJURY); 126 (PUNISHMENT); 133 (DECEIVING WITNESS TO AFFECT TESTIMONY); 132 (OFFERING FORGED, ALTERED, OR ANTE-DATED BOOK, DOCUMENT, OR RECORD); 136 (PREVENTING OR DISSUADING WITNESS FROM ATTENDING); & 137 (INFLUENCING TESTIMONY;

BRIBE OR FRAUDULENT INDUCEMENT); AND ALSO, TITLE 18 (U.S.C.), SECTIONS; 1621 (PERJUR:); 2381; 2382; 241. & 242. "I" AGREE____ (initial) DISAGREE_____(initial) THAT "I" CAN BE SUED IN A COURT OF PROPER JURISDICTION, AND/OR CRIMINALLY PROSECUTED FOR BREAKING CRIMINAL LAWS,AND VIOLATING A CITIZEN'S RIGHTS AND FREEDOMS, WHICH MEANS_____(initial) WHICH DOES NOT MEAN_____ (initial) THE TOTAL DESTRUCTION OF MY CAREER, SO HELP ME GOD. THE MEDICAL HEARING SET FOR AUGUST 13th, 1976, IS____(initial) IS NOT____(initial) A COURT OF PROPER JURISDICTION; AND THE HEARING WILL____(initial) WILL NOT BE____(initial) PRESIDED OVER BY A JUDICIAL JUDGE; AND THAT THERE WILL____(initial) WILL NOT BE_____(initial) A JURY TO DETERMINE A JUST VERDICT; AND THAT THIS HEARING HAS_____(initial) HAS NOT____(initial) THE APPEAL RIGHTS AS GUARANTEED UNDER THE AUTHORITY OF THE U.S. CONSTITUTION, AMENDMENT 5, 6, ART. 3, SEC. 2. FINALLY, "I", HAVE_____ (initial) HAVE NOT____(initial) USED WORTHLESS-PHONEY FED NOTES AS A MEDIUM OF EXCHANGE, GOING CONTRARY TO ART. 1, SEC. 8 & 10; U.S. CONSTITUTION, WHICH MEANS "COIN"---SILVER AND/CR GOLD ISSUE, AND THAT THE U.S. CONSTITUTION DOES____(initial) DOES NOT_____ (initial) ALLOW THE MAUFACTURE OF paper money; AND THAT THE MONEY IN USE TODAY HAS A PAR-VALUE OF:_____ use your own words, please.

_____. SIGNATURE:_____. DR. PAUL J. DUGAN

"I", HAVE_____(initial) HAVE NOT____(initial) COMMITTED PERJURY BY THE VERY USE OF WORTHLESS-PHONEY FED NOTES, SO HELP ME GOD.

##########

SUBSCRIBED TO AND SWORN TO PAUL J. DUGAN, M.D. DID INITIAL THE ANSWERS OF HIS CHOICE, AND DID SIGN THE FOREGOING INSTRUMENT ON THIS_____DAY OF_____, 1976.

SIGNATURE:_____ SIGNATURE:_____
DR. PAUL J. DUGAN WITNESSED

SIGNATURE:_____(NOTARY PUBLIC)

COUNTY OF:_____)
)
STATE OF :_____)

AMERICAN CANCER SOCIETY, INC.
777 THIRD AVENUE • NEW YORK, N.Y. 10017 • (212) 371-2900

RESEARCH
EDUCATION
SERVICE

July 11, 1977

Senator Edward M. Kennedy
Chairman, Senate Subcommittee on Health
United States Senate
Washington, D. C.

Dear Senator Kennedy:

The American Cancer Society had hoped to be able to present testimony during your up coming hearings on Laetrile. Our request to have a witness appear before your Committee was denied on the basis that the agenda was full. The Society represents an important element in the national dialogue on Laetrile through our program on education of the public about unproven methods of cancer management.

As we cannot present verbal testimony before you and the Committee, we respectfully request that the attached statement be included as a part of the Laetrile hearing record.

Thank you very much.

Sincerely,

Robert C. Eyerly, M.D.

Robert C. Eyerly, M.D.
Chairman, Committee on Unproven
Methods of Cancer Management

cc: Mr. N. Polster

American Cancer Society
777 Third Avenue
New York, New York 10017

Statement on Laetrile
for U.S. Senate Health Subcommittee

My name is Robert C. Eyerly, M.D. I am a graduate of Jefferson Medical College, a Fellow of the American College of Surgeons, and hold appointments as Associate Surgeon, Geisinger Medical Center, Danville, Pennsylvania, and Clinical Assistant Professor of Surgery, Temple University School of Medicine. I am Past President of the Pennsylvania Division of the American Cancer Society, and since 1973 have been a Director-at-Large of the Society's National Board of Directors. Since 1974 I have served as Chairman of the Society's Committee on Unproven Methods of Cancer Management.

The information in the following paragraphs is presented to the U.S. Senate Health Subcommittee by me as a fully qualified expert in the field of cancer diagnosis and treatment, on behalf of the Board of Directors of the American Cancer Society, Inc., 777 Third Avenue, New York, New York 10017.

Laetrile, identified as the chemical amygdalin and produced from ground, defatted apricot kernels and concentrates of apricot and peach pits, is not a new discovery. For more than 20 years, the proponents of this drug have been refuted by, to name only a few: the Cancer Commission of the California Medical Association, the California Cancer Advisory Council, the American Medical Association, the National Cancer Institute, the American Cancer Society and the National Nutrition Consortium. The Food and Drug Administration has also reviewed the subject of Laetrile on several occasions.

Legal action against the proponents of Laetrile began as early as 1962, when they were charged with, and pleaded guilty to violating the new drug provisions of the Federal Food, Drug and Cosmetic Act. In March 1963, the FDA reported that it had found "no competent, scientific evidence that Laetrile is effective for the treatment of cancer," and in 1965, the proponents agreed to a permanent court injunction against further distribution of the drug. A year later, the proponents pleaded guilty to violations of the injunction.

In April, 1970, an Investigational New Drug Application to test Laetrile was awarded by the FDA, thus giving the proponents permission to obtain the drug for experimental and clinical studies. This was widely publicized and resulted in a resurgency of interest in Laetrile. However, the FDA review of the IND application disclosed a number of serious clinical problems and the IND

was terminated in less than a month. Once again, in September 1971, an ad hoc committee of five oncology consultants independently reviewed and evaluated Laetrile and found "no acceptable evidence to justify clinical trials" of the drug. Shortly thereafter, the FDA prohibited the interstate shipment of Laetrile in the United States, until basic studies had been performed. The FDA requested that the proponents provide clinical records of patients treated with Laetrile; four or five case histories were sent to the FDA, but they were completely unacceptable in terms of biopsy, documentation and other scientific criteria.

However, Laetrile is still illegally available in the United States. In the spring of 1975, the U.S. Custom officials uncovered an extensive international smuggling operation that imported contraband Laetrile into this country from Mexico and Germany.

Furthermore, in an attempt to circumvent the federal ban on Laetrile, the proponents have renamed it Bee-Seventeen, the "anti-neoplastic vitamin" and Aprikern. These oral preparations have been distributed to many health food stores across the country. The FDA has issued a public warning that they are misbranded and potentially dangerous; the ingestion of five capsules of Aprikern or two packets of Bee-Seventeen can be fatal in a child.

Despite such warnings, too many Americans have been or will be persuaded, through the propoganda of the proponents, to use Laetrile rather than known, effective cancer treatments.

According to the proponents of Laetrile, amygdalin is split by the enzyme beta-glucosidase and releases glucose, benzaldehyde (a mild anesthetic) and cyanide, which is lethal to cells. Supposedly, cancer cells contain more enzyme than normal cells and thus receive a larger amount of cyanide. Normal cells are said to contain another enzyme, rhodanese, that detoxifies cyanide and therfore prevents unwanted destruction. There are many flaws in this hypothesis.

For example, studies have shown only traces of beta-glucosidase in animal tissues, and even less in experimental tumors. Furthermore, there is no pronounced difference in the level of rhodanese between normal and cancerous tissue.

Amygdalin administered parenterally (by injection) is probably excreted almost intact in the urine. Taken orally, it is decomposed in the intestinal tract by beta-glucosidase into highly lethal hydrogen cyanide. Laetrile is 40 times more toxic when taken orally than parenterally.

A review of all reported material available to the American Cancer Society shows that Laetrile is not effective in the prevention or treatment of cancer in human beings. Reports of its ability to prevent, arrest or cure cancer are, in the main, anecdotal. Nonetheless, because of public pressure to begin clinical

testing, Laetrile has undergone extensive experimental study by Sloan-Kettering Institute, of the Memorial-Sloan-Kettering Cancer Center for Cancer Research and the Catholic Medical Center also in New York, the National Cancer Institute in Bethesda, Maryland and Arthur D. Little, Inc., an independent research laboratory in Boston.

In 1973, Sloan-Kettering Institute conducted a preliminary experimental study which indicated that amygdalin had some inhibitory effect on the development of tumors and lung metastases in a strain of mice that develop spontaneous mammary cancer. Their findings were prematurely leaked to the press and received extensive publicity by the proponents of Laetrile. Attempts to reproduce these initial results have not been successful. Two experiments were begun in 1974 at the Catholic Medical Center using bioassay to verify data objectively. Researchers found no inhibition of primary tumor growth and no difference in the incidence of metastases between mice treated with amygdalin and controls.

Sloan-Kettering Institute has supported four additional studies of Laetrile. Far from duplicating the initial findings, researchers discovered that the Laetrile-treated animals fared worse than the controls. Two later studies, which modified the original experiment, also had negative results.

Other research institutes have confirmed these negative findings. Extensive experimental studies at the National Cancer Institute found no evidence of activity using Laetrile in leukemia L1210 and P388, melanoma B16 and Walker 256 tumor systems. Four additional studies have been carried out under the auspices of the National Cancer Institute at a leading cancer research center in the South. They studied Laetrile in Ridgeway osteogenic sarcoma, Lewis lung carcinoma and leukemia P388. The osteogenic sarcoma system, which is particularly sensitive to antitumor agents did not respond to amygdalin, nor did the other animal systems. Arthur D. Little, Inc. conducted a similar experiment using leukemia L1210 and P388, melanoma B16 and Walker 256 carcinosarcoma. They also found no evidence of any selective effect using amygdalin alone or in combination with beta-glucosidase.

Based on these experimental studies, there is no scientific evidence to justify clinical trials. While experimental studies can obviously only anticipate results in humans, they are essential to protect the public from worthless or harmful agents. The National Cancer Institute has many drugs that have shown no antitumor activity in the laboratory, and therefore do not warrant a clinical trial. To make an exception for Laetrile is to open the door to potions and snake oils.

Although legal action has been taken against Laetrile at the federal leval by the FDA and it is illegal to transport it in interstate commerce, in the past year, 11 state legislatures have passed laws legalizing the use of Laetrile under

the guise of "freedom of choice" legislation. This situation not only sets up conflicting state and federal regulatory efforts, but also sets the stage for reaping a potentially grim harvest of deaths from cancer that could very likely be avoided. It would be the highest order of governmental irresponsibility to its citizens to take any action at the federal level to legitimatize, or give dignity to an out and out, fraudulent, useless and probably dangerous nostrum.

As part of its public responsibility, the American Cancer Society has organized a unique, comprehensive collection of all pertinent data on unproven methods of cancer management. Its National Office is one of the principal repositories for such information in the country. Furthermore, the Society's Committee on Unproven Methods of Cancer Management, comprised of physicians, lawyers, representatives from the National Cancer Institute, the FDA and other health agencies, meets twice a year to assess future professional and public eductional programs, to recommend and encourage anti-quackery legislation and to advise the American Cancer Society in its endeavors to more effectively control cancer quackery.

Recent proposals have been made to test Laetrile clinically in patients. Although the American Cancer Society disagrees with the rationale expressed for such testing, our official policy on this subject was approved by the Board of Directors on 6/9/77, and is expressed below.

In view of recent developments, the Committee's summary statement expressing the Society's official position on Laetrile has been revised to read as follows:

"1. A review of all reported material available to the American Cancer Society shows that Laetrile is not effective in the prevention or treatment of cancer in human beings.

"2. Since there is a growing public and legislative interest in Laetrile and in its effect and use, and since the Society has a responsibility for informing the medical profession and the public at large on matters concerning cancer, the American Cancer Society reaffirms its support for the protection of the cancer patient through strict adherence to FDA established methods of scientific testing, and further, that it does not approve of any exceptions to such methods for any particular substance."

American Cancer Society, Inc.

July 11, 1977

EMBASSY OF ISRAEL
WASHINGTON, D.C.

שגרירות ישראל
וושינגטון

July 1, 1977

Dr. Sidney Arze
Vice President Professional Education
American Cancer Society
New York

Dear Dr. Arze,

As per your request on the telephone, please find, hereunder, remarks that has been made by Prof. Manchel, Director General of the Ministry of Health in Israel, regarding Laetrile:

1. In the enquiry that we have conducted, we have ascertained that this drug is not in use either at Hadassa Hospital, Beilinson or Tel-Hashomer Hospitals.

2. Dr. Rubin left the Beilinson Hospital and we have been told that he is in the U.S.

3. Dr. Issahary, Medical advisor to the Aircraft Industry, studied the subject in the U.S. and wrote an outline for the Director General of the Aircraft Industry, but he does not have any knowledge whatsoever on the use of Laetrile in Israel.

4. With regard to the use of the drug itself, it is not available in Israel and no importlicence has been granted; nor has there been a request for such licence. Furthermore, use of an unregistered drug is not permitted, and Laetrile is not registered among the drugs permitted for use in Israel.

Sincerely,

E. Effati

E.Effati,
Scientific Counselor

INTERNATIONAL HEALTH COUNCIL

AN INFORMATION AGENCY
DEDICATED TO SURVIVAL

WALTER ERMER, D.D.
EXECUTIVE DIRECTOR

15328 EDOLYN AVENUE
CLEVELAND, OHIO 44111
Phone: 216 / 671-6638

October 28, 1977

STATEMENT BY WALTER ERMER, D.D., FOR THE LAETRILE HEARING RECORD, BY THE SENATE COMMITTEE ON HEALTH, JULY 12, 1977.

I am a retired business executive from heavy industry who has dedicated the rest of my life at full time as a volunteer to solving the cancer problem. An honorary degree as Doctor of Divinity was awarded for the free counselling of over 1,000 cancer victims, helping hundreds to die and hundreds to live longer and more functional lives. To date, I have now counselled with about 2,000 victims so I do know something about the end results of various cancer therapies. Many qualified physicians even from other parts of the world come here to learn, and there are hundreds of physicians treating their families and friends with nutritional therapy, including Laetrile, without the knowledge of their peers. I am also the author of a book called "A Program For Prevention and Detection of Pre-Cancer", and a copy is enclosed for the record labelled as Exhibit A.

The cancer epidemic is presently raging out of control. The Medical Establishment, science, American Cancer Society, National Cancer Institute, Food and Drug Adminstration have all failed and are actually obstructing progress. In spite of their failures, Congress and the Adminstration still listen to these failures, but will not listen to those who have succeeded. We the people have no interest in scientific dogma, no interest in the status of these failures, no interest in promoting the welfare of the Disease Industry; we are only interested in a longer and better life. We can see positive results in Nutri-Therapy of which Laetrile is an integral part. You should permit all harmless materials, including Laetrile, to be used by any doctor or victim who want the freedom to use it and let science fill in the building blocks dictated by dogma over the next generation. All we are interested in is a longer and better life for these poor souls right now in their own country; why force them to leave this police state to seek freedom in some free country?

Let's review a little history. I was in contact with Senator Yarborough and his staff in 1969 and "sparked" the Senate investigation into cancer, followed by the National Cancer Act. We had twelve scientists, physicians and laymen who knew cancer and wanted to testify. The Committee, favorable to the Disease Industry would not hear us. There can be no other explaination, the Disease Industry could not risk losing a multi-billion dollar industry! No need to go into details but the formulation of the National Cancer Act was engineered by the Disease Industry so they would benefit in the amount of hundreds of millions of dollars, and the people paying the bill would get nothing. We forecast failure at that time and our forecast has come true, since in spite of the millions, cancer deaths are on the increase- not decrease. The entire National Cancer Act must be repealed or restructured by those who know cancer and not by those who have failed.

Presidents Nixon, Ford and now Carter have been in violation of the law, the National Cancer Act. Their appointments to the National Cancer Advisory Board have been illegal and immoral, appointing those who would support the policies of the National Cancer Instutute that has failed. Those with conflict of interest and lack of knowledge were appointed. I am not going to dwell on their acts, we must be positive and look ahead.

Consequently, I furnished the White House with the names of five prospects who know cancer and Nutri-Therapy for the professional part of the board, which requires ten appointees. The other five can be those acceptable to the NCI and Disease Industry. I also furnished the names of eleven members of the public well versed in the cancer problem of which eight can be selected to fill the non-professional part of the board, all of them without conflicfof interest. Presidents Nixon, Ford and Carter have not acted on this all important board so it is time for Congress to act and more clearly outline the type personel required for the board.

Enclosed is a copy of a letter entitled Exhibit "B", written by one of our dedicated workers to the Pennsylvania Legislature on the subject of legallizing Laetrile in the state. This is enclosed to show the Committee that there are thousands of people fighting for freedom in this police state. Laetrile is only the tip of an iceberg showing a bumbling bureaucracy undermining the health of the American people/ This senate committee must not only legalize Laetrile but establish the basic historic relationship between a doctor and his patient as law in this country, so as to prevent all third party interference.

Laetrile is not a drug even though our opposition tries to make it so but it is handicapped by the unreasonable requirements of the FDA. Laetrile is in the public domain so no one can afford to put up the millions needed for FDA approval, since FDA insists on calling it a drug. The Efficacy Clause in the Food and Drug Act is a miserable failure since many drugs developed here in the USA go to foreign countries where the people benefit from our technology. This Senate Committee must release Senator Jesse Helms' "Medical Freedom of Choice"Bill, S1683, to the floor for a vote by the entire Senate.

The FDA Hearings in Kansas City on Laetrile were a complete sham. The FDA ruled out my evidence and that of all Laetrile supporters on the basis it was all hearsay, anectdotal, and not scientific. Yet the FDA permitted testimony supporting their position to be included in the record when it was hearsay, anecdotal and not scientific. All you have to do is read the record and you will easily see for yourself. A copy of my testimony is s enclosed as Exhibit "C".

Since the Kansas City Hearings, FDA has been stalling and harassing cancer victims bringing in Laetrile under court order. This is certainly in contempt of court and people are dying because of their actions. Not only are they in contempt of court but in contempt of Congress. Under the Freedom of Information Act, I asked for a list of those who received a fee and/or expenses to testify at Kansas City. They are ignoring this simple request that would not take over an hour to prepare, and since I am a taxpayer, it is my right to see how my money is being spent. This committee must put this run-away bureauacrcy under control. Let them abide by the law they claim to enforce.

Enclosed is a copy of my letter to Senator Kennedy refuting his stand on Laetrile, entitled Exhibit "D". It covers many points in this problem. We ask that it be included in the Hearing Record.

Also enclosed is a copy of a letter sent to Senator Kennedy, entitled Exhibit "E", dated July 17, 1977. This letter covers a "locking up" of any test run by NIH on Laetrile. They are so biased that no one will believe any test reports they might issue.

Since President Carter is responsible for the failure of the National Cancer Institute and since he is directly responsible for the actions of the Food and Drug Adminstration killing off our cancer victims by banning Laetrile and other harmless materials, we ask this committee to start impeachment proceedings at once. President Carter should be impeached on his denial of HUMAN RIGHTS of the hapless cancer victim.

Sincerely,

Walter Ermer, D.D.

Walter Ermer, D.D.

EXHIBIT "B"

OPEN LETTER TO THE PA. HOUSE
OF REPRESENTATIVES

Mr. Chairman, Honorable Representatives of the people of Pennsylvania, this fall you will be conducting hearings on Laetrile. It appears that Laetrile, the new and controversial cancer treatment, will be on trial at these hearings. It is not Laetrile that should be on trial. The people responsible for Cancer Research during the past forty years are the ones who should be on trial. I mean the National Cancer Institute, The Food and Drug Administration, Sloan Kettering Institute, The American Cancer Society, and The American Medical Association. All of these together are known as The American Cancer Establishment.

Let's look at the record. Forty years ago the Congress established The National Cancer Institute. Since that time six **billion** dollars have been allocated for the crusade against cancer. This has been the longest and most expensive Medical Research Program the world has ever known.

What have we, the people, received for our money. During these forty years cancer has gotten completely out of hand — it has become pandemic. One in four of us have it now or will get it before we die. The National Cancer Institute recently reported that one in three of our children born today will have it at some time in their lives. The rate of increase has risen steadily until it was over three percent last year. This is the **rate** of increase, Gentlemen, not the increase in numbers of cases. This rate of increase, if continued, means we will all have cancer within twenty-five years. Obviously the prevention of cancer has failed and even gone backward.

The cost of dying from cancer, too, has gotten out of hand. Reliable estimates place it at about twenty thousand dollars per victim. Many families are bankrupt because of cancer.

During the past forty years scarcely any progress has been made in curing this disease. By adding skin cancers to their statistics, The Cancer Establishment has made it appear that 30% of all cancers can now be cured. (Skin cancers are the easiest to cure and comprise 90% of all cancers.) If skin cancers are excluded, as they should be and were when figures were first kept, the increase in cures has been little more than one percent. Cancer researchers are frustrated, and the American people are disappointed. They have lost faith in the Research Program, in the people who are conducting these programs, and (sad to say) are losing faith in their doctors.

For years The American Cancer Society and The American Medical Association repeatedly said that nutrition had nothing to do with cancer, that dietary treatments of cancer are quackery. They have done everything in their power to ridicule this approach in controlling cancer. In 1976 approximately 800 million dollars were allocated by Congress for fighting cancer. A paltry six million dollars were earmarked for nutritional research **over the opposition of The Cancer Establishment.**

We are happy to see that the Medical Establishment (at last) is looking into immunotherapy. This is the method of treating cancer through the body's own defenses. Twenty years ago Dr. Andrew C. Ivy was crucified for going into this field; today it is the white hope in cancer research. Today doctors are arrested for using Laetrile in trying to save their patients' lives. Twenty years from now, it will be used routinely in our hospitals if something better hasn't come along.

The American people are angry. They want the Cancer Establishment to stop wasting our money on highly toxic drugs, half of which cause cancer. They want a large share of our research dollar spent in nutritional research of which Laetrile is only a small part. Laetrile is a non-toxic nutritional substance made from food. We want Laetrile tested in our hospitals, on volunteers, under the supervision of doctors trained in nutrition. We do not trust the spokesmen for the multibillion dollar Orthodox Cancer Establishment.

The American people can be fooled for a long time. They can be bled white, butchered on operating tables, burned with radiation, and poisoned with chemicals without complaining until one small voice is raised in protest, then another, and then many more until **a mighty roar of anger sweeps across the nation.**

Gentlemen, we want you to legalize Laetrile in this great state of Pennsylvania. We want you to return **freedom of choice** to the people.

Thomas H. Mansell, Chairman
Committee for Freedom of
Choice in Cancer Therapy,
Beaver Valley Chapter 0193

EXHIBIT "C"

INTERNATIONAL HEALTH COUNCIL.

AN INFORMATION AGENCY
DEDICATED TO SURVIVAL

WALTER ERMER, D.D.
EXECUTIVE DIRECTOR

15328 EDOLYN AVENUE
CLEVELAND, OHIO 44111
Phone: 216 / 671-6638

TESTIMONY ON LAETRILE BY WALTER ERMER, D.D.,

Food and Drug Administration Hearing, Kansas City, Mo., 5/2/77.

Mr. Commissioner, I am representing the International Health Council and Cancer Victims Anonymous in this presentation. I am a retired business executive and have worked full time as a volunteer researcher on this cancer problem for the last thirteen years. I have counselled with over 1,000 cancer victims, helping many leave a life in this vicious police state for a better life in the next world. I have followed hundreds to life or death and have some statistics to offer. At the time of the survey, 173 had submitted exclusively to the destructive orthodox treatments approved by the Food and Drug Administration and only 6.4% were still alive. 171 had used Nutritional Therapy, [redacted]. All we care to demonstrate is that cancer victims live longer on Nutritional Therapy than they do on the destructive orthodox that has your blessing. I submit Bulletin #81 as exhibit "A" for the record. As a matter of definition, Nutritional Therapy is a complete Health Building Program with an integral part being Amygdalin which is also called Laetrile and B-17, proper diet, proper use of food supplements, detoxification, elimination of carcinogens, proper living habits.

Amygdalin is a concentrated food factor and not a new drug. Since FDA incorrectly calls it a new drug, let us examine your contention. Amygdalin is listed in the United States Pharma copea of 1870, see Exhibit "B", so the Grandfather Clause in the Food and Drug Act prevents FDA from claiming jurisdiction. The U.S.Court of Appeals, 4th District, #71-1243, May 23, 1972, upheld the validity of the Grandfather Clause, and nothing said or done by FDA can affect the old status of a product. FDA does not have the legal force to turn an old drug into a new one.

FDA stresses the role your so-called "qualified experts" play in determining safety and efficacy, but you have no "experts". If we had any "experts" in the United States the cancer epidemic would be controlled and we would not be losing over 1,000 victims each day! Since you have no experts you are forced to evaluate Amygdalin by the experience and observation of those who have seen extended life span.

To further question your credibility in this inhuman oppression, you specify only evidence from adequate and well controlled clinical investigations yet you do not permit the clinical testing of Amygdalin in the United States! For example, IND 6734, granted to McNaughton and cancelled before tests could be started. With this incredible paradox existing and a cancer epidemic raging out of control, you must stop interfering between a doctor and his patient, let them do what they want with any harmless material.

While we further examine FDA's illegal acts, your present position banning harmless Amygdalin is in violation of Amendment 14 of the United States Constitution, where we are guaranteed equal protection under the law. I am sure the Secretary of HEW and top officials of FDA have sworn to uphold the Constitution, so why don't you? Why are FDA officials perjuring themselves? You are operating under a double standard, one standard for cancer victims and proponents of harmless Amygdalin, and one standard for the proponents of highly toxic chemotherapy approved by FDA, that condems people to the grave long before their time. Our problem today is survival of FDA

approved treatments, not survival of the disease. This statement is further confirmed by the extensive studies of Dr. Hardin Jones and I am sure FDA has a copy of his work. For example, case #320 in my files, male, had an exploratory operation on 4/24/73 and was closed as inoperable, with a diagnosis of mesothelioma in terminal condition. He was treated with your approved methotrexate, 5FU, cytoxin, and deteriorated to the point where he was unable to work. On 11/5/73 he realized he was dying and changed to Nutritional Therapy. He went back to work and this picture dated 7/23/75, Exhibit "C", demonstrates his well being. He was collecting some fluid in his pleural cavity over a period of seven months that contained no cancer cells. He went to the Veteran's Hospital on 7/26/75 to be drained. The physicians injected silver nitrate into the pleural cavity and he was declared totally disabled 8 days later. For comparison, I submit this picture as exhibit "D", taken on 12/20/75, after silver nitrate and before he died. I hereby charge the Food and Drug Administration with negligent homicide for permitting silver nitrate and other dangerous drugs to be manufactured and sold to this hospital for human use. It is despicable that harmless Amygdalin that was so beneficial to this man is suppressed, and deadly silver nitrate that killed him is permitted. This double standard is unconstitutional, you should support the Constitution and not perjure yourself.

Previously I stated Amygdalin was a concentrated food factor and not a drug. Regardless of how you twist the facts around to accomplish your aims, and contrary to what many people believe, Amygdalin is not a cure for cancer or anything else. There is no cure for cancer and never will be in my opinion but there are controls that lie within our way of life. Amygdalin like many other foods are required for optimum health. It is a concentrated food factor that will rapidly compensate for a life time deficiency of nitrilosides in the civilized diet, and correct a vital metabolic malfunction. After the body functions properly it will control cancer and many other malfunctions, so it is not food that directly corrects the problem. I previously mentioned Case #320 and demonstrated in the Pictum Exhibit "C" how well he did on Nutritional Therapy including Amygdalin as a food.

Case #462, male, exploratory 11/19/74, inoperable retro-peritoneal lymphosarcoma, estimated weight 10Kg (22.2 lbs). He was declared terminal with two months to live. He went to Dr. Contreras in Tijuana Mexico on 12/19/74. On 1/20/75, his terminal date, he went back to work, has been working ever since and feels great. His girth is almost normal and probably will not reduce anymore since there has no doubt been a fibroid mass left behind.

Case #508, female, breast tumor, first noticed in 1967, no treatment. On 3/20/74 it was the size of a small grapefruit, she refused a mastectomy, stating she was going to leave this earth the way she came in. Her arm was also affected and she was declared terminal by her doctor. She self administered Nutritional Therapy in cluding Amygdalin Tablets and the tumor reduced tb the size of a plum in two weeks. She gained weight, feels good, and today the tumor as flat and the size of a dime, so it probably will remain this size for the rest of her life.

These are a few of the more spectacular responses I wish to report on from improved body function resulting from improved living habits including the proper use of Amygdalin in the diet. I have seen many more.

My contention that Amygdalin is a food is further confirmed by FDA since it is listed in your GRAS list as a safe food.

I previously demonstrated in Exhibit "A" that Amygdalin used as a concentrated food with other changes in living habits will extend human life over that experienced with your approved highly toxic drugs.

By suppressing the food Amygdalin, FDA is in further violation of the 1st Amendment to our Constitution, interfering with our practice of religion. God gave us food in many forms and our religious freedom entitles us to partake of God's Bounty without hinderance from FDA or any other agency.

Also, violation of the 9th Amendment to our Constitution by FDA is evident. We the people have retained the right to eat what we want, including Amygdalin, and we have not delegated the authority to FDA or anyone else to abrogate this basic right.

In closing this presentation, I say: "FDA get off the backs of the hapless cancer victim who wants Amygdalin, stop sacrificing the lives of millions of Americans to satisfy your fanatical drive for power, live up to the oath you made to support the Constitution of the United States, let us live in peace as a free nation instead of a despicable police state!"

Thank You!

Walter Ermer, D.D.

Minor deviation from the written text given orally:-

Insert #1. "Mr. Commissioner, we have been subjected to a 3 hour bombardment of brainwashing by the egghead, quacks, misinformed and lying members of the Establishment and I am tired of it, and as a member of the public I don't buy it!"

Insert #2. " 17 had used Nutritional Therapy and over 60% were still alive." (This is a true statement but more conservative because the actual figures are unbelievable)

Exhibit "D" #3

INTERNATIONAL HEALTH COUNCIL

AN INFORMATION AGENCY
DEDICATED TO SURVIVAL

WALTER ERMER, D.D.
EXECUTIVE DIRECTOR

15328 EDOLYN AVENUE
CLEVELAND, OHIO 44111
Phone: 216 / 671-6838

October 3, 1977

Honorable Edward M. Kennedy, Chairman
Subcommittee On Health
United States Senate
Washington D.C., 20510

Dear Senator:

Thank you for your letter of September 20th regarding my letter to the White House, on the subject of your July 11th Laetrile Hearings. I have worked as a volunteer, mostly full time, on the cancer problem, have counselled between 1500 and 2000 victims, have seen hundreds die and hundreds live longer and better lives including physicians and their families, so I know something about the end results in cancer. Following are some comments about your letter:

In your second paragraph you state witnesses were heard on both sides in your Hearing. Your witness list demonstrates the bias and unfairness of the hearing, since the unqualified opponents from the Disease Industry and fellow travelers far outnumbered the proponents representing the public who pays the bill in money and life. The public should always outnumber those serving them who are taking their money. In my letter to you of July 17th, which was not acknowledged (a copy is attached), I complained about discrimination against the cancer victims which is a minority group, particularly those from this area who were not accepted for testimony. The Disease Industry and fellow travellers do not know the first thing about cancer, they have failed since time began, so you had no experts as oponent witnesses. If you did, we would not be losing 1100 Americans each day - worse than all the wars put together. There are thousands of cancer victims today who have been forced by the Establishment and government to treat themselves, and they know more about cancer than the conventional doctor or your opponent witnesses.

In your third paragraph you mention the word "cure", a word used by the Disease Industry to mislead the public and those promoting Nutritional Therapy. There is no "cure" for cancer and never will be, but there are controls that lie in our way of life; controls never to be found in the conventional multiple cutting, burning and poisoning. Yes, unfortunately victims grasp at straws when conventional methods fail and will seek nutri-therapy as a last resort. Only 2% will seek nutri-therapy first. If the situation were reversed and 98% were to use nutri-therapy first, some 80% to 90% would experience longer and better life. We seldom see nutri-therapy first before the damage is done, but when we do, the results are phenomenal. If fact the main problem is to survive the conventional treatment, not the disease, and this has been substantiated by the studies of Dr. Hardin Jones.

In your fourth paragraph you state that our people are not capable of sifting fact from fancy. You are taking sides with the eggheads in the Disease Industry against the people you represent. You think our people, including your constituents, are a bunch of "dummies" (a term used by a cancer victim in the FDA Hearings at Kansas City). Unfortunately almost all panic into the destructive conventional treatment and the learn the horror of the methods too late. Mr. Senator, if you and the Medical

Establishment can not see horrible results of the accepted conventional treatment, the cancer victim and his family can. Likewise if you and the Establishment can not see longer and better life from Nutri-therapy, including Laetrile, the cancer victims and their families certainly can. This is why the people are fighting for their freedom and will continue to fight as long as our government continues to back the Establishment by permitting them to bleed us financially and kill us off.

In your fourth paragraph you say the FDA has a humanitarian role. Pure bunk!. They have not demonstrated any compassion what so ever in their sadistic oppression of the dying cancer victim. Again, if you can not see these sadistic bumbling bureaucrats in their true light, the public certainly can. This stupid agency is causing a disrespect of all government functions in the eyes of the public, and it is up to our representatives in Congress to take appropriate action. The "informed judgement" you mention of the Disease Industry including FDA, is a pack of lies and misinformation to cover up their ignorance.

Of course in all this, we realize President Carter is directly responsible for a large part of the 1100 deaths each day, caused by FDA bumbling. FDA is a part of his adminstration so the responsibility is his. The Senate should start impeachment proceedings against President Carter for denying the human rights of those 1100 cancer victims dying each day, in favor of the human rights of people in Africa and Russia. Perhaps the President and Congress are in favor of these deaths to take the load off Social Security, I don't know but it looks suspicious.

In your fifth paragraph you say you are personally skeptical about the validity of Laetrile. Have you personally seen even 100 cancer victims use Nutri-therapy including Laetrile, who have not been damaged fatally by conventional therapy? If not, then you are not in a position to judge. The tests conducted by the Disease Industry are invalid and the unethical practices surrounding Laetrile, you mention, are almost entirely within the Disease Industry. I have found the sale, distribution and use of Laetrile to be mainly by dedicated humanitarians risking financial ruin by their government.

Since you asked N.I.H. to evaluate Laetrile, I must say that our people do not trust them and will not accept their findings unless the tests are completely locked up as described in my letter of July 17th.

We are not asking for more words, but some action. Get these monkeys off the backs of the dying cancer victims; let the people with their doctor decide what is best for them without any interference from some faceless bureaucrat. Thank you for listening!

Sincerely, Walter Ermer, D.D

Walter Ermer, D.D.

Copies:
Marc Rosen, The White House
L.H.Fountain, Gov. Operations Committee
John Glenn, U.S.Senate
Richard Abodeely, Lowell Mass.,
Mrs. Susanne Beaty, Belmont Mass.
Jo Ann Gilson, Stoughton Mass.

Exhibit "E"

INTERNATIONAL HEALTH COUNCIL®

AN INFORMATION AGENCY
DEDICATED TO SURVIVAL

WALTER ERMER, D.D.
EXECUTIVE DIRECTOR

15328 EDOLYN AVENUE
CLEVELAND, OHIO 44111
Phone: 216 / 671-6638

July 17, 1977

Edward M. Kennedy, Chairman
Subcommittee On Health
United States Senate
Washington D.C., 20510

Dear Senator:

I wish to take exception to the actions of your committee who discriminated against our people by not permitting them to testify at your recent Hearings on Laetrile. Our groups represent thousands of Americans all over the United States including your state of Massachusetts, and this denial of representation is a gross miscarriage of justice. This present action by your committee is a repetition of the actions of the Senate Committee Investigating Cancer in 1969. Twelve scientists, physicians and laymen who really knew cancer, were suggested by me but denied a hearing by the committee. The committee knew what we had to offer, knew it would benefit the cancer victim, knew it would be detrimental to the income of the entire Disease Industry. Consequently, the National Cancer Act has failed, the National Cancer Institute has failed, the millions of tax money you have spent has been unproductive. As you know, cancer is an epidemic taking the lives of 1,100 Americans each day with the toll rising. This carnage is worse than all our wars put together, so it is time for Congress and the Adminstration to put their priorities in proper order.

In the news reports covering your hearing, it was stated: "Friend, foes of Laetrile agree to showdown test". We made no such agreement. With all the lies, intrigue, and bias demonstrated by the opposition against the Cancer Victim minority, they can not be trusted with such a test. The following criterea must be met before our people would accept and support any such clinical test:

1. Material selected must be known to us as effective. There are ineffective materials available.
2. Sloan Kettering, National Cancer Institute and others paid by NCI or the American Cancer Society are not qualified to test because of demonstrated bias. We would accept Dr. Harold W. Manner of Loyola University, and possibly some others.
3. Proponent observers must be present during all phases of the test, and we would have to approve the observers selected.
4. The materials to be used and all records must be locked up with double locks so they are not accessable unless both proponent and opponent observers are present.
5. The tests must include all facets of accepted Nutritional Therapy and not just Laetrile alone. The test must be on a Program.
6. Patients involved shall not have been damaged by multiple surgery, radiation or toxic chemotherapy. Selection of patients must be approved by both opponents and proponents.
7. Final evaluation and releases to be done by both factions.

Regards,

Walter Ermer, D.D.
(For IHC and Cancer Victims Anonymous)

DEAN BURK FOUNDATION, Inc.
4719 Forty-Fourth Street · Washington, D.C. 20016
Telephone (202) 363-6279

November 16, 1977.

Honorable Edward Kennedy,
4220 Dirksen Building,
U.S. Senate, Washington, D.C. 20510.

Attention: Kathy Henderson

Dear Senator Kennedy:

Following a telephone conversation yesterday with Kathy Henderson, I wish to submit herewith testimony to be included in the Report of your Committee on the Hearings on Laetrile held early in July.

With appreciation of this privilege,

Sincerely,

Dean Burk

Dean Burk, President,
Dean Burk Foundation, Inc., and
U.S. National Cancer Institute, 1939-1974, Ret.

DEAN BURK FOUNDATION, Inc.
4719 Forty-Fourth Street · Washington, D.C. 20016
Telephone (202) 363-6279

(1)

I am DEAN BURK, President, Dean Burk Foundation, Inc., 4719 44th Street, Washington D.C.

(1) I graduated from the University of California at Berkeley in 1923, and received my Ph.D. from that Institution in 1927. This Ph.D. was in the field of biochemistry, in the Department of Plant Nutrition, with a minor in chemistry in the Department of Chemistry.

(2) Prior to my forty-five years employment with the United States Government as a research civil servant (1929 to 1974), I did biochemical and nutritional work at the University of London (University College), Kaiser Wilhelm Institute for Biology in Berlin, Germany, and in the Department of General Physiology at Harvard University (1927 to 1929). I was associated with Cornell University Medical College, New York City, as Associate Professor of Biochemistry from 1939 to 1941.

(3) During my forty-five years of Civil Service with the United States Government, I worked in the Department of Agriculture from 1929 to 1939, and then in the National Cancer Institute of the National Institutes of Health of the Department of Health, Education and Welfare for thirty-five years (1939 to 1974). My last position with HEW before mandatory age-restirement in 1974, was that of Head of the Cytochemistry Section of the National Cancer Institute. I was Guest Scientist at the United States Naval Medical Research Institute, Department of Experimental Medicine, in Bethesda, Maryland from 1974 to 1976.

(4) Attached in Exhibit A, pp. 22-23, is a brief statement of my curriculum vitae listing various awards and appointments in my lifetime to date. I am listed in Who's Who in America and in Who's Who in the World. Approximately 60,000 Americans are listed in the Marquis Who's Who in America; only about 6,000 of these are listed in the Marquis Who's Who in the World, and I am one of them.

(5) I have been active in the field of cancer since 1927, now fifty years, and, in collaboration with several hundreds of scientists and medical doctors, have worked in nearly every field of cancer, and have produced over one hundred and fifty scientific papers in this field alone, out of a total of some 300 scientific papers altogether. Some of this work involved some five years of scientific study in Germany, and some three years of scientific work in England, together with other work and attendance at many international scientific congresses in still other European countries. I have performed tens of thousands of experiments with laetrile, most of them in the U.S. National Cancer Institute.

In the following pages and exhibits I shall show that, in my opinion, laetrile is generally recognized by qualified experts as a safe and effective treatment for cancer,-as a food and vitamin, not as a "new drug."

In attempting to arrive at a satisfactory distinction between a food and/or (2) vitamin on the one hand, and a new drug on the other, the following considerations must be kept in mind:

(6) Although the Federal Food, Drug, and Cosmetic Act defines in Chapter II - DEFINITIONS - Sec. 201 (321)(g)(1)"The term "drug" means (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals;,,," nevertheless, foods and vitamins have been widely recognized as exceptions with respect to (A), (B), and (C) (cf. Exhibit A, pp. 4-7).

Thus, in a 15-paged letter written on March 1, 1974 by then-FDA Commissioner Alexander M. Schmidt, M.D., to Arthur Koch, National Health Federation, 121 2nd Street, N.E., Washington, D.C. 20002, who had petitioned that fluoride be classified as a drug under the above-cited section of the F.D.C. Act, Commissioner Schmidt denied this petition, stating that

"The petition erroneously concludes that fluoridated water is a drug under the Federal Food, Drug, and Cosmetic Act. It is instead a nutrient, necessary in normal diets to assure good health, and is therefore properly regulated as a food."

"The petition misinterprets the definition of "drug" in the Federal, Food, Drug, and Cosmetic Act because it fails to distinguish between nutritional (food) and therapeutic (drug) uses of a substance. The petition argues that because the intended use of fluoridated water is aiding in the prevention of a disease, tooth decay, the substance is therefore a drug within the meaning of 21 U.S.C. 321 (pp. 5-9). This proposed interpretation of the statute is inconsistent with the design of the Act, however, and cannot be sustained."

"It is clear that a nutrient, offered as such, was not meant to be treated like a drug under the Act. The interpretation sought to be applied would result in all food being treated as drugs. That consequence would follow because the fundamental reason all food is eaten is to prevent the appearance of diseases that result from improper diet. Failure to eat enough food results in protein-calorie malnutrition diseases such as kwashiorkor and maramus. Failure to take in all the proper nutrients results in vitamin-deficiency diseases like scurvy and pellegra or in other abnormalities."

"Underlying this concern for good nutrition is, of course, the intention to prevent disease. ...General nutritional education does not constitute the specific claims for disease prevention that must accompany a product to make it a drug within the meaning of 21 U.S.C. 321(g)(1)(B).?...."scientific and medical knowledge must be used to distinguish nutritional from therapeutic uses of a substance." (Emphasing italics added).

(7) As a vitamin (B-17), amygdalin would be precluded from being classed as a new drug, in view of Congressional law 94-278 (Proxmire Amendment) signed by the President April 22, 1976; and indeed also by the United States Court of Appeals, 2nd Circuit, decision of August 15, 1974 as upheld by the U.S. Supreme Court by virtue of denial of certiorari. (cf. Exhibit A, pp. 5-10).

Clearly, amygdalin acting as a food and vitamin, and playing a nutrition role in its mechanism of alleviation of human cancer, requires no designation as a new drug, any more than does vitamin C (ascorbic acid) in its mechanism of alleviation of scurvy, and similarly through the list of all other vitamins, as well as nearly all foods.

Let us now examine how the foregoing general considerations of (6) and (7) (3) so in fac apply to the case of laetrile in particular, as a food and as a vitamin, and not a new dru

(8) In the decision of the United States Court of Appeals, 10th Circuit (75-1725), the opinion is given that "As we view it, the reason that the Food and Drug Administration is anxious to classify Laetrile as a new drug is so as to bring it within the new drug certifications procedures of the Food, Drug and Cosmetics Act. Section 505(a) of the Act, 21 U.S.C. Section 355(a). This provision bars the introduction into interstate commerce of a new drug without an approved new drug application having been filed pursuant to the Act just cited." But, "the FDA's record is grossly inadequate and consists merely of a conclusory affidavit of an official of the FDA which in effect declares it (laetrile) is a new drug because the FDA says it is and thus is subject to all of the statutory vagaries of such a designation." (October 12, 1976).

Subsequently, upon remand to the United States District Court for the Western District of Oklahoma, Judge Bohanon in a Jan. 4, 1977 MEMORANDUM OPINION AND ORDER ordered that "pursuant to 5 U.S.C.Paragraph 705, that while this case is on remand to the FDA, and until such time as the FDA proffers to the Court an administrative record containing substantial evidence of its determination that Laetrile is a "new drug" under the terms of the relevant statute, such determination is held to be without force or effect as to the plaintiff class in this case," and that hereafter "this suit shall be certified and treated as a class action suit," under Rule 23 of the Federal Rules of Civil Procedure. Further, the Court stated, "Based on the complete absence of any evidence tending to establish a rational basis for the agency's determination, the Court would also be compelled to find, in applying the standards of 5 U.S.C Paragraph 706, that the agency's determination was arbitrary, capricious," and represented "an abuse of discretion," and that it should be overturned for these additional reasons.

(9) To the judiciary considerations briefly outlined in (8), I may add that, in my judgment and experience, the FDA determination is scientifically without substantial basis, arbitrary, capricious, merely conclusory without evidence, and, I affirm, prevaricative to an unbelievable degree, as indicated below. FDA officials and FDA outside appointees have made innumerable statements to the effect that laetrile is not a vitamin, but always, to my knowledge, in merely conclusory manner with clear and intended neglect of overwhelming evidence to the contrary, some of which I shall present in attached Exhibits for any and all to see and study. To paraphrase the wording of the 10th Circuit Federal Appellate Court, "because the FDA conclusorily declares that laetrile is not a vitamin (B-17) does not make it not a vitamin." As pointed out in (7) above, the status of laetrile as a vitamin (B-17), to be indicated below, proscribes and makes moot its being a new drug.

Laetrile as Vitamin

(10) To begin with, all vitamins are by Federal statute definition foods (cf. Exhibit A, pp. 1-2, 5-10), and, as indicated in Exhibit B, laetrile is listed in the HEW-FDA GRAS List (foods "Generally Regarded as Safe") under the heading of natural extractive from bitter almond, apricot, or peach kernels (syn. seeds, nuts). The only specified proviso is that such extractive be "free from prussic acid." Exhibit C summarizes evidence that laetrile contains no ordinarily measurable or measured quantity of prussic acid, any and all statements to the contrary notwithstanding. Being on the GRAS List proscribes laetrile from being classified as a food additive, in accord with the Federal statute definition in the Federal Food, Drug, and Cosmetic Act - Chapter II, Definitions - Sec. 201(321)(s).

320

*P. [illegible] of the 1976 edition of the FDA Code Regulations, Title 21 CFR 121.101(e)(2), and earlier editions.

(11) pp. 18-21 of Exhibit A, summarizes the extensive evidence that (4) has existed for over one hundred years, that laetrile, at conventionally applied dosages for cancer treatment, is nontoxic in animals and man over a very wide range of application.

(12) Pp. 7-9 of Exhibit A gives a widely accepted definition of vitamins and their varying natures, background, and interpretation. The summarized definition at the top of p. 8 is in close harmony with that given by Professor David M. Greenberg, Emeritus University of California Medical School, and Consultant, Cancer Advisory Council, California State Department of Health, on p. 346 of his article in Western Journal of Medicine, vol. 122, May 1975. But Professor Greenberg makes in this article a studied neglect of his definition to the instance of laetrile data of the vitaminic nature of laetrile now to be reported, briefly summarized on p. 15 of Exhibit A, following discussion on pp. 11-14.

Animal data.

(13) p. 15 of exhibit A summarizes amygdalin efficacy against cancer in animals as observed in three widely separated countries of the world, and five laboratories therein, up to date of 1975; more such work has appeared since. Not all such data can be presented here - by any means - but it may be illustrated in Exhibits D and F, 159-page (5) and may found in extenso in a letter submitted to the FDA on March 25, 1977

Exhibit D sets forth some of the data referred to in Item (1), p. 15, Exhibit A, taken by Dr. Kanematsu Sugiura, Sloan Kettering Cancer Center (New York).

Exhibit F sets forth a small fraction of the data taken by the Scind Laboratories (San Francisco), 1968.

In (13) above and (14) below, laetrile shows all the essential properties (cf. Exhibit A, p. 8, and p.11; and Greenberg, J.West. Med.122,p. 346, 1975) and attributes that define a vitamin, and, in this instance, a (B) vitamin: it is

nontoxic, water-soluble, an exogenous nutrient or food factor, and active in relatively small, essentially catalytic, non-calorific amounts, and is essential or beneficial in normal metabolism and/or physiologic functioning to overcome deficiency lesions and symptoms of nutritional disease. In the foregoing animal data the deficiency lesions and symptoms of nutritional disease are best illustrated by the action of amygdalin in lengthening of animal lifetime or decreasing development of metastases, or both, and increase in health and well-being, all properties objectively measured in the experiments reported, as may readily be seen upon detailed examination of the data.

Human data.

(14) Some of the first, clear-cut published data indicating a positive and vitamin action in humans was reported by the Cancer Commission of the California Medical Association in 1953 (California Medicine, 78, 320-326) and later republished by the California State Department of Health Cancer Advisory Board in 1963 et. seq., which

reported in a study of 44 terminal cancer patients that "all of the physicians whose patients were reviewed spoke of increase in the sense of well being and appetite, gain in weight, and decrease in pain (cf. Exhibit A, bottom of p. 11 et seq.). Although the Commission regarded all of these criteria of action as being only subjective (an aspect not essentially material to definition of a vitamin), nevertheless all of these criteria are in principle objective also, as "perceptbile to persons other than the patient" (dictionary definition of (objective"). The Commission also acknowledged a probable effect on nitrogen metabolism. (5)

Since 1953, and to some extent before, scores of publications throughout the world have reported thousands of patients who appear, from observing physicians' reports, to have benefitted objectively as well as subjectively from administration of laetrile. It is idle to declare that such observations are without value, medically or scientifically, even if they do not represent ideal methods of ascertaining probable cause and effect relationship, which is, indeed, seldom if ever attained in the field of human cancer, any and all statements to the contrary notwithstanding. In any event, widely varying opinions on this aspect prevail in the field of medicine, to such an extent that no one opinion can as yet be said to be definitive and universally accepted, and probably never will be. is based

by Dr. John Richardson, M.D. on his experiences with some 5000 cancer patients receiving laetrile along with related treatments, and a similar report by Dr. Ernesto Contreras is scheduled based on about the same number of patients. During the past year the Governments of Australia and Israel have set up clinical testing laetrile on human cancer patients, based upon inspection visits by respective government medical appointees to study the results and clinics of Drs. Richardson and Contreras and other medical centers in the United States and elsewhere, which Australian-Israel testing would not have been set up without solid basis, results of which must be awaited.

Respectfully submitted,

Dean Burk

Dean Burk,
President, Dean Burk Foundation, Inc.
National Cancer Institute, 1939-1974, Ret.

List of Exhibits

A. A Brief on Foods and Vitamins: Vitamin B-17, B-15, and B-13, By Dean Burk (23 pp.).

B. FDA GRAS List, FDA Code Regulations, 1976, Title 21 CFR 121.101(a)(2), pertaining page

C. Letter to Attorney Gregory Stout, from Dean Burk, February 16, 1977 detailing evidence for the lack of prussic acid in laetrile. (1 p.).

D. Qualifications of Dr. Kanematsu Sugiura (1 p.), Letter of Dr. Sugiura to Dean Burk, April 13, 1975 (6 p.)

E. Studies on and analysis of vitamin effect of laetrile in increasing life span of mouse with Lewis lung cancers, data of Southern Research Institute-NCI (54 pp.).

F. McNaughton Foundation data on Anti-tumor Effects of Amygdalin in Walker 256 Carcinoma (Second Series) carried out by the Scind Research and Development Co., Inc., 1968. (1 p.).

(Exhibit A)

A Brief on Foods, Vitamins, and Vitamin B-17 (Amygdalin, Nitriloside, Laetrile),

by Dean Burk

The Dean Burk Foundation, Inc.
4719 — 44th Street, Washington, D.C. 20016

SUMMARY

Based on Federal (Congressional) statutes, amygdalin (nitriloside, laetrile, vitamin B-17) is a *food* (or food component), *not* a drug ("new" or "old"), and is thus subject to agency regulations of foods with respect to conditions of commerce, advertising, labeling, sanitary production, health safety, etc.

Scientifically, and as a food consumed for millions of years, amygdalin is a *vitamin* for certain animals and humans that is useful or essential in their normal metabolic or physiologic functioning and that must be supplied exogenously in the diet in relatively small, essentially catalytic, noncalorific amounts.

Regulatorily, but without commitment as to already widely available scientific knowledge as to its vitaminic nature, nontoxic amygdalin could be treated, like bioflavonoids, para-aminobenzoic acid, inositol, as "marketable as individual products or mixtures thereof, provided that the possibility of nutritional, dietary or therapeutic value is not stated or implied."

The F.D.A. has, as of May 28, 1975, eliminated its earlier proposal that high potency vitamin/mineral products are drugs, but continue to be *foods*, and continue to be regulated as such. (Federal Register, Vol. 40, p. 23246).

FOODS

DEFINITIONS

According to the Federal Food, Drug, and Cosmetic Act (as amended August 1972), Title 21 USC, Chapter II (Definitions), Sec. 201 (321)(f),

> "The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for *components* of any such article" (emphasis added).

Similarly, the State of California Sherman Food, Drug, and Cosmetic Law, Chapter 1573, Division 21, Article 1, has essentially the same definition:

> "26012. "Food" means any of the following: (a) Any article used or intended for use for food, drink, confection, condiment, or chewing gum by man or other animal. (b) Any article which is used or intended for use as a *component* of any article designated in subdivision (a)" (emphasis added).

In short, a *component* of a food is, statutorily, a *food*. A food component may be either of natural occurrence in the food, or something added to a food, such as a "food additive" (Federal Sec. 201(g)(1)(s); California 26013)); a food additive is only one form of food component, and only one of many, such as a "food supplement for special (particular) dietary use" (21 USC 403(343)(j).

To call a food by any other name or designation (such as drug, cosmetic, doof, sun or moon[1]) makes it no less a food, and no less subject to being treated as such under the Food provisions of the Federal and State statutes just cited. This is clearly brought out in part in the Federal Sec. 201 (321)(g)(1)(C), which states that "The term "drug" means . . . (c) articles *(other than food)* intended to affect the structure or any function of the body of man or other animals," and similarly in the State of California "26010 (c) Any article *other than food,* which is used or intended to affect the structure of any function of the body of man or any other animal" (emphasis added.) Hence, where a food serves bodily structure or function (as is ordinarly the case), the designation of a food as a drug is interdicted and contraindicated by both the Federal and State statutes just cited; designation as food must take precedence over designation as drug. Vitamins are unquestionably components of foods, and hence are inseparable from definition as food, scientifically, logically, and statutorily (21 USC 343 (j).

FOOD vs. DRUG

Now, since a large number of foods that normally serve bodily structure or function have often been found to play, *pari passu,* an essential or unavoidable role in the diagnosis, cure, mitigation treat-

1. "Petruchio: How bright and goodly shines the Moone. Kate: The Moone, the Sunne; it is not Moonelight now. Pet.: I say it is the Moone that shines so bright. Kate: I know it is the Sunne that shines so bright. Pet.: It shall be the moone, or star, or what I list. Kate: And it be the moone, or sunne, or what you please. Pet.: I say it is the Moone. Kate: I know it is the Moone. Pet.: Nay then you lye; it is the blessed Sunne. Kate: Then God be blest, it is the blessed sun." From: The First Folio. Printed by Isaac Iaggard, and Ed. Blount, London, 1623, pp. 225-6, The Taming of the Shrew.

ment or prevention of a *disease*, it follows that the *"other than food"* exception and restriction appearing *supra* in the Federal 201 (321) (g) (1) (C) and in California 26010 (c) must likewise apply, if *incompatability, contradiction, and inconsistency* are to be avoided, to the respectively and immediately preceding subdivisions Federal 201 (g) (1) (B) and California 26010 (b), wherein the meaning of "drug" is further given as an

> "article which is used or intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animal."

In short, here again, whenever bodily structure or function is involved on the part of a food, designation as food must take precedence over designation as drug, so far as the meaning and scope of the word "article" in the two last-cited statute subdivisions is concerned. For, if *this were not true*, then any otherwise *bona fide* use of a food to serve bodily structure and function that further happened, inadvertently or otherwise, to be effective in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals, would nevertheless then be statutorily prevented and interdicted from being used as a food to serve bodily structure or function! At least not without being first approved of and sold as a drug, with all that that could entail,[2] even unto beefsteak.

Although the Federal (B) and California (b) subdivision definitions of "drug" cited in the foregoing paragraph do not explicitly contain the *"other than food"* exception found in the immediately following and respective (C) and (c) subdivisions, nevertheless the history of actions taken subsequent to the writing, voting, and signing into law of the (B) and (b) subdivisions shows extensive *implicit* use of the *"other than food"* exceptions in applying subsections (B) and (b). No better illustration of this widespread action is provided than by the extensive regulatory use of the concepts and practices of the Minimum Daily Requirement (MDR) and more recent Recommended Daily Allowance (RDA) with respect to vitamins and minerals being treated as foods, not drugs, beginning over 30 years ago, and confirmed by the recent August 15, 1974 decision of the U.S. Court of

2. E.g., Potentially, the burdensome provisions of Paragraph 502, 21 USC (355) for approval of "new drugs"; the many provisions of subchapter V of the FDC Act, including the more elaborate label requirements of paragraph 502 21 USC (352); the elaborate investigation now being conducted by the FDA into the composition, labeling, and sale of over-the-counter drugs, including "vitamin-mineral products (21 CFR (130.301) (b) (8), with the possible result that products could be sold only on prescription or other limiting conditions (*id.* (a) (5) (i); or result in various restrictions on sale in some states which automatically impose limitations on any product deemed a "drug" under federal law. (Cf. decisions of the U.S. Court of Appeals, 2nd Circuit, Aug. 15, 1974, p. 5250, now the law of the land following denial of certiorari by the U.S. Supreme Court, Feb. 24, 1975).

Appeals, 2nd Circuit (upheld by the U.S. Supreme Court by virtue of denial of certiorari) that no specified upper limits of level of vitamin application are yet to be set or ordered by the FDA, to whom the matter was remanded for further consideration, and so long as toxicity was not involved (as in vitamins A, D, K), (National Nutritional Foods Association and Solgar Company, Inc., et al. vs. F.D.A. etc Nos 1189-1203).

As for the FDA's earlier proposed regulation 125.1 (h) (38 FR 2142, 1973) that vitamin preparations containing more than 150% of the U.S. RDA were thereafter to be classed as drugs (no longer mere foods), the above Appellate Court said," We therefore hold that paragraph 125.1 (h) is invalid . . . will cease to have any independent restrictive force. . . . While we reach this holding as a question of insufficient evidence . . . an administrative interpretation *in such conflict with a legislative definition* might also be invalidated on the ground of exceeding the agency's statutory regulatory authority" (p. 5253) (emphasis added). As of March 8, 1975, FDA spokesmen announced that "The decision by the Second Circuit thus is now final and the FDA intends to comply fully with all of the Court's decisions. . . . In the future, FDA will no longer seek to regulate a vitamin or mineral as a drug simply because it exceeds in potency 150 percent of the U.S. RDA." ("The FDA's Vitamin Regulations," by S. H. McNamara, Associate Chief Counsel, FDA). The new Proxmire-Schweiker bill (S548, 94th Congress, First Session, — Congressional Record, Vol. 121, No. 13, Feb. 1973) is aimed at making FDA relinquishment of its regulation 125.1 (h) insured by permanent legislation.

So, although most vitamins, many minerals, and some other foods (e.g., essential amino acids) have often, in serving bodily structure and function, inadvertently or unavoidably been involved "in the diagnosis, cure, mitigation, treatment or prevention of *disease* in man or animals, "nevertheless the (B) and (b) subdivisions have not ordinarily been invoked to treat such food articles as "drugs." An added reason for this is that Congress has never explicitly stated that vitamins and minerals are drugs, but, on the contrary, has *specifically* classed them as foods by placing them explicitly in the Food Section 403 (343) (j), in addition to the aforementioned exemption in Sec. 201 (321) (g) (1) (C).

Furthermore, and without pursuing the matter here in detail, the *"other than food"* exception of this subdivision (C) similarly applies to the (A) and (D) as well as (B) subdivisions. The (A) subdivision refers to "articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia, or official National

Formulary, or any supplement to any of them." Obviously the word "articles" cannot here mean *"any and all* articles" since these pharmacopoeias *do* contain vitamins and minerals that are nevertheless regarded by Congress as foods in the two explicit statutory subdivisions just cited. The Ejusdem Generis rule has been repeatedly upheld by the U.S. Supreme Court, namely, that specific words in a statute dominate and take precedence over general words wherever there may be apparent contradiction: "However inclusive may be the general language of a statute, it will not be held to apply to a matter specifically dealt with in another part of the same enactment" (353 US 222, 228-229, 1957).[3] The use of an article in some aspect of *disease* should thus not immediately and invariably conjure up the word "drug" rather than "food," and furthermore since both plain common sense and conventional medicine also widely recognizes distinctions between various types of disease, e.g., nutritional and infectious, where "food" and "drug" respectively are indeed involved, in the main.

CLASSES OF FOODS

The nutritional and functional aspects of foods may be classified into three broad — not necessarily mutually exclusive — groups that satisfy bodily requirements for structure and function: (1) calories (e.g., proteins, carbohydrates, fats), (2) minerals, and (3) (of major interest for this BRIEF) vitamins. Aspects of either essentiality or mere desirability may be involved in all three groups, i.e., the requirements may be absolute or relative, total or partial.

VITAMINS[4]

DEFINITIONS

Vitamins vary widely in chemical composition, biological function, and nomenclature, but the following generalizations commonly hold:

3. For further detailed discussion see BRIEF of John Joseph Matonis submitted to U.S. Court of Appeals, Second Circuit, Nos. 73-2826, 2834, March 15, 1974, pp. 8-16 inclusive. Neither the Matonis BRIEF nor the final appellate court decision made explicit use of the *"other than food"* Argument as advanced in the 3rd and 4th paragraph of this present BRIEF, the binding force and wide scope of which appears to have escaped general appreciation, even in the FDA Regulations proposed August 2, 1974 (FR 38, No. 148, Pt. II).

4. A vitamer is any one of a number of compounds that may possess a given vitamin biological activity; thus, there are e.g., niacin vitamers, thiamine vitamers, biotin vitamers, pryridoxin vitamers, Amygdalin vitamers (B-17), pangamate vitamers (B-15), orotate vitamers (B-13), A vitamers, D vitamers, K vitamers, etc. (Dorland's Illustrated Medical Dictionary, 20th Edition, 1944). Vitamers may also be regarded as "replacment vitamins", and may involve more than one chemical component as in some pangamte preparations. Just prior to the development of the vitamer concept, R. J. Williams had proposed the word *isotel* (equi-purpose) to somewhat the same effect.

Vitamins are organic or organic-mineral compounds that are required in calorically small or insignificant amounts by any given living organism (animal, plant, or microorganism) for its normal metabolic and physiologic life function, *and* must be supplied *exogenously* in the given organism's diet or nutrition as derived from production by other living organisms or by chemical synthesis by man. Many vitamins function by providing active chemical groups for enzymic (catalytic) life reactions. The absence, partial or total, of vitamins gives rise to "deficiency" diseases, lesions, or symptoms, or, in the ultimate even death, all of which may be alleviated or prevented upon provision of the appropriate vitamins as foods exogenously supplied in the diet. Some vitamins are so ubiquitous that to demonstrate their functional need and existence it is often necessary to add antivitamins to the diet, e.g., avidin to show biotin need, or sulfonamides to show para-aminobenzoic acid need, etc., a situation often widely overlooked or neglected in e.g. FDA vitamin regulations and concepts.

The history of virtually every vitamin has involved varying degrees of recognition and demonstration of biological function, chemical composition, and nomenclature, with *never* universal agreement or consensus on all aspects. True, considerable general agreement or consensus is often attained, but nevertheless some degree of uncertainty in one respect or another has always persisted, more so than in many other branches of science. For this reason, it becomes almost impossible, *on the negative side,* ever to declare scientifically that a given compound is *not* a vitamin for some organism(s) somewhere, and hence ever to declare scientifically that "said given compound is *not* a vitamin," at least not without resorting to fiat, decree, or plain ignorance. In short, "In science it is almost impossible to prove that there are no ghosts" (Otto Warburg, 1935).

On the positive side, however, it is much easier and sounder scientifically for a compound to be considered a vitamin, wherever and whenever the given compound meets the foregoing definition generalizations, including the requirements that it be essential or useful in the normal metabolism or physiologic functioning of a given organism to whose diet or nutrition it must be supplied exogenously in relatively small, essentially catalytic, noncalorific amounts. In higher animals, exogenous supply may be either oral, parenteral, or via synthesis by intestinal microorganisms. In short, positive declaration is much more accurately feasible than is negative declaration, so far as vitamins are concerned.

Also, it should be noted that, once such facts are set forth, "general consensus" need play little role in adding to or subtracting from their truth, since consensus is frequently poorly defined or definable, is often unduly delayed, plainly wrong or incorrectly judged, as the long history of science and medicine has shown time and again, particularly with respect to new observations and discoveries with which the "consensus" mind is not yet prepared or able to cope. And, in the area of legislation and regulation, although it may be convenient to rely upon and impose the dubious force of general consensus, via fiat, decree, or arbitrary dogmatism, low priority should be given to it with respect to scientific truth or proof. Certainly, the rule of one-man-one-vote seldom has applicability for scientific matters, where opinions and conclusions can vary enormously, as can likewise individual capacities of scientists. History has shown time and again that one Newton, one Pasteur, or one Pauling has merited equation with not one but up to hundreds, even thousands, of general consensus voters let alone regulatory voters. From this point of view, the actual quality of consensus remains unevaluable until its make-up is well specified, which is seldom to be met with in legislation and regulations that use e.g. the standard phrase, "generally recognized among experts qualified by scientific training and experience . . .", that can be twisted to mean almost anything, for purposes of fiat. It is essential in both scientific and fair regulatory matters to make room and ample allowance for widely differing opinions and conclusions. All of this is particularly true in the field of vitamins, where concepts have always been changing from the very beginning of the vitamin concept, and leave no room for dogmatic assertions, especially on the negative side. An interesting challenge is presented in the case of vitamin B-17 now to be considered.

VITAMIN B-17 (NITRILOSIDE, AMYGDALIN, LAETRILE) AS FOOD

After years of study by Dr. Ernst Krebs, Jr., vitamin B-17 was named by him to include the some dozen compounds collectively known as nitrilosides or cyanophoric glycosides that are produced in over 1000 species of plants and that are of dietary significance in animal nutrition, metabolism, and function (Jour. Applied Nutrition, pp. 74-88, 1970). The most commonly available chemical form of such vitameric nitrilosides is *amygdalin*, a compound first isolated in 1830 as a white, crystalline, highly water-soluble, slightly bittersweet,

nontoxic substance later found to occur in the seeds of many fruits and in parts of other edible plants. It has been eaten by man since his primitive days up until now, and is a notable constituent of the diets of wild carnivores and herbivores, as well as of domesticated sheep and cattle, etc. In accordance with the Federal statutes 21 USC 201 (321) (f) and (g) (1) (C), amygdalin is thus a *food*, not a drug (c.f. paragraphs 1, 2, 3, of this BRIEF), any and all statements to the contrary notwithstanding.

Chemically, amygdalin is D-mandelonitrile-beta-D-glucosido-6-beta-glucoside (Merck Index), and contains no free cyanide, benzaldehyde or glucose in significant quantity, although it may be hydrolyzed by the enzyme glucosidase into these three, otherwise tightly bound together, constituents in the molecular ratio of 1:1:2—much as meats, milk, cheese, eggs and other proteins may similarly produce cyanide when decomposed by suitable enzymes or catalysts. Any statements to the effect that amygdalin contains free cyanide or hydrocyanic acid in significant quantity, such as frequently and widely disseminated in the press by the FDA, are false, and, as investigation has shown, willfully so, in an effort to mislead not only the vast general public but alas also its own staff, and to create a highly misinformed "general consensus."

NONTOXICITY

Amygdalin has been known and widely recognized for over one hundred years as nontoxic for man (See Appendix A), even at dosages many times greater than (to use the language of the Food, Drug, and Cosmetic Act. Sec. 402 (342) (a) (1)) that which "does not *ordinarily* render it injurious to health" (emphasis added). Conventional dosages taken by thousands of Americans range from one to ten grams of amygdalin daily, without toxicity or pharmacologic injury, and from the days of primitive man onward such dosages have often been consumed in his diet, varying with the population involved and food sources available.

As stated by R. D. Montgomery with reference to possible decomposition of amygdalin in the mouth and stomach, "With regard to the intact glucoside amygdalin, in the absence of effective glucosidase, it has been shown that neither saliva or dilute hydrochloric acid at body temperature can release significant amounts of HCN ("Cyanogens" in "Toxic Constitutents of Plant Foodstuffs", ed. by I. E. Liener, Academic Press, N.Y. 1969). The enzyme glucosidase is rapidly destroyed by stomach acidity.

Few substances have been so widely investigated regarding nontoxicity and chemical definition as has amygdalin, by pharmacologists and chemists in many countries of the world, for over 125 years. In varying degrees ingested amygdalin is partly broken down in the lower intestines to sugar and free cyanide, but, what is important, at a rate so slow that the body can detoxify this cyanide with total bodily safety, usually forming the compound thiocyanate, a normal constituent of blood. Another reported path for elimination of amygdalin is conversion in the liver to the glucuronide form (glucuronic acid replacing the diglucoside gentiobiose in amygdalin), such as takes place with many metabolites normally, via formation of glucuronides.

AMYGDALIN AS VITAMIN

Amygdalin would appear to meet all the earlier assigned attributes for definition as a vitamin for certain animals and man: after production by plants, it is available exogenously in relatively small, essentially catalytic, noncalorific amounts that are essential or beneficial in the normal metabolism and physiologic functioning to overcome deficiency lesions and symptoms of nutritional disease. Reports of such actions by pure or impure preparations of amygdalin have appeared in many standard pharmacopoeias since the 1830's (e.g., U.S. Dispensatory, 1834), following the discovery and crystallization of amygdalin in 1830 by Robiquet and Boutron (Journ. de Chim., VI, pp. 380, 750). Many of the actions then listed[5] continue to be reported in pharmacopoeias and handbooks to this day with additions of still other actions. The first known accounts of anticancer activity appeared in 1845-6 (J. D. Inosemtzoff, M.D., in Gazette Medicale de Paris, No. 37, Sept. 13, 1845, pp. 577-582; Journ. Chirurgie/Augenheilkunde, 35, 6-28, 1846, who treated his patients with oral amygdalin at dosages scarcely smaller than those in use today).

AMYGDALIN EFFICACY IN MAN

Of more than historical interest are the results reported by the Cancer Commission of the California Medical Association in 1953 (California Medicine, *78*, 320-326) and adopted by the California State Department of Health Cancer Advisory Board in 1963 *et seq*. In a study of 44 terminal cancer patients, the Commission reported that "all of the physicians whose patients were reviewed spoke of increase in the sense of well being and appetite, gain in weight, and decrease in pain." The Commission regarded all these criteria of action as

5. In asthma, acne, impetigo, prurigo senilis, sedatives, laxatives, antihelmintics, edema, cough medicines, and others.

being only subjective, but of course they were objective also, in accordance with widespread dictionary definition of "objective" as "perceptible to persons other than the patient," and each action could have been measured objectively, if desired, in terms of scale weight, food consumption, lessened demand for pain reliever, etc. However, the semantic question here of subjective vs. objective is not material to the actual evidence reported by the Commission as to *fact* of action.

The Commission (and later Cancer Advisory Council) went even further and "indicated that Laetrile (shown by them to be the naturally occurring amygdalin) may exert a temporary metabolic effect, probably on nitrogen metabolism," in addition to the four already cited actions. The Commission did not regard the various actions of amygdalin observed as affecting the cancers *directly*, but rather as "being due to the *general effect on the host*" (the patient). This interpretation by the Commission is possibly largely correct, since none of the patients they studied had received a *total* dosage of amygdalin, given over periods of weeks or months, that amounted to as much as what is now commonly employed in the *daily* treatment of human cancer patients with amygdalin, namely 3 grams or more, which is of the order of megavitamin dosages of vitamin C and niacin.

Although amygdalin (laetrile, nitriloside, vitamin B-17) is now being widely referred to as an anticancer vitamin, it must be realized that the term is to be employed without necessary commitment as to mechanism of action, e.g. whether it acts "directly" on the cancer cell as many have thought and written about extensively, or whether it also acts "indirectly" via relatively nonspecific nutritional, metabolic, or even immunological, improvements in general body status that may extend over to the alleviation of cancer as well, along lines already considered in paragraphs 3 and 4 of this BRIEF. An excellent example of another nontoxic anticancer agent that acts indirectly upon cancer cells so far as is known, is the mineral hydrazine sulfate which has been shown to act upon the liver by preventing or inhibiting it from doing something undesirable that cancers make it do by producing large quantities of lactic acid from glucose sugar, which the liver is then forced to convert by a biochemical, energetically extremely expensive, enzymatic process known as gluconeogenesis, back to glucose sugar that the cancer needs indispensably for its continued growth (Medical World News, Oct. 19, 1973, p. 25, on work of Dr. Joseph Gold).

More and more members of the legal and medical professions are coming to favor the indirect view, which is more in line with the

indirect view set forth *supra* by the California Cancer Commission and adopted by the Cancer Advisory Board of the California State Board of Public Health. Some half a dozen legal cases in California have been resolved in the last year or two as a result of reliance upon the less committal indirect view, and medical physicians throughout the country are coming to require written prior patient consent with respect to treatment with amygdalin on a nutritional/metabolic basis rather than on a cancer *per se* basis that is necessarily highly restrictive and committal; and, indeed, more and more purchasers of amygdalin (and similar products) are being required by distributors to first sign statements such as "the materials herewith ordered by me are intended for food use only and not intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease."

In the foregoing connection, it is to be noted that the State of California Health and Safety Code, Sec. 1705 limits the definition of the term "cancer" to "all malignant neoplasms regardless of tissue of origin, including malignant lymphoma, Hodgkins disease, and leukemia," i.e. to malignant tissues and cells themselves, and does not purport to cover other metabolic and nutritional aspects of cancer taking place throughout the rest of the body, such as increased gluconeogenesis in the liver and kidney, increased lactic acid accumulation, increased HCGH and/or other hormones, decreased liver catalase, reduced blood hemoglobin and red cells, and dozens of other systemic effects that can be produced in the body by cancers. The statutory restriction involved here resembles the legal restriction developed in the Merchant of Venice between a pound of flesh on the one hand and drops to quarts of blood on the other. In short, the statutory restriction of definition in Sec. 1705 fails to recognize the full scientific and medical nature of cancer by a wide mark, as is so often the case in other statutory and regulatory definition and considerations of medicine and science.

The Superior Court of California, County of San Diego, has very recently confirmed (1-2-75) in its decision in case No. CR-32978 that, given the definition of "cancer" in Sec. 1705, then Sec. 1701.1, "does not prohibit the prescription or use of nutrients, unapproved drugs or medicines for cancer patients *for purposes other than* diagnosis, treatment, alleviation or cure of "cancer" per se (the tumor)," and that "Cancer patients have equal access to vitamins and nutritional substances and are not deprived of any substance available to the general public . . .," "A doctor who wishes to prescribe Laetrile or any other vitamin or nutrient to his patients who happens to be a

cancer victim, may do so as long as his intention is to treat the patient's general health and not the cancerous growth per se," and "It is easy for the doctor to articulate to his patient the purpose for his prescription of a nutrient so that there will be no misunderstanding on the part of either doctor or patient." The effective force of the two "per se" qualifications in the foregoing quotations cannot be overestimated, nor, likewise, the Court's directions as to modes of establishing purpose and *intent* on the part of the doctor and patient. The Court ruled that Sec. 1707.1 of the California Health and Safety Code was indeed constitutional and furthermore "must be interpreted in the light of the legislation definition of cancer as set forth in Section 1705 of the same Code, and that *intent* "becomes all important and must be read into the statute."

Nevertheless, Sec. 1701.1 has since been declared unconstitutional on Feb. 3, 1975 by Judge Cianchetti of the Citrus Municipal Court (West Covina), who held that the statute is "overbroad" because it prohibits the "alleviation or cure of cancer" unless the doctor uses a substance that has first been approved for that purpose by the appropriate Federal or State health agency. The constitutional questions were extensively briefed and argued by attorney George W. Kell on behalf of his cilents Dr. James R. Privitera, M.D. and Carrol Leslie in Citrus Municipal Court Nos. 111,824, 111,825, and 113,066. All charges were dismissed by the Court. The matter is now on appeal to the Appellate Department of the Los Angeles Superior Court.

In any event, and partly because of the aforeoutlined statutory restriction (not limited to California), no less than ~~twenty~~ fifty thousand Americans are now taking laetrile, as well as still others throughout the world, essentially without abrogation of existing law, and as further supportively confirmed in various court decisions. These many thousands of Americans also take laetrile despite the sophistical statement attributed to FDA Commissioner Alexander M. Schmidt (cf. M.L. Culbert, "Vitamin B 17" Arlington House, New Rochelle, N.Y., 1974), "the fact that 10 to 15 thousand people believe they've taken something that does them some good does not prove anything. We require some evidence, however slim, some rationale. We have traced down every lead we could find to try to determine some valid sign of efficacy (from Laetrile) and have not found any." Thousands of Americans are well aware that in this last sentence the Commissioner was intentionally not telling the truth, or that at best the FDA is a very poor and incompetent "tracer" in this connection, as many of their related actions and writings have amply demonstrated, in a manner

already fully detailed elsewhere, and in a manner already amply called to the Commissioner's attention. Chapter 12 of Culbert's book just referred to contains a detailed analysis of the extensive sophistry employed by the FDA, NCI, AMA, ACS and State Departments of Health in connection with laetrile (amygdalin), and its nevertheless rapidly increasing utilization by man including a modicum of physicians, as well as in animal studies as will now be indicated.

AMYGDALIN EFFICACY IN ANIMAL SYSTEMS

Anticancer vitamin activity by amygdalin (laetrile) has been observed in a wide variety of animal cancers, with high statistical significance, in more than five independent research institutions in three widely separated countries of the world, including e.g.:

(1) Sloan-Kettering Cancer Center (New York), with CD_2F_1 mice bearing spontaneous mammary carcinomas: inhibition of formation of lung metastases, inhibition of growth of primary tumors, and greater health and appearance of animal hosts, upon treatment with 1-2 gm crystalline amygdalin/kg body weight/day (Report of K. Sugiura, June 13, 1973).

(2) Southern Research Institute (Birmingham, Alabama) for the National Cancer Institute, in a majority of 280 BDF_1 mice bearing Lewis lung cancers, treated with up to 400 mg crystalline amygdalin per kg body weight, with respect to increased life span (Report, December 3, 1974).

(3) Scind Laboratories, University of San Francisco, 400 rats bearing Walker 256 carcinoma (200 treated with amygdalin, 200 controls), with 80% increase in life span at optimum dosage (500 mg amygdalin/kg body weight) (October 10, 1968). Cf. FDA-IND application No. 6734. pp. 247-8, 00080-00093. NCI Director Carl Baker wrote Congressman Edwin W. Edwards on Jan. 26, 1971: "The data provided by The McNaughton Foundation *certainly* indicates some activity in animal tumor systems" ((emphasis added).

(4) Pasteur Institute (Paris), with human cancer strain maintained in mice treated at optimal dosage of 500 mg Amygdalin Marsan/kg body weight/day; increased life span and delayed tumor growth up to 100% (Dec. 6, 1971 report by M. Metianu).

(5) Institut von Ardenne (Dresden, Germany), H strain mice bearing Ehrlich ascites carcinoma treated with bitter almond amygdalin *ad libitum* in addition to the regular chow diet: increased life span and decreased rate of cancer growth, treatment beginning 15 days before cancer inoculation (Arch. Geschwulstforsch. 42, 135-7, 1973).

As in animal and human vitamin experimentation in general, the results reported varied in quantitative response and reproducibility, but are similar in form to the anti-deficiency use of vitamin C in scurvy, niacin in pellegra, vitamin B-12 in pernicious anemia, vitamin B-1 in polyneuritis, vitamin B-6 in dermatoses and neurological diseases, among several dozen conveniently listed in the Merck Index as useful or essential vitaminic food factors accessory to proteins, carbohydrates, fats and minerals required for either well-being or survival.

Regarding the experimental evidence of amygdalin anticancer activity indicated *supra* the following untruthful and therefore irresponsible statements have been made among many scores that could be cited:

(1) FDA Commissioner Schmidt, as cited on and about March 25, 1974 in the newspaper press throughout the country: "Every study to date has not found any evidence of efficacy" with laetrile, and "If there was one shred of evidence from animal or cell systems I would issue an IND" (Investigational New Drug status that approves clinical testing on humans, a form of approval, incidentally, that requires no prior human data). Since amygdalin (laetrile) is, as already clearly indicated, a food and not a drug ("new" or "old"), an IND would not be in order, but merely treatment and handling as a food on the part of FDA.

(2) Dr. Frank Rauscher, Director, National Cancer Institute, "I would certainly not turn off laetrile if it had an iota of activity that we could pinpoint. Unfortunately, there's no evidence at all" (March 31, 1974, Mike Wallace "60 Minutes" CBS National Television Show.)

Dr. Jesse L. Steinfeld, former Surgeon General of the USPHS, laetrile "has repeatedly been tested in animal tumor systems at the National Cancer Institute. In no instance did laetrile have activity in any animal tumor system" (Interoffice Memorandum sent to Department Heads of the Mayo Clinic, January 1974).

(3) Dr. Charles Moertal of the Mayo Clinic, "Extensive animal tumor studies conducted independently at two outstanding cancer research centers — New York Sloan-Kettering and the Southern Research Institute — have shown this drug *(sic!)* to be totally without evidence of anticancer activity" (letter published in the Rochester Minnesota Post Bulletin, Jan. 21, 1974).

AMYGDALIN AS A NONESSENTIAL FOOD INGREDIENT (NEFI)

Although the evidence that amygdalin is scientifically to be regarded as a food, a vitamin, and indeed vitamin B-17, is overwhelm-

ing, nevertheless, like the evidence that the earth is round not flat, concurrence will probably never be universal as distinguished from general, human nature, responsible or irresponsible, being what it is.

Regulatory agencies and even courts of law may prefer, for convenience, and for avoidance of commitment to or recognition of scientific knowledge now widely available, to treat amygdalin in line with Sec. 125.2 (b) (5)(FR 40, 23247, May 28, 1975), as it does now for bioflavonoids, para-aminobenzoic acid, inositol and similar substances *regulatorily regarded* as "having nutritional properties but may be *sold as ordinary foods by themselves or in combination with one another.*" (e.g., Vitamin B-17, B-15, B-13). As earlier reported in the March 8, 1975 lecture by FDA Counsel S. H. McNamara (cited in paragraph 6 of this BRIEF), "Anyone who wishes to consume ingredients such as bioflavanoids, para-aminobenzoic acid *and the like* is free to do so. Manufacturers may freely sell tablets of such ingredients. ~~However, under the regulations, they may not add these worthless (sic!) ingredients to dietary supplements of vitamin and/or minerals" (emphasis added). Petruchio has spoken! So be the Moone the Sunne~~! A nutritionist in the FDA Nutrition and Consumer Science Division, Bureau of Foods, has stated that if amygdalin is indeed nontoxic, "it would be free to be used just like bioflavonoids," and legal counsel outside the FDA has advised his clients to so distribute and market amygdalin, as a nonessential food ingredient (NEFI), which they have already proceeded to do in food stores and elsewhere. None of this, of course, affects the scientific status of amygdalin (laetrile, nitriloside, vitamin B-17) as truly a vitamin, for some animals and humans, as described earlier in this BRIEF.

APPENDIX

SUMMARY STATEMENTS ON NONTOXICITY OF AMYGDALIN (VITAMIN B 17, LAETRILE) IN ANIMALS AND MAN

(1) With 45 years of study and research on the cancer problem, the last 35 years in the U.S. National Cancer Institute (National Institutes of Health), Bethesda, Md., and files of virtually all published literature on the use of amygdalin with reference to cancer, and with innumerable files of unpublished documents and letters, I have found no statements of data on demonstrated, sustained, pharmacological harmfulness to human beings of amygdalin at any dosages recommended or employed by physicians in the United States and abroad, up to the high level of 200 milligrams per kilogram body weight per day (= 15 grams/75 kilogram man/day), administered either orally or parenterally; and, more specifically, no such statements by official opponents of the use by humans of amygdalin, including, in their major publications:

(a) Report by the Cancer Commission of the California Medical Association on "Treatment of Cancer with "laetrile" " (California Medicine, Vol. 78, 320-326, 1953, the basic document most commonly referred to).

(b) Report by the Cancer Advisory Council, State of California Department of Health, on "Treatment of Cancer with Beta-Cyanogenetic Glucosides ("Laetriles")", 1963, 152 pp, containing reports on 130 cases of human cancer patients treated with amygdalin.

(c) Report by the American Cancer Society, Inc., 1971, 7 pages, and earlier versions thereof dating back to 1961, including its currently and widely distributed booklet, "Unproven Methods of Cancer Treatment."

(d) Reports by the State of California Department of Public Health to the California Legislature, 1972 and various years earlier, on "Regulation and Control of Diagnosis and Treatment of Cancer Pursuant to Section 1719, Health and Safety Code.

(e) Report on "The Cancer Law, 1959-1964" issued to the Governor of California on the "Activities and Actions of the State of California Department of Public Health and Cancer Advisory Council, January, 1965, pp. 32-41.

96-492 O - 77 - 26

(f) Numerous statements and letters issued by the U.S. National Cancer Institute, U.S. Food and Drug Administration, and American Medical Society, including the FDA Ad Hoc Committee of Oncology Consultants report of August 1971, as published in the "National Cancer Attack Act of 1971 (Hearings before the Subcommittee on Public Health and Environment, Committee on Interstate and Foreign Commerce, House of Representatives, 92nd Congress, 1st session, 1971 (pp. 726-731).

(2) Within my personal experience and observations, various normal and cancerous human adults (lay and physicians) have taken up to 200-300 milligrams amygdalin/kilogram body weight/day, orally or intravenously, for varying periods of days-weeks without evidence of notable toxicity. Common oral dosages of 10-20 milligrams amygdalin/kilogram body weight/day (far, far below any so-called MTD-Maximum Tolerated Dose) have been taken routinely for years by many human adults without evidence of notable toxicity. The first (to my knowledge) recorded and published cancer patients to be treated with amygdalin were reported by Dr. T. Inosemtzoff (Gazette Medicale de Paris, Vol. 13. pp. 577-582, 1845; Journal Chirugie and Augenheilkunde, Vol. 35, pp. 6-28, 1846), some 130 years ago. A young man of 20 received 46,000 milligrams amygdalin orally over a period of several months and was apparently living three years later at the time of the report. A woman of 48, with extensive metastases from a primary right ovarian tumor, received varying amounts of amygdalin over a period of years and was surviving 11 years later at the time of the last published report. No sustained pharmacologic harm was reported with these patients.

(3) Obviously, all substances, without exception, can be toxic and even lethal at some sufficiently high or inappropriate dosage; conversely, they can be employed at dosages neither toxic nor lethal that can be predetermined. A few spoonfuls of plain water taken into human lungs through the windpipe can be lethal within minutes; a thimbleful of plain air taken into the human blood stream can be lethal within minutes under suitable conditions; as may similarly a lighted match applied by a person to the entrance of an automobile gas tank filled with gasoline. The problem is always to ascertain a dosage treatment that is well below a dosage yielding sustained pharmacologic harm (toxicity). This was first done with amygdalin and humans as outlined above in the early 1830-40's. With dogs, which commonly behave quite similarly to humans, the first pharmacologic experiments were reported by F. Woehler and Frerichs (Ann. der Chemie and Pharmacologie, Vol. 65, pp. 335-348, 1848, who showed that a totally nontoxic single dosage would lie somewhat below

500-1000 milligrams amygdalin per kilo of body weight, a value confirmed many times since then. In the past 125 years, large numbers of such determinations have been made on man, dog, rabbit, rats, mice, etc., and reported in article reviews and reports, indicating predetermined dosages that yielded no sustained pharmacologic harm (toxicity), with quite recent such reports described in the McNaughton Foundation FDA-IND application 6734 of April 6, 1970 et seq. comprising some 1000 pages of submitted material (cf. particularly pp. 46-226, 00001-00007, 00114-00122 — tests on acute, subacute, and chronic toxicity studies in mice, rats, guinea pigs, rabbits and dogs treated intraperitoneally, intramuscularly, or orally with amygdalin over a wide range of dosages, all indicating virtual nontoxicity (LD 50 of the order of grams/kilogram body weight). The dosages of amygdalin that are nontoxic are far higher, in terms of milligrams per kilo of body weight, than virtually all anti- cancer agents now approved by the FDA for usage on an IND or NDA basis by doctors and hospitals throughout the United States. Thousands of humans have taken amygdalin dosages of 1000-3000 milligrams and more daily without any notable evidence of pharmacologic harm, during the past 10 years and more, by both oral and parenteral routes.

(4) Prof. D. M. Greenberg (Prof. Emeritus of Biochemistry, University of California at Berkeley-San Francisco) and Consultant to the Cancer Advisory Council of the California Department of Public Health, wrote on October 13, 1969 to Mr. Larry Rucker, "There is no question that pure amygdalin (Laetrile) is a nontoxic (compound)."

(5) Dr. Carl Baker, then-Director of the National Cancer Institute, wrote on July 9, 1970 to Mr. A. R. L. McNaughton, President of The McNaughton Foundation of California, "You will note that attachment 3 presents the results of NCI-CCNSC) experiments in which 400, 200, and 100 mg/kg of amygdalin were given alone to mice and found nontoxic." Higher dosages were not tested.

(6) Dr. Bryant Jones, Deputy Director of the Division of Oncology and Radio Pharmaceuticals FDA, stated on October 1, 1970 that so far as toxicity is concerned amygdalin is probably nontoxic (innocuous). He said "We do not have a great deal of concern over the toxicity of amygdalin," and indicated that the animal safety-toxicity data supplied by The McNaughton Foundation IND was satisctory (see Report, by Dr. Miles Robinson, M.D., on "Conference on FDA's Termination of IND 6734 for Laetrile-Amygdalin a report submitted to Senator William Proxmire at the latter's request; see pp. 17-21 thereof.

(7) For over 100 years standard pharmacology books have indicated that amygdalin is nontoxic, by standards regarded as nontoxic. A good review is given in the classic article by the American pharmacologist Reid Hunt in his article in Handbuch der experimentelle Pharmacologie, Edited by A. Heffter, Berlin, 1923, pp. 702-832. See also:

(b) J. Houben's Fortschr. der Heilstoffchem., 2. Abt., Leipzig, 1932

(c) Real-Enzyklopaedia der Gesamten Pharmazie, by J. Moeller and H. Thoms, Urban and Schwarzenberg, Berlin, 1904, pp. 570-573.

(d) Dispensatory of the United States of America, by J. P. Remington and H. C. Wood, J. B. Lippincott, Philadelphia and London, 20th Edition, pp. 137-139.

(e) Samples of the U.S. Dispensatory, 1834, 1838, 1843, 1845, 1847, 1851, 1858, 1918, e.g., 1854, p. 92 "Amygdalin appears not to be poisonous when taken pure into the stomach.

(f) (Recent reviews):
P. G. Reitnauer, "Mandelsaurenitril-Arzneimittel-Glycoside in Krebsforschung and Krebstherapie in Arzneimittel-Forschung, Vol. 22, 1347-1361, 1972 (Mandelonitriloglycosides in cancer research and cancer therapy).

H. M. Summa, "Amygdalin, ein physiologisch wirksames Therapeutikum bei malignen Geschehen," 33 pages MS, Jossa-Arznei, Steinau, Germany, April 1972 ("Amygdalin, a physiologically active therapeutic for malignant tumors.").

(g) From FDA IND 6734, Vol. V, October 31, 1970, p. 00114: "Otto Jacobsen in his "Die Glycoside" (V. Eduard Trewenck, Breslau, 1887, 174 pp.) wrote "Das Amygdalin ist nicht giftig ("Amygdalin is not toxic."). and provide references then over 20 years old in his bibliography of 99 papers on amygdalin.

F. R. Davidson, in his "Synopsis of Materia Medica, Toxicology and Pharmacology," 3rd Edition, C. V. Mosby, 1944, wrote: "The glucoside amygdalin when given by injection produces no harmful effect."

FROM MARQUIS WHO'S WHO IN AMERICA

Vol. 38, 1974-75

AND

MARQUIS WHO'S WHO IN THE WORLD

Vol. II (1974-75)

Burk, Dean, biochemist; b. Oakland, Calif., Mar. 21, 1904; s. Frederic and Caroline (Frear) B.; B.S. U. of Calif., 1923, Ph.D., 1927; fellow Nat. Research Council and Internat. Edn. Bd., 1927-29 at U. of London (Univ. Coll.), Kaiser Wilhelm Inst. for Biology, Harvard; married Mildred Chaundy, January 28, 1929; children — Diana (Mrs. Richard A. Barker), Wendy (Mrs. Charles Maiorana), Frederic Chaundy; Asso. Phys. Chemist Fixed Nitrogen Research Lab., Dept. Agr., Wash., 1929, chemist, 1937-39; sr. chemist Nat. Cancer Inst., Nat. Insts. Health, Bethesda, 1939-48, prin. chemist, 1948-51, head chemist 1951-58, chief chemist 1958-74; asso. prof. biochemist Cornell U. Med. Coll., 1939-41; research master grad. faculty George Washington U., since 1947. Guest research worker U.S.S.R. Acad. Scis. (Biochem Inst.), Moscow, 1935. Mem. bd of dirs. Science Resources Foundation; Recipient of Domagk prize for cancer research, 1965: decorated Knight comdr. Med. Order Bethlehem; Fellow A.A.A.S. (organizer, chmn. research confs. on cancer, 1942-45); Mem. Am. Chem. Soc. (Hillebrand Award, 1952), Am. Soc. Biol. Chemists, Am. Assn. Cancer Research, Am. Soc. Plant Physiologists, Soc. Exptl. Biology and Med., (Chmn. 1949-50, sec.-treas. 1948-49), Am. Inst. Biol. Scis., N.Y., Washington Acad. Sci., Soc. Gen. Physiology, L.I. Biol. Assn., Harvey Soc, Chem Soc. Washington, Max Planck Assn. Goettingen, Inst. for Cell Physiology, Berlin. Royal Society Medicine, London; National Trust, Gt. Britain; Dolmetsch Found. Haslemere (foreign); Gamma Alpha, Sigma Xi; Clubs, Cosmos Club Wash. and Commonwealth Club of California; Author: Cancer, 1945; Approaches to Tumor Chemotherapy, 1947; Cell Chemistry, 1953. asso. editor: Record Chem. Progress, 1943; Proceedings Soc. Exptl. Biol. and Med., 1948-53, Enzymologia since 1937. Contbr. 250 sci. articles, Home: 4719 - 44 St. N.W. Washington, D.C. 20016.

Appointments and Awards, 1973-1974

1. Foreign Scientific Member, Max Planck — Institute of Biochemistry, Munich, Germany.
2. Honorary President, German Society of Medical Tumortherapy, Heidelberg, Germany.
3. Editorial Board, Krebsgeschen, Heidelberg, Germany.
4. Editorial Board, Cancer Biochemistry and Biophysics, Brunswick, N.J.
5. Cancer Control Society Humanitarian Award, Los Angeles.
6. Wisdom Society Award of Honor, Los Angeles.
7. Knight of Mark Twain Society (Succession to Sir Alexander Fleming), Missouri.
8. Distinguished Service Award in Biochemistry, Dictionary of Interntaional Biography, England.
9. Humanitarian Award, International Association of Cancer Victims and Friends, Los Angeles.
10. Guest Scientist, U.S. Naval Medical Research Institute, Bethesda, Maryland, 1974-1976.

THE DEAN BURK FOUNDATION

The Dean Burk Foundation, Inc., with headquarters at 4719 - 44th Street N.W., Washington, D.C. 20016 (Tel. 202-363-6279) was incorporated in the District of Columbia on November 18, 1974 as a non-profit corporation and non-private (public) foundation, and will be devoted to research on health, nutrition, chronic and degenerative diseases including cancer, will publish reports on same, will assist other groups and individuals with common goals, and will provide related educational material. The Foundation is exempt from Federal income tax under section 501(c)(3) of the Internal Revenue Code. The present "Brief on Foods, Vitamins, Vitamin B-17 (Amygdalin, Nitrilosode, Laetrile), Vitamin B-15 (Pangamate), and Vitamin B-13 (Orotate)" is the Foundations first publication and another on "Fluoridation-Linked Human Cancer, and the Delaney Amendment," is in preparation.

 (Extract from FDA GRAS LIST.) (Exhibit B)

(2) ESSENTIAL OILS, OLEORESINS (SOLVENT-FREE), AND NATURAL EXTRACTIVES (INCLUDING DISTILLATES)

Common name	*Botanical name of plant source*
Alfalfa	Medicago sativa L.
Allspice	Pimenta officinalis Lindl.
Almond, bitter (free from prussic acid)	Prunus amygdalus Batsch, Prunus armeniaca L., or Prunus persica (L.) Batsch.
Ambrette (seed)	Hibiscus moschatus Moench.
Angelica root	Angelica archangelica L.
Angelica seed	Do.
Angelica stem	Do.
Angostura (cusparia bark)	Galipea officinalis Hancock.
Anise	Pimpinella anisum L.
Asafetida	Ferula assa-foetida L. and related spp. of Ferula.
Balm (lemon balm)	Melissa officinalis L.
Balsam of Peru	Myroxylon pereirae Klotzsch.
Basil	Ocimum basilicum L.
Bay leaves	Laurus nobilis L.
Bay (myrcia oil)	Pimenta racemosa (Mill.) J. W. Moore.
Bergamot (bergamot orange)	Citrus aurantium L. subsp. bergamia Wright et Arn.
Bitter almond (free from prussic acid)	Prunus amygdalus Batsch, Prunus armeniaca L., or Prunus persica (L.) Batsch.

Exhibit C

February 16, 1977.

DECLARATION

Mr. Gregory Stout, Attorney-at-Law,
235 Montgomery Street,
San Francisco, California 94104.

Dear Mr. Stout:

In response to your request for definitive information as to the presence or absence of prussic acid in the extractive amygdalin (laetrile) derived from the seeds (syn. nuts, kernels) of bitter almonds, apricots, or peaches, as listed in the HEW-FDA GRAS list (foods Generally Regarded as Safe) of 1976 and for years earlier, I may say that amygdalin contains no measured or ordinarily measurable quantity of prussic acid (syn. hydrogen cyanide, hydrocyanic acid, HCN), any more than does ordinary table salt or sugar.

The absence of prussic acid in amygdalin was first announced by the discoverers and namers of amygdalin (Robiquet and Boutron, Journ. Chim. Med. VI, pp. 380 and 750, 1830), and so further reported in the U.S. Dispensatory for 1834 (Part I, p. 80), and further confirmed by the great German chemists Liebig and Woehler (Ann. Chim. Phys., 64, 185-209, 1837 and Annalen, 22 (1), 1-24, 1837) in their classic articles, as further reported in the U.S. Dispensatory for 1843 (Part I, p. 80), and in many later Dispensatories and Pharmacopoeias since, and universally confirmed by thousands of experimental chemists since, all over the world.

Prussic acid was discovered by the Swedish chemist Scheele in 1782, and soon became detectable and measurable with great sensitivity and specificity by a variety of methods well known to chemists and physiologists. The properties of prussic acid are succinctly described in various editions of the Merck Index (a standard reference book of commonly encountered chemical and biochemical compounds), as of molecular weight 27.03, boiling point 26° Centigrade, as a colorless gas of characteristic odor, and very weakly acid, miscible with water and alcohol, all without any indication of the presence of prussic acid in amygdalin.

The cyanide radical (which is not prussic acid) is very tightly bound into the chemical structure of amygdalin, and the various literature sources listed above indicate that this radical can only be released as prussic acid from amygdalin by the catalytic action of the enzyme glucosidase found in many plant materials and some animal tissues, just as the cyanide radical can also be released from many proteins in meat, eggs, milk, gelatin products, cottonseed meal, peptones, etc., by the catalytic action of enzymes found in many bacteria in and out of the intestinal tracts of man and animals (Emerson, Cady, and Bailey, "On the Formation of Hydrocyanic Acid from Proteins," Journal of Biological Chemistry XV, 415-417, 1913; cf. also Clawson and Young, "Preliminary Report on the Production of Hydrocyanic Acid by Bacteria", loc. cit. pp. 419-422, 1913). Prussic acid may also be obtained slowly (hours, days) by decomposing amygdalin with hydrochloric acid at elevated temperature (Caldwell and Courtauld, J. Chem. Soc., 91, 666-671, 1907).

In my many years of research work in the U.S. National Cancer Institute, I have had occasion to attempt to detect prussic acid in numerous commercial preparations of amygdalin from all over the world, with negative results. I used various delicate, well known chemical tests (e.g. precipitation with silver nitrate, red color formation in the Robbie copper-phenolphthalin test, etc.) and also several very delicate biological tests with cancer and normal cells that would respond to traces of prussic acid. Amygdalin dissolved in water shows less than 1 part in 10 million of any acid, prussic or otherwise.

Thus, the GRAS list requirement that the extractive amygdalin be "free from prussic acid" is met.

Sincerely,

Dean Burk

Dean Burk (U.S. National Cancer Institute, 1939-1974, Ret.)

Exhibit D.

Some Qualifications of Dr. Kanematsu Sugiura

Dr. Sugiura was born in Nagoya, Japan on June 5, 1892, and currently resides at 18 Oak Street, Harrison, New York, and at the age of nearly 85 still works daily at the Walker Laboratory of the Sloan Kettering Institute for Cancer Research, 145 Boston Post Road, Rye, New York, having joined the sister institution, Memorial Hospital, New York City in 1917, with continued production and research at these institutions since that time.

Dr. Sugiura received his B.S. at Brooklyn Poly Institute in ~~1915~~ 1915, his M.A. at Columbia University in 1917, and his D.S. at Kyopo Imperial University in 1925. From 1947 he was an associate at Sloan Kettering Institute for Cancer Research after it was so organized after World War II, and a Member from 1950 to 1961; and Emeritus from 1962 to the present. At Sloan Kettering he was also an abstractor of Chemical Abstracts, Bilogical Bulletin. He was recipient of the A. Leonard Prize from the American Roentgen Society in 1925; Order of Sacred Treasure Third Class from Emporer Hirohito, Japan, in 1960; citizen Cup from the Japanese Government in 1969 Honor Certificate, Gold Plaque from the Japanese Medical Association in 1965; certificates for cultural services from Kanazawa University in 1966, and Niigata University in 1966. He has been a Member of the American of the American Association for Cancer Research for many decades; also the American Chemical Society, Society for Experimental Biology and Medicine, New York Academy of Sciences, Japanese Association for Cancer Research, and a Fellow of the American Association of Scientists. His studies include a long list on diet, hormones, enzymes, chemotherapy (alkylating agents, pyrimidine analogs, purine analogs, steroids, antibiotics, quinolones, all in normal and cancer-bearing animals of many species. In recent years he has conducted many experiments on the anti-cancer effectiveness of laetrile (amygdalin, B-17). On numerous public occasions he has expressed his personal viewpoint and findings that laetrile in his hands markedly reduces metastases in various strains of mice.

Dr. Sugiura has probably done more experiments on the treatment of cancer in animals and with a great variety of anticancer agents than any man alive, and still works six to seven days a week in his laboratory. He is a man of impeccable character and never-challenged integrity. I had the pleasure of working with him (in his laboratory across the street from Cornell University Medical College, where I was Associate Professor of Biochemistry) 1939-1941, and have kept up frequent contact with him and his work ever since. The attached personal letter received from him, and various signed reports of experiments he has performed with laetrile, report some of his ~~experimentation~~ experimentation with laetrile in animals since 1972.

April 13, 1975

Dr. Glen Burk
Room 107 Building 28, Stop 42
U.S. Naval Medical Research Institute
National Naval Medical Center
Bethesda, Maryland 20014

Dear Dr. Burk:

Thank you very much for the copy of your article "A Brief on Foods, Vitamins, and Vitamin B-17 (Amygdalin, Nitriloside, Laetrile)" which you so kindly sent to me last week. I read your article with great interest. I also thank you for quoting my work on page 12 on the effect of amygdalin on the growth of spontaneous mammary cancer in CD$_8$F$_1$ mice.

I made 6 separate experiments using ten to 30 animals for each experiment for controls which received 0.5 cc saline daily (April Sunday) intraperitoneally and 10 to 30 experimental animals for each experiment which received 2000 mg/kg/day of amygdalin daily intraperitoneally for a prolonged period as controls. The animals were kept on normal diet (Purina Laboratory Chow) and tap water.

At the start of experiments tumors were generally small — 1.0 to 1.5 cm. diameter. Some tumors were large — 2.0 to 2.5 cm. diameters.

When primary tumors became large (generally more than 4 weeks from the start of the experiments and having tumors more than 2.5 cm. diameter) animals are sacrificed for the presence or absence of metastases in the lungs and thoroughly or histologically examined. However, when animals died the lungs were examined grossly and histologically for metastases.

The results show that repeated intraperitoneal injections of 2000 mg/kg/day of amygdalin for 4 to 9 weeks had an inhibitory action on small tumors (less than 1.5 cm. diameter). However, it failed to destroy the spontaneous mammary cancer in mice completely.

Amygdalin had a strong inhibitory effect on the development of lung metastases. Controls — 20% had no lung metastases, had 80% lung metastases. Amygdalin — treated — 70% no lung metastases and 30% lung metastases.

The general health and appearance of amygdalin-treated animals with large tumors were better than those of control animals with large tumors.

On May 8, 1973, we started a new experiment to find out the effect of amygdalin on the development of spontaneous mammary cancer (a prevention experiment) and lung metastasis in female C D8 F1 mice. At the start of the experiment these mice were approximately 5 months old and had no spontaneous tumor. These mice had at least one pregnancy. We used 30 mice for control group and 30 mice for experimental group.

Results at the end of 22 months: Daily prolonged intraperitoneal injections of 1000 mg/kg/day of amygdalin did not prevent the development of mammary cancer in mice completely. However, it had a definite reduction in development of mammary tumor — 70% positive in controls against 40% in amygdalin-treated mice. It also shows amygdalin had a strong inhibitory effect on the development of lung metastases in mice — 75 per cent inhibition against 22 per cent in controls.

The general health and appearance of the amygdalin-treated animals were as good as that of the controls in spite of 22 months of injection. The body weights of control animals without tumor and that of amygdalin-treated animals without tumor all gained weight.

I made a similar study with Swiss albino mice —

on the effect of prolonged treatment with amygdalin on the growth of spontaneous mammary tumors (adenocarcinomas) in Swiss albino mice. The diagnoses of tumor tissues were made from a post-mortem microscopic examination of tumors at the end of the experimental period. The controls received 0.5 cc of saline daily intraperitoneally (except Sundays) and the experimental animals received 1000 to 3000 mg/kg/day of amygdalin daily intraperitoneally (except Sundays). We used approximately 50 tumor-bearing animals for controls and approximately 50 tumor-bearing animals for the experimental group. The largest tumor had a diameter of 2.5 cm., and the smallest tumor had a diameter of 0.6 cm.

The results show that repeated intraperitoneal injections of 1000 to 3000 mg/kg/day of amygdalin for 2 to 18 weeks failed to destroy the spontaneous breast cancers in Swiss-Webster albino mice. However, it seems to stop the continuous growth of small tumors (about 1.5 cm. diameter or less) more often than that of the control group.

It also shows that amygdalin had a strong inhibitory effect on the development of lung metastases in mice — 77 percent inhibition in amygdalin-treated animals against 7 percent inhibition in controls. These results obtained with mammary tumors occurring in Swiss albino mice are essentially the same as those

obtained with mammary tumors occurring in CD8F$_1$ mice — that repeated intraperitoneal injections of 2000 mg/kg/day of amygdalin inhibited the growth of small tumors and development of lung metastases in mice.

Amigdalin is not a cancer cure but a good palliative drug for cancer. Our goal is to find a cancer cure for humans.

Very sincerely yours,

Kanematsu Sugiura

(Kanematsu Sugiura)

Exhibit 7

ANTI-TUMOR EFFECTS

OF AMYGDALIN

IN WALKER 256 CARCINOMA

(Second Series)

Materials and Methods

Forty Sprague-Dawley Rats (55-65 gms.) were inoculated with 0.2 cc of a 1:6 Walker 256 Carcinoma homogenate. The homogenate was injected I.M. into the right hind leg of each experiment animal. The tumors were palpable five days following inoculation. After confirmation of tumor take, two experimental groups (n = 10 for each) were treated with amygdalin in doses of 500 mg/kg for each group. The drug was injected intraperitoneally. Two groups of 10 rats each received saline alone and served as controls.

Results:

Group No.	Dose (mg/kg)	Survival Time (days)	Mean (Days)
IX	500	28,29,30,30,30 30,31,32,60,60	42
X	Saline	19,19,20,22,22 24,24,26,26,26	23
XI	500	27,28,28,29,29 30,32,32,60,60	36
XII	Saline	19,19,20,22,22 24,25,25,26,26	23

* From SCIND Research and Development Co., Inc. data, 1968.

Note: All treated animals lived longer than any untreated Controls

Senator CHAFEE. The committee is recessed pending this vote.

[Whereupon, at 1:20 p.m., the subcommittee recessed, subject to the call of the Chair.]

○