JOINT HEARING

SENATE COMMITTEE ON HEALTH, EDUCATION, WELFARE AND STATE INSTITUTIONS -- ASSEMBLY COMMITTEE ON COMMERCE

The meeting was called to order at 3:15 p.m. on Wednesday, March 2, 1977, in the Senate Hearing Room, 131, with Assemblyman Harley Harmon in the Chair.

PRESENT:	ASSEMBLY	SENATE
	Mr. Harley Harmon	Chairman Jack Schofield
	Mr. Don Mello	Vice-Chairman Joe Neal
	Mr. Robert Barengo	Senator William Raggio
	Mr. Daniel Demers	Senator Richard Blakemore
	Mr. Don Moody	Senator Wilbur Faiss
	Mrs. Karen Hayes	Senator William Hernstadt
	Mr. Robert Price	
	Mr. Nash Sena	
	Mr. Robert Weise	

GUESTS: See Exhibit "A"

A.B. 121

Chairman Harmon called for a motion to consider and discuss amendment #38 to A.B. 121:

Senator Schofield: Motion to adopt Amendment #38
Assemblyman Hayes: 2nd the Motion.
The Motion passed.

Chairman Harmon opened the discussion on the Amendment only, with Mr. Marvin Kratter speaking in behalf of the drug involved, Gerovital H3. Mr. Kratter submitted a written testimony to the Committee, (Exhibit "C").

Senator Neal asked Mr. Kratter what were his qualifications to support this drug? Mr. Kratter replied that he was the owner of many private corporations, primarily related to Real Estate developments, and he owned 52% of the Rom-Amer Pharmaceuticals, Ltd, Company which has the right to distribute GH3 in the United States. Senator Neal suggested that sole ownership of this Company will cause a monopoly in pricing of this drug. Mr. Kratter said that he might be willing to sell licenses for distribution of this product, but since he represents thousands of share-holders, he could not distribute this product, profit-free.

Assemblyman Weise asked if Mr. Kratter felt that a statute was necessary in order to produce GH3? Mr. Kratter said that physicians feel uncomfortable if distribution of a drug is not endorsed by the Federal Drug Administration, or not approved by the State of Nevada.

Assemblyman Weise asked how will the patients know about this drug? Mr. Kratter said that the presence is well known due to the I.N.D. (Investigation New Drug) tests done on animals, and the "Double Blind" tests conducted with human patients, which were approved by the F.D.A.

Senator Hernstadt asked if the Rom-Amer Company had sole and exclusive right of distribution of this drug in the United States? Mr. Kratter said yes.

Assemblyman Hayes asked how does this drug work? Mr. Kratter answered that the major claims are in the area of curing or helping to cure geriatric depression.

Assemblyman Price asked if the drug could be produced without the adoption of this amendment? Mr. Kratter said yes, his company could produce the drug, but the physicians would probably not distribute it. Mr. Kratter added, that as stated in the amendment, the distribution would be done by prescription only.

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Dr. Morton Kurland, Psychiatrist, spoke next as proponent of GH3. Dr. Kurland said that he had worked with Dr. Max Hayman (Exhibit "D") in conducting a study of depressed patients. Dr. Kurland said that they used the "Double Blind " method where ½ of the patients used GH3 and ½ of the patients used a saline solution without the knowledge of whether their drug was authenic or not. There were 33 people on the active drug, and 30 on the saline solution, with the youngest patient being 45 years of age, and the oldest being 83 years old. The tests showed a significant difference in behavior, and there were no noticable side effects. The doctors concluded that the drug was non-toxic.

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Dr. Ted Jacobs, Internist, and share-holder in the Rom-Amer Company, said that in January and October of 1974, he treated nine (9) patients who were all aware that they were receiving the GH3. One of the patients dropped-out, six of the patients showed marked improvement in their depression, one showed slight improvement, and one showed none at all. Dr. Jacobs said that he also takes injections himself.

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Dr. Harold Feikes, M.D., said that he was on the Board of Directors of the Rom-Amer Company, and he has witnessed two clinical observations, one of the patients being his own

father. Dr. Feikes said that it helped his father overcome his depression, and even eliminated a tremor in his hands.

Dr. Elias Ghanem, M.D., said that he treated his father with GH3, and within four weeks, his depression had completely disappeared.

Senator Neal asked if the effect of GH3 is temporary only? Dr. Morton Kurland said that the patients taking the drug have daily dosage, and it has only been used to treat depression.

Assemblyman Hayes asked if any genetic research has been done on this drug? Mr. Kratter said that it was felt that this was not necessary, as GH3 has been used for so many years in several countries.

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Dr. Harold Harper, Surgeon, spoke in behalf of GH3, and said that he had studied the effects of the drug, first-hand in Bucharest, Romania, where it is produced and used in clinics, and has used it himself. Dr. Harper said that he had first learned about the drug in 1968, during a study on aging he was conducting. In the clinic in Bucharest, GH3 tests are conducted on over 7,000 animals, primarily white rats. Dr. Harper said that the drug is non-toxic and can be mixed in any physician's office, because the ingrediants are so basic. Dr. Harper said that he saw films in Romania that showed that GH3 also has positive effects in healing arthritis.

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Mrs. Mary Henderson, private citizen, spoke in behalf of GH3 and Laetrile, and submitted a written statement for the record, (Exhibit "E").

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Mrs. Phipps and Mrs. Loeb both gave personal testimonies in behalf of Laetrile and stated that they were in total support of A.B. 121's adoption, as they were cancer patients, and had felt very positive results from the Laetrile treatment. Mrs. Elaine Camp also related a story of her cousin who had undergone the normal cancer treatment, of cobalt and chemo-therapy and had suffered drastic side effects, but had found very great relief when she began to take the Laetrile treatment.

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Mr. Thomas Padden read a statement in behalf of Mr. Michael Culbert, editor of "The Choice", who said that for five years the Committee for the Freedom of Choice has been leading the drive for adoption of Laetrile and GH3. Mr. Culbert wrote that the therapy is legal in 27 other countries, the latest being Israel. Mr. Culbert stated that 1100 cancer patients die each day in the U.S. who are not treated, or have been treated with the usual methods of radiology, chemo-therapy, cobalt and surgery. Mr. Culbert said the

only report that claimed the failure of Laetrile happened to be the 1953 California Commission Report, which, if read closely, should convince anyone that even the 44-terminal, non-ambulatory patients to whom low dosage of Laetrile were administered felt uniformly better. Mr. Culbert also wrote that the Laetrile treatment costs much less than chemical therapy which may range from $15,000 to $80,000 per patient. Mr. Culbert stated that his figures indicate that approximately 65% of cancer patients find at least some improvement by using the Laetrile program, particularly in the relief of pain and improvement in the quality of life. And this is most impressive when almost 90% of the above 65% are considered terminal cancer patients. Mr. Culbert stated that A.B. 121 does not disallow orthodox cancer treatment, but merely allows for freedom of choice,(Exhibit "E-1").

Assemblyman Weise asked if there could be open-market competition with this drug? Mr. Patton answered yes, that anyone can make it. Mr. Patton said to Senator Hernstadt that he did not know of any drug manufacturer in Nevada that has expressed an interest in producing Laetrile.

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Mr. Ralph Pearl, columnist of the L.V. Sun, gave a personal account in favor of the Laetrile treatment. Mr. Pearl testified that with Laetrile and proper diet, he was still alive after four years, when he had been told he was terminal. Senator Hernstadt asked what the treatments cost Mr. Pearl? Mr. Pearl answered that the Laetrile and the other enzymes he took cost approximately $4.00 per day.

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Dr. John Detar, Urologist, spoke in favor of A.B. 121, and stated that it is ironic that individuals have the choice offered in other medical problems, such as pregnancy or abortion -- treatment or "right to life", but cannot choose the type of cancer treatment they wish to receive. Assemblyman Weise asked if the use of Laetrile would conflict with other types of treatment? Dr. Detar responded by reading a letter from the American Cancer Society which said in the second paragraph, "if this bill (A.B. 121) were to be passed, it would be tantamount to allowing Laetrile to be an accepted cure for cancer. Thus depriving some cancer patients of necessary proven methods of treatment." Dr. Detar said that this statement by the A.C.S. is an 'absolute lie'. Patients should be able to receive Laetrile along with the conventional measures. Senator Neal asked how does Laetrile affect the cancer cells? Dr. Detar said that he has read the hypothesis on this, and understands that it is a technical process having to do with the cyanide radical and oxygenation of cancer cells.

The Joint Hearing recessed for dinner until 7:30 p.m.

The Joint Hearing reconvened at 7:30 p.m.

Dr. Harold Harper spoke again, this time in behalf of Laetrile. Dr. Harper stated that he was not on anyone's payroll, nor did he have any interest in any pharmaceutical company, and he paid his own expenses to get to this meeting from Los Angeles. He said that the public is in a great dilemma today concerning the safety and efficacy of drugs. This is because .30¢ of every consumer dollar is spent on products that require approval of the F.D.A. And, the F.D.A. frequently prohibits the use of drugs that have been proven safe and efficacious elsewhere, and it takes between eight to ten years to get new drug approval. Dr. Harper added that from his own personal experience, he knows of many cancer patients who were given less than a year to live, and are still surviving after five years due to the use of laetrile and accompanying enzymes and vitamins.

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Dr. E. Paul Wedel, stated that he is licensed to practice in Oregon and has an inactive license in good standing in California. In his testimony, he referred to a book entitled, Complimentarity in Biology by Dr. James Pershing Isaacs, and the major portion of Dr. Wedel's testimony is attached, (Exhibit "F").

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Dr. Gary Gordon of Sacramento, California, President of the American Academy of Medical Preventics, commented that his work during the past ten years has placed him in close contact with many physicians who use unorthodox treatments, including laetrile. He knows of no patient under this treatment who has had any adverse effects. Dr. Hans Nieper of Germany had told Dr. Gordon that laetrile alone is only working about 40% effectively, but when enzymes are added it is closer to 60%, and A.N.C. and Zinc are added it is up to 80% over-all efficacy. F.D.A. will only test the laetrile itself, and not in conjunction with the other agents.

Senator Schofield asked Dr. Gordon about the laetrile clinic in Tijuana, Mexico. Dr. Gordon said that the clinic would welcome a visit by the Senate Committee.

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Dr. Douglas Brody of Lake Tahoe is in general practice with a background in internal medicine and nutrition. He has had an opportunity to observe many patients being treated with laetrile and enzymes, and he also had an opportunity to observe patients in the office of Dr. John Richardson of Albany, California, and has been very impressed with the safety of the program and the apparent relief in pain. Dr. Brody said that it is striking that the use of laetrile and nutritional therapy has enabled patients to get off of narcotics without withdrawal symptoms. Patients appear to have an improved feeling of well-being and their appetite improves.

Mrs. Frances Miller spoke in regards to her personal experience with laetrile, under treatment from Dr. Ernesto Contreras in the Tijuana clinic. She expressed her desire to have it legalized in the U.S., so she does not have to suffer the embarrassment and humiliation of smuggling it across the border.

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Betty Lee Morales, secretary of the National Health Federation, appeared as a proponent of the bill. She stated that the N.H.F. believes that Americans have the right of choice if it is not harmful. The F.D.A., the American Cancer Society, and the American Cancer Institute do not have the right to interfere with the sacred relationship between patient and physician. Ms. Morales has visited fifty-two countries studying cancer in relation to nutirition and individual life-styles. She stated that no responsible doctor ever speaks of laetrile therapy as a cancer cure, but the choice of treatment should be allowed.

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Charles W. Baker, a businessman from Reno, testified that in 1975, he was told that he had contracted cancer. Mr. Baker went on the laetrile therapy from Dr. John Richardson and is now in better shape than before he started treatment.

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Ms. Joan Atkinson, a registered nurse, described her personal experience in having a lung removed for cancer and how laetrile helped her in her subsequent treatment of cancer. Her husband also appeared to support her testimony.

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Betty Taylor and Lola Farrell also gave personal experiences in support of laetrile.

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Roland C. Bartlett of Las Vegas, stated that he had spent several years traveling throughout Europe and Central and South America investigating GH3, and he knows its value for restoring hair, skin-care and rejuvenation. As part of his testimony Mr. Bartlett presented a letter to Senator Gaylord Nelson, (Exhibit " G").

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Dr. Roger D. Miercort was the first speaker who represented the opposition to A.B. 121. The doctor said that he disagreed with some of the statements made by previous witnesses. He said that he has seen many terminal cancer patients survive over five years; survival statistics with conventional treatment exceed 5%. In his own practice, he can count on curing 1/3 and helping 1/3. However, if individuals could be persuaded to see their physicians earlier, conventional treatment could cure one-half of the patients. Dr. Miercort said that in accord with a request from Assemblyman Demers, he would submit three letters concerning cases where laetrile treatment failed, (Exhibits "H", "H-1" & "H-2"). In addition, Dr. Miercort also showed two sets of x-rays to the Committees. The doctor continued by saying that cancer is a multitude of diseases, which will respond totally differently to different methods

of treatment. Dr. Miercort further stated that there is no simple non-toxic method of treatment, that for every treatment of a malignancy, there is some hazard. The doctor said that he feels he can legally give laetrile to his patients, and he does not understand why "all the fuss" unless the object of the bill is to manufacture and sell the drug. As the bill is now written, Dr. Miercort feels there is no protection for the consumer. Dr. Miercort submitted a letter from Dr. Fred M. Anderson for the record, (Exhibit "I").

In response to a question from Senator Schofield, Dr. Miercort said he did not know if laetrile would be easily accessible to him or not, as he did not plan to use it.

Assemblyman Demers questioned Dr. Miercort's statement that he could legally administer laetrile to his patients, and read from the Nevada State Board of Medical Examiners' rules that, "No doctor can administer any drug or medication that has not been approved by a Federal regulatory agency." Dr. Miercort conceded that if that was in the regulations, then he was wrong.

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Dr. Robert Young, representing the Federal Food and Drug Administration, was the next speaker. F.D.A. is a consumer protection agency and their investigation has failed to conclude that laetrile has a value in the diagnosis, treatment and cure of cancer. There is no evidence that establishes the validity of the theory that laetrile kills cancer cells or has any affect on animal tumors. Dr. Young said the F.D.A. will conduct a public hearing on laetrile on May 2, 1977, in Kansas City, Missouri. Dr. Young concluded by stating that individual case reports do not constitute a proper scientific study, and that these claims are often unsubstantiated and misleading.

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Dr. Stewart Nightengale, also representing the F.D.A., explained how the Administration functioned under the Food, Drug and Cosmetic Act, and the current status of legal and administrative procedures. It is the contention of the Administration, that laetrile is a new drug which is subject to all the provisions of the above mentioned act, and because laetrile is not approved, it is violative when it is introduced into interstate commerce for use as a drug. See (Exhibit "J") attached testimony.

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Mr. Ronald Harrison spoke about his mother, Eleanora Harrison, who is now at Southern Nevada Memorial Hospital. Mrs. Harrison has been under the care of Dr. Barbosa and Dr. Contreras in Tijuana. Mr. Harrison stated that after spending $26,000 and seven months in treatment, his mother has approximately one week to live as of the date of this hearing. Mr. Harrison asked the Committee to consider carefully the consequences before legalizing laetrile in the U.S.

Dr. Roland D. Wussow of the National Cancer Institute, Office of Cancer Communications, spoke in opposition to A.B. 121, and submitted a written testimony for the record, (Exhibit "K").

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Dr. Barry Morrison, Assistant Director of the National Cancer Institute, said that the Institute has been conducting experiments since 1937, and progress in medicine is a process of scientific change and scientific advancement, which is deliberately achieved. Dr. Morrison remarked that in all their tests of laetrile, it has been found negative as a cure for cancer. Dr. Morrison submitted documents showing the nature of the tests the National Cancer Institute and the National Institute of Health have performed, accompanied by two articles taken from the literature which show the extreme detail and complexity of these studies, (Exhibit "L").

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Dr. James W. Forsythe, cancer therapist, works with Dr. Roger D. Miercort at Washoe Medical, and treats approximately 85 patients per day. Dr. Forsythe said that the sanction and endorsement of laetrile will delay proper treatment for cancer patients, and the freedom of choice puts the decision on an emotionally sick person to decide on his own type of treatment.

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Mr. Orville Kelly, a cancer patient, who works as a consultant for the National Cancer Institute and is founder of 'Make Today Count'(a national organization for advanced cancer patients and their families), felt that everyone fears cancer so greatly that they are looking for an easy way out, but Mr. Kelly felt that laetrile treatments are not the answer. He said that cancer patients must rely on people who have expertise.

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Connie Edwards, a volunteer for the American Cancer Society, said that finances should be considered, and although $4.00 per day sounds small for laetrile, that adds up to $120.00 a month, and to a social security recipient who is receiving from $220.00 to $320.00 per month, that is a large drug bill. She asked if the State of Nevada, through its social agencies will be responsible in endorsing this bill and give assistance to the medically indigent patients who will obviously come here to receive a drug they cannot legally receive in other states? She also asked, will the indigent patients be able to receive Federal assistance for a drug which is declared illegal by the Federal government?

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Dr. Dean Burk, a senior biochemist, stated that he had been working in the field of cancer for fifty years and for thirty-five years, had been working in the National Cancer Institute. Dr. Burk also worked in laboratories in European countries, and has consulted over 10,000 cancer patients.

Dr. Burk contended that laetrile is not a drug, but has been a food for man for many years, and is in actuality a vitamin. The F.D.A. is trying to establish that it is a new drug, but they are now enjoined by the Tenth Circuit Federal Court from making such a declaration, so there is no legal basis for declaring laetrile as a drug. Dr. Burk presented the Committees with a booklet entitled, A Brief on Foods and Vitamins, which discusses amygdalin (laetrile) as Vitamin B-17. Attached is a copy of the letter Dr. Burk sent to Assemblyman Demers in which he expresses his views on the legalization of laetrile, (Exhibit "L").

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Chairman Harmon dissolved the Joint Hearing and stated that there would be a two minute recess, after which the Assembly Commerce Committee would take action on A.B. 121.

Assemblyman Weise: Motion that no action be taken by the Committee until a later date for the following reasons:

All of the testimony had not been received; the Committee had not had time to digest the information submitted; he would like an opportunity to determine if laetrile would come under the jurisdiction of the Nevada Cancer Council, and an opportunity to possibly re-amend the bill.

The Motion 'died' for a lack of a second.

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A.B. 121 (Exhibit "M")

Assemblyman Hayes: Motion that the Committee adopt Amendment #38 to A.B. 121
Assemblyman Moody: 2nd the Motion.

The Motion passed. (Assemblyman Weise voted "NO"; Mr. Harmon, Mr. Mello, Mr. Demers, Mrs. Hayes, Mr. Moody, Mr. Price and Mr. Sena voted "YES")

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Assemblyman Mello: Motion to amend and Do Pass
Assemblyman Sena: 2nd the Motion

The Motion passed. (Assemblyman Weise voted "NO"; Mr. Harmon, Mr. Mello, Mr. Demers, Mrs. Hayes, Mr. Moody, Mr. Price and Mr. Sena voted "YES")

The meeting of the Joint Committees was adjourned at 12:05 a.m.

The minutes of the Joint Hearing on laetrile, A.B. 121, are respectfully submitted by:

Jane Dunne

Jane Dunne, Assembly Secretary

Sheba L. Woolley

Sheba L. Woolley, Senate Secretary

Approved by:

Harley L. Harmon

Assemblyman Harley Harmon, Chairman

EXHIBIT "A"

GUEST LIST

PROPONENTS	OPPONENTS
Mr. Marvin Kratter	Dr. Roger D. Miercort
Dr. Morton Kurland	Dr. Robert Young
Dr. Ted Jacobs	Dr. Stewart Nightengale
Dr. Harold Feikes	Mr. Ronald Harrison
Dr. Elias Ghanem	Dr. Roland D. Wussow
Dr. Harold Harper	Dr. Barry Morrison
Mrs. Mary Henderson	Dr. James W. Forsythe
Mrs. Phipps	Mr. Orville Kelly
Mrs. Loeb	Connie Edwards
Mr. Thomas Padden	
Mrs. Elaine Camp	
Mr. Ralph Pearl	
Dr. John Detar	
Dr. E. Paul Wedel	
Dr. Gary Gordon	
Dr. Douglas Brody	
Mrs. Frances Miller	
Betty Lee Morales	
Charles W. Baker	
Mrs. Joan Atkinson	
Betty Taylor	
Lola Farrell	
Mr. Roland C. Bartlett	
Dr. Dean Burk	

Adopted ☐ Lost ☐ Date: Initial: Concurred in ☐ Not concurred in ☐ Date: Initial:	Adopted ☐ Lost ☐ Date: Initial: Concurred in ☐ Not concurred in ☐ Date: Initial:	Amendments to Assembly / ~~Senate~~ Bill / ~~Joint Resolution~~ No. 121 (BDR 40-362 Proposed by Committee on Commerce EXHibit "B"

1977 Amendment No. 38

Replaces Amendment No. 211A.

Amend section 1, page 1, delete lines 1 through 14 and insert:

"Section 1. Chapter 453 of NRS is hereby amended by adding thereto a new section which shall read as follows:

1. The board shall conduct inspections of manufacturers of amygdalin (laetrile) and Gerovital H3.

2. The board may establish reasonable fees, to be collected from the manufacturer, for the purpose of paying the costs of the inspections."

Amend section 2, page 1, line 18, after "(laetrile)" insert "or Gerovital H3".

Amend section 2, page 1, delete lines 19 and 20 and insert: "requested the substance."

Amend section 3, page 2, delete lines 3 through 5 and insert: "lin (laetrile) or Gerovital H3 to a patient under his care who has requested the substance."

Amend the bill as a whole by adding a new section, designated section 4, following section 3, to read as follows:

"Sec. 4. Chapter 638 of NRS is hereby amended by adding thereto a new section which shall read as follows:

A pharmacist is not subject to any penalty for:

1. Filling a prescription for amygdalin (laetrile) or Gerovital H3 the prescription is issued to a patient by his physician, osteopathic physician or osteopathic physician or surgeon; or

2. Dispensing Gerovital H3, without a prescription, if the use is for topical application only."

Amend the title of the bill to read as follows:

"AN ACT relating to substances; permitting the use of amygdalin (laetrile) and Gerovital H3 under certain conditions; and providing other matters properly relating thereto."

BY MARVIN KRATTER

Exhibit "C"

STATEMENT TO JOINT COMMITEE

HEARINGS ON AB 121, MARCH 2, 1977

GENTLEMEN OF THE JOINT COMMITTEES:

May I first express my appreciation for this opportunity to present to you our Company's position on the amendments to AB 121.

I feel it incumbent on me to disclose to this distinguished committee that I am personally the owner of 52.5% of the stock of our Company, ROM-AMER PHARMACEUTICALS, LTD., and that the majority of the balance of the outstanding stock of this Company, which is a publicly-owned company traded over-the-counter, is held by approximately 1,000 residents of the State of Nevada. Our offices are located in Las Vegas, and we are about to become a Nevada corporation.

Our Company, ROM-AMER PHARMACEUTICALS, LTD., has been in business for approximately seven years, when it first obtained the rights from the Romanian Foreign Trade Organization to distribute its medical product, Gerovital H3, in the United States. During that time, it has spent over $1 million in testing and research activities in an attempt to have Gerovital H3 cleared for sale pursuant to the rules and regulations of the United States Government's Food and Drug Administration.

The Food and Drug Administration has approved two IND's for the injectable and oral use (pill form) of the product. An IND is an acronym for "Investigation

New Drug," - the application which must be approved by the Food and Drug Administration to permit the testing of the drug in humans. Generally, IND's are only granted after animal studies have been completed (which was the case with Gerovital H3) to establish the product's safety before testing the drug in humans. The clinical testing, which has since been carried out on approximately 750 to 1,000 patients, has been conducted by recognized, distinguished clinical medical investigators.

Actually, although by FDA definition Gerovital H3 is a "New Drug," the basic medicine in this drug, procaine-hydrochloride, has been known for 72 years, and used in this country and all over the world. Those of you who have ever had to visit a dentist are familiar with this medicine under the trade name of "NOVOCAINE." The other contents of Gerovital H3 include a preservative (one similar to that used in preserving tomato catsup) and two other compounds which are used to regulate and buffer the acid-alkaline balance of the product, and to regulate its rate of absorption into the body.

It can thus be seen that this product is really not, in fact, a new drug, but is one merely by FDA definition, since all of the contents are known drugs listed in the United States Pharmacopeia.

The first clinical research work on this product was started back in 1956, by Dr. Ana Aslan, the Director of the Romanian Institute of Geriatrics in Bucharest, Romania, and the use of the drug throughout 42 countries in the world has been increasing ever since. At the present time, for example, both the injectable and pill form of the drug are sold in West

Germany, without prescription, and in England, Switzerland, France and Spain, with prescription.

To my best knowledge, there have never been any reported cases within the scope of the clinical investigation within the United States and Canada, (or in any of the other countries where the drug is now being sold), of any serious debilitating side effects or toxicity, and while the drug originally started being used as an anti-aging drug (i.e., one that would make old age more tolerable, happier and more productive, but not necessarily as a life-extender), there have been increasing reports of other uses, including but not limited to, as an anti-depressant, as an anti-arthritic, as a vasodilator improving circulation and in certain skin applications involving skin problems and other external body manifestations such as hair loss and color changes in certain cases.

Unfortunately, at the present time, only wealthy senior citizens of the State of Nevada can avail themselves of this drug, if they have the money to travel to Romania, where the drug is administered in 17 clinics operated by the Romanian government, or travel to Mexico or The Bahamas, or if they can afford to pay outrageous black market prices to smugglers who are importing the drug into the United States illegally.

It is my belief and the belief of several U.S. Senators, including our own distinguished Howard W. Cannon, expressed in a letter to a Las Vegas resident on August 12, 1976, a partial quotation from which follows, that:

"While there is no legislation currently before the Congress that addresses issues specifically related to Gerovital and Laetrile, Congressman Symms of Idaho has introduced a bill which would eliminate the requirement that new drugs be regulated according to their effectiveness. The bill states that such drugs should be regulated solely to assure their safety. While it does not appear that this bill will win approval this year, it is my view that if a drug is not harmful, people ought to be able to use it." (Emphasis added.)

This same general opinion was shared and expressed by Senator Ernest Hollings, a Democrat from South Carolina, in FAMILY WEEKLY of August 26, 1973, and a favorable impression was also expressed by Senator Thomas Eagleton of Missouri, in a Chicago Tribune story on December 19, 1972. The Hollings and Eagleton opinions are enclosed herewith as Exhibits 1 and 2.

The problem with clearing this medicine through the Food and Drug Administration has primarily arisen because of the extensive testing that that agency requires to prove the drug's efficacy and efficiency as an anti-depressant. While the Company has had large amounts of clinical research work done by medical clinicians fully acceptable to the Food and Drug Administration, and while generally all of the reported conclusions of these clinicians do not reveal any real danger from the use of this product, the Food and Drug Administration has accepted these reports with a recommendation that they be used only to help create new further and more

expensive efficacy research procedures known as "double-blind studies." These studies involve persuading depressed patients in need of help to agree that, as part of a testing program, instead of receiving Gerovital H3, they may only be receiving a placebo, which is a saline solution. Getting large numbers of depressed people to agree to this type of guinea-pig testing is an extremely difficult chore.

It is not my intention, nor would it be appropriate or fair, for this request for your action to be considered in any way an attack upon or a criticism of the Food and Drug Administration. That agency is only doing its job as mandated by Congress in 1962, when the powers and duties of the agency, which previously had related only to the safety of drugs, was expanded (in an over reaction to a bad drug incident relating to safety) to include the requirement of verifying the efficiency and efficacy of drugs. Unfortunately, the determination of the efficiency or efficacy of a drug lies frequently "like beauty, in the eye of the beholder" or, in this case, in the individual and subjective reactions of each person who uses a drug. Human beings are not octane-consuming machines of an absolute uniform and stereotype composition, and particularly is this the case in the ability of any testing mechanism to reflect the innermost results obtained in the treatment of a depressed person.

The Company's position in sponsoring the amendments to AB 121 which would, in effect, legalize the use of Gerovital H3 within the State of Nevada by physicians and by prescription, is, that the public, particularly our senior citizens who are so desperately

in need of help during the times of depression which occur during their waning years, who feel unproductive and who become a medical burden on the community, should be entitled, (given the acceptance of the premise that this medicine is safe and non-toxic), to be allowed to use it on a real life, everyday basis and not have to fade away and do without for the five to eight years that the FDA's required efficacy studies usually require. As you will notice from the reference to the Senator Cannon letter above-mentioned, both Congressman Symms of Idaho, and Senator Cannon, as well as Senator Hollings, feel that this procedure should be followed.

This new idea of limiting the FDA's authority to pass only on the safety and not the efficacy of drugs is shared by many of our federal legislators and on January 4, 1977, two bills, H.R. 53 and H.R. 54, were introduced into the House of Representatives with the following preamble:

"A bill to expand the medical freedom of choice of consumers by amending the Federal, Food, Drug and Cosmetic Act to provide that drugs will be regulated under that act solely to assure their safety; to the Committee on Interstate and Foreign Commerce."

The following Congressmen, including our own Mr. Santini, were sponsors of the introduction of these bills:

By Mr. SYMMS (for himself, Mr. BEDELL, Ms. CHISHOLM, Mr. COCHRAN, Mr. COLLINS of Texas, Mr. CRANE, Mr. HAMMERSCHMIDT, Mr. KETCHUM, Mr. KINDNESS, Mr. LA FALCE, Mr. LAGOMARSINO, Mr. LOTT, Mr. MCDONALD, Mr. SANTINI, Mr. TREEN, Mr. WAGGONNER, Mr. BOB WILSON, Mr. CHARLES WILSON of Texas, Mr. HALL, and Mr. MARTIN):

By Mr. ANDERSON of California (for himself, Mr. CORMAN, Mr. DE LUGO, Mr. EDGAR, Mr. FASCELL, Mrs. HOLT, Mr. JOHNSON of California, Mr. KETCHUM, Mr. KINDNESS, Mr. KREBS, Mr. LAGOMARSINO, Mr. LEHMAN, Mr. LENT, Mrs. LLOYD of Tennessee, Mr. MAZZOLI, Mr. MEEDS, Mr. MOLLOHAN, Mr. MOTTL, Mr. MURPHY of Illinois, Mr. MURTHA, Mr. O'BRIEN, Mr. ROE, Mr. SISK, Mr. SLACK, and Mr. YATRON):

These names present a complete spectrum of the political shadings of the House of Representatives and include both staunch conservatives as well as liberals like Miss Shirley Chisholm. On January 6, 1977, an additional bill was introduced, H.R. 150 , by Mr. Ashbrook.

The essence of these bills is that the FDA is to be charged only with regulating drugs to assure their safety and to provide that in the labeling of any drug that is passed by the FDA in this manner that its label will contain a clause clearly indicating "that this drug has not been tested or reviewed for efficacy by the Federal Government."

As part of the exhibits which are being submitted to you today, you will also find a letter from Sidney Cohen, M.D., Professor of Psychiatry, Neuro-Psychiatric Institute, University of California; Thomas Ban, M.D., Professor of Psychiatry at Vanderbilt University, Nashville, Tennessee, and McGill University at Montreal, Canada; Dr. Leonard Cammer, Clinical Associate Professor of Psychiatry, New York Medical College and Flower Fifth AVenue Hospital; and Dr. Max Hayman, Professor of Research Psychiatry at UCLA.

You will, today, also hear firsthand from a major clinical researcher, Dr. Morton L. Kurland, Associate Clinical Professor of Psychiatry, University of Southern California School of Medicine, and also Medical Director of the Desert Hospital Mental Health Center at Palm Springs, California.

In addition, you will be hearing from three distinguished practicing physicians from Las Vegas, who have firsthand knowledge from their use of this medicine.

Also submitted are excerpts from a Foreword to an Evaluative Study called, "DRUG REGULATION AND INNOVATION, by Professor Henry G. Grabowski of Duke University. (READ)

It certainly seems odd that Americans going to highly civilized, highly regulated countries like West Germany, Great Britain, France and Switzerland, should be able to avail themselves of good medicines which are not available to the people of Nevada, particularly when over a 20-year period that same medicine has been used by millions of people in these countries, particularly in Romania, where it was used for a four- to five-year period on thousands of people in 44 governmentally established centers under controlled experiments.

Enclosed also as Exhibit 5, for your consideration, is an excerpt from a book called, GH3 WILL IT KEEP YOU YOUNG LONGER?, by Herbert Bailey, setting forth the results of a study on 15,000 people reported to the International Symposium of Gerontology at Bucharest, Romania, in June of 1972. The main objective of this testing was "to prolong the active life period of workers, especially those undergoing temporary working incapacity and to prevent the process of infirmity." A careful reading of this chapter

will, in my humble opinion, convince you of the desirability of legalizing this medicine for sale within the State of Nevada. (READ)

In conclusion, what we are asking you to do is to make legal, within our great state, a medicine which by its nature has almost become an international vitamin, and to give to your constituents in our state a freedom of choice. I think that freedom of choice was in a fair and statesman-like manner best expressed by Governor Jay Hammond of the State of Alaska, on June 24, 1976, who, in commenting on a similar bill offered to him for signature, said, among other things:

"My decision not to veto the bill, in spite of the recommendation to do so from several physicians, hospitals and the Food and Drug Administration is based on one strong personal conviction -- the individual's right to decide on a course of conduct or a mode of treatment, given the alternatives available. In my opinion, that right outweighs the shortcomings of the bill and the possible complications for the medical profession. . . . Such choices must be made by the patient and his physician. (Emphasis added.)

"As a layman, I cannot judge these things. As a governor, I can only review the bill, consider the thoughtful testimony and correspondence and determine what seems to me in the best interests of persons affected. In this instance, I am persuaded by patients, their families, and physicians and have concluded that it allows each Alaskan to decide for himself."

I have great faith that the physicians in our state are honest, competent, objective human beings and that they will not misuse in an unethical manner, their rights to prescribe and administer this drug and then only in agreement with their patients' desires. We have a pioneer history and should not hesitate to pioneer in giving our people their inalienable right to preserve their health in consort with their physicians.

Our last exhibit is a letter received this week from a lady in Scottsdale, Arizona, which speaks for itself.

In closing, I would recommend you to the preface to the Bailey book mentioned before, which is reproduced here as Exhibit 6. (READ)

I strongly urge you to pass these amendments and brighten the lives of so many of our Nevada senior citizens.

Family Weekly
AUGUST 26, 1973

By Rona Jaffe: The Special Ties That Bind Women

Tasty Turkey Tip For a Barbecue That Saves Dollars

Rod McKuen: How Life Finally Forced Me to Be Myself

Ask Them Yourself

Want to ask a famous person a question? Send the question on a postcard, to "Ask," Family Weekly, 641 Lexington Ave., New York, N.Y. 10022. We'll pay $5 for published questions. Sorry, we can't answer others.

FOR SEN. ERNEST HOLLINGS (D-S.C.)

What is the advantage of Gerovital, the Rumanian drug that you and other senators are seeking to bring into this country?—R. Z., Hayward, Calif.

● Gerovital, called the "youth drug," is widely used in Europe and Mexico. It was developed by a 73-year-old woman doctor, Ana Aslan, in Bucharest. Tom Eagleton, Howard Cannon of Nevada and I had an Army doctor from Walter Reed Army Medical Center check out the claims for this drug as a cure for arthritis, for making hair grow and general rehabilitation. The doctor came away much impressed. Still, the U.S. bans the drug. I think we ought to obtain its entry into this country to help the elderly.

Chicago Tribune Tuesday, December 19, 1972 Section 2 — 3

EXHIBIT 2

Senators Press Search for Eternal Seniority

Washington

Maxine Cheshire

● THE VISIT of three U. S. senators to the Bucharest Geriatric Institute in Romania several weeks ago may pave the way for experimentation in this country with a controversial "youth" drug that has been credited with "revitalizing" such world leaders as Nikita Khrushchev and Konrad Adenauer.

Sen. Thomas Eagleton, member of the Senate's special Committee on Aging, was joined by Nevada's Sen. Howard W. Cannon and South Carolina's Sen. Ernest F. Hollings for an inspection tour of the famous clinical facilities for the elderly.

The group was briefed by Dr. Ana Aslan, the 73-year-old creater of Gerovital, a procaine formula widely-used in Europe but outlawed here by the FDA since the 1950s as a suspected hoax.

Dr. Aslan claims Gerovital has "cured" such complaints of old age as arthritis, arterjosclerosis, wrinkled skin, baldness, gray hair, angina pectoris, heart disease, deafness, neuritis, neuralgia, Parkinson's disease, various psychic ailments.

Both Khrushchev and Adenauer underwent Gerovital treatments. So did Saudi Arabia's old King Ibn Saud, Britain's Field Marshal Montgomery and former Vice President Henry Wallace.

None of the three U. S. senators who went to Bucharest took Gerovital while they were there. Their visit was merely for study purposes.

Sen. Eagleton was favorably impressed with what he learned, a staff member said afterward. He brought back papers on Dr. Aslan's work that now are in the process of being translated into English.

The manufacturers of Gerovital are expected to ask the FDA soon to ease its restrictions and permit the drug to be imported here, at least for the purposes of further study by U. S. scientists.

● SOME OF SEN. GEORGE McGovern's campaign workers with as much as three weeks' unpaid salary coming to them, have taken their plights to the D. C. Minimum Wage Board, which can enforce payment. At the first hearing last week, a secretary was awarded her claim, and other hearings are scheduled. Matriarch Rose Kennedy, who has not had her portrait painted in half a century, plans to sit next week for Palm Beach artist Dick Banks. The artist, who just got back from London where he painted Peter Sellers' wife, Miranda, gets between $3,000 and $5,000 per painting.

Eagleton Eyeing Gerovital.

UNIVERSITY OF CALIFORNIA, LOS ANGELES

BERKELEY • DAVIS • IRVINE • LOS ANGELES • RIVERSIDE • SAN DIEGO • SAN FRANCISCO

SANTA BARBARA • SANTA CRUZ

OFFICE OF THE CHANCELLOR
LOS ANGELES, CALIFORNIA 90024

February 24, 1977

Commerce Committee of the Assembly
The State Legislature
Carson City, Nevada

Gentlemen:

It is my understanding that you have under consideration legislation that will permit the sale of Gerovital (GH3) by physician's prescription in the State of Nevada. As one of the clinical investigators of this drug working under an Investigational New Drug application from the Food and Drug Administration, I would like to provide you with the results of my own experience in a large scale open trial of GH3. The study was done in association with Keith Ditman, M.D.

It was administered to a series of 233 patients with mild to moderate depressive states or with chronic physical conditions with a reactive depression. One or more courses of medication were given consisting of three injections weekly for four weeks with a non-medicated period interspersed between courses.

In evaluation of a drug for approval for commercial use, three elements should be carefully considered: (1) safety, (2) efficacy, and (3) potential for abuse. I would like to comment on all three items.

1. Safety

In our series no patient sustained moderate or severe side effects of any sort. Mild side effects were uncommon with transient dizziness being reported in 12 (of 233) instances. We recorded rare complaints of nausea, flushing and drowsiness, all minor and temporary in nature. No patient required discontinuance of the medication because of an adverse effect. The laboratory tests conducted, complete blood count, 12 blood chemistries, urine analysis and ECGs showed no deviation from normal. It was our conclusion that GH3 is a drug with an unusually wide safety margin as used by us. Other investigators report similar experiences.

2. Efficacy

In a paper presented at the American Academy of Psychosomatic Medicine, November 20, 1973 at Williamsburg, Virginia and subsequently published in Psychosomatics 15:15-19, 1974, we presented our results with the first 41 patients given GH3 therapy. We found some degree of improvement from slight to marked in 85% of our patients

and no improvement in 15%. The improvement consisted of mood elevation and a reduction in depressive symptoms. A few of the patients with chronic pain spontaneously reported a reduction of pain. Our subsequent experience tended to confirm this initial report.

3. Potential for abuse

I am particularly concerned about problems of drug abuse and have worked on the Federal level to assist in prevention and control of dangerous substances. Rom-Amer Pharmaceuticals requested that I review the Gerovital and the procaine literature regarding actual or potential abuse liability. This was done and reported to them in my letter of February 17, 1975. In summary I found no evidence of Gerovital abuse in the world literature. Procaine is also not an abused substance. It is found as an adulterant in some samples of cocaine as are benzocaine and xylocaine. This is because of its local anesthetic effect in case the buyer tests the material by tasting. This is analagous to the adulteration of heroin with quinine to produce a bitter taste. In summary, no problem of abuse should be anticipated with Gerovital.

It is a pleasure to transmit this information to you.

Sincerely yours,

Sidney Cohen, M.D.

SC:dec


Evaluative Studies
DRUG REGULATION AND INNOVATION
Empirical evidence and policy options
Henry G. Grabowski

EXHIBIT 4

FOREWORD

[3] The FDA has forced U.S. firms to manufacture more and more abroad in recent years because of increasing delays in approval of New Drug Applications (NDAs). "Regulations prohibit drugs from being exported without an approved NDA. With the greatly increased time required to attain NDA approval . . . in 1975 twelve new chemical NDAs were approved with an average of over eight years from IND filing to NDA approval . . . indeed with the possibility that it might never be approved here—there is more and more of a pattern for U.S. firms to introduce a new drug in a number of foreign countries before attempting to market it in the United States. Being unable to export from the United States, these firms must establish production facilities abroad. . . ." *New Drugs: Pending Legislation* (Washington, D.C.: American Enterprise Institute for Public Policy Research, 1976), p. 49. See also comments by Halberstam and Lasagna, *Reforming Federal Drug Regulation* (Washington, D.C.: American Enterprise Institute, 1976), pp. 2-3.

Anomalous situations develop where U.S. doctors send patients abroad for treatment in order to use a drug not available here.[4]

One of the bitter ironies of this situation is that the 1962 amendments were spurred by an alarm over the *safety* of new drugs—by the fears created by the thalidomide incident. The irony lies in the fact that the 1962 amendments are keeping off the market new drugs that are safer than the drugs they would replace. Professor William Wardell's study of the lags in the introduction of new drugs in the United States cites, as one example, the five-year delay in the appearance on the U.S. market of a benzodiazepine hypnotic. If it had been available in the United States as it was in Great Britain during those five years, Professor Wardell estimates that 1,200 lives would have been saved.[5]

[6] The 1962 amendments did add a requirement that no investigation of toxicity and therapeutic effects in human beings could begin until thirty days after filing a new-drug investigational plan (IND) giving the results of animal tests and detailing proposed research protocols for human tests. The FDA was also given the power to halt new-drug investigations if it felt that any data supplied at that point or later threatened the safety of human volunteers. In view of prior experience, however, this new power was not required to improve safety. E. A. Carr, discussion in "Clinical Pharmacology and the Human Volunteer," *Clinical Pharmacology and Therapeutics*, vol. 13, no. 5, Part II (1972), pp. 790-795.

[7] Professor David Schwartzman, in *The Expected Return from Pharmaceutical Research* (Washington, D.C.: American Enterprise Institute, 1975), estimates that the average research and development cost of a new chemical entity as of 1973 amounted to $24.4 million (p. 28) exclusive of the cost of capital invested in research and development. As of 1960, he estimates research and development costs per new chemical entity of $1.3 million (p. 42). This eighteen-fold increase in costs would have been only a nine-fold increase according to independent estimates by Professor Sam Peltzman (*Regulation of Pharmaceutical Innovation* [Washington, D.C.: American Enterprise Institute, 1974], p. 112), and Professor Martin Baily ("Research and Development Cost and Returns: The U.S. Pharmaceutical Industry," *Journal of Political Economy*, vol. 60, no. 1 [January/February 1972], p. 78) if the 1962 amendments had not been passed. The nine-fold increase was expected to occur because of the increasing amount of testing for safety as new procedures were developed enabling the performance of new tests and because of inflation. An indirect confirmation of the doubling of research and development costs caused by the 1962 amendments is provided by Britain's National Economic Development Office, *Focus on Pharmaceuticals* (London: Her Majesty's Stationery Office, 1972), which pointed out that "the UK's innovative efficiency was between 2 and 2½ times that of the U.S." (p. x).

[8] Symms Bill—H.R. 14426; Kennedy-Javits Bill—S. 2697; Rogers et al. Bill—H.R. 14289; all 94th Congress.

[9] This is, in part, a consequence to be expected from the bias in the assembly of data concerning the effects of a drug released for general use. Professors Lasagna and Wardell point out that "A situation has arisen in which we now have methodology available which, while defective, is being used to estimate the total harm of drugs to the community; but we have no comparable methodology available for measuring the total benefit of drugs to the community." (*Regulation and Drug Development*, p. 95).

Perhaps the perversity of FDA reviewing officers stems fundamentally from the role in which they have been cast. Legislation has cast those who would market the medicines we need in the role of malefactors intent on robbing the public by selling ineffective drugs—malefactors quite as willing as burglars with guns to damage those from whom they seek to extract funds. Reviewing officers, then, think of themselves as policemen stopping burglars from plying their trade. They cast themselves in the role of stopping new drugs from reaching the market where they would defraud and damage unsuspecting customers.

[18] The widened array of choice is important in the treatment of patients even if the new drugs are no more effective than those already available. Professor Wardell has pointed out that "Failure to show a difference in efficacy between a new drug and an older one should not be taken to mean that the new drug cannot be a worthwhile advance. . . . First, each drug's efficacy may be exerted on a different segment of the population; if both drugs were available, the proportion of patients treatable might be much higher than if either drug were available alone. By the same argument, a drug that is 'on average' less effective and more toxic than existing therapy may still be highly desirable for some segments of the population. Our current simplistic statistical concepts of efficacy and safety usually fail to take this into account. Second, it is common to find that the spectrum of side effects differs for each drug, or that the pharmacokinetics are different enough to confer different dosage regimens upon each drug. Third, in the actual treatment of many types of conditions, a patient should receive several drugs in turn on a trial-and-error basis until the one that is best for his needs is determined empirically. These realities of therapeutics for individual patients are generally ignored in the current requirements for evidence of drug efficacy. All these factors can be crucial for tailoring therapy to an individual patient to achieve maximal efficacy, safety, comfort, convenience, and compliance with the therapeutic regimen. To achieve these goals it is desirable to have a number of alternative therapies from which to choose." Wardell, "Therapeutic Implications of the Drug Lag," p. 76.

We have received little benefit from the 1962 amendment, and we are paying large penalties. The sick are being deprived of effective treatment for some of their ailments. Drugs, some of which are drugs of choice, are available abroad but not here. The rate of pharmaceutical innovation has been depressed, further depriving those in need of effective treatment. The international position of the U.S. pharmaceutical industry has suffered a setback that is apparently growing more severe. Our share of innovations is declining and pharmaceutical research is shifting to overseas locations.[20] This is having undesirable effects on the value of the dollar and on U.S. prestige, and a secondary impact (which has not yet been measured) is likely to be shown in depressed support for academic pharmacology and less rapid advance in basic knowledge. These are all "benefits" of the 1962 amendments which I, for one, am quite willing to do without.

Yale Brozen

Graduate School of Business
University of Chicago

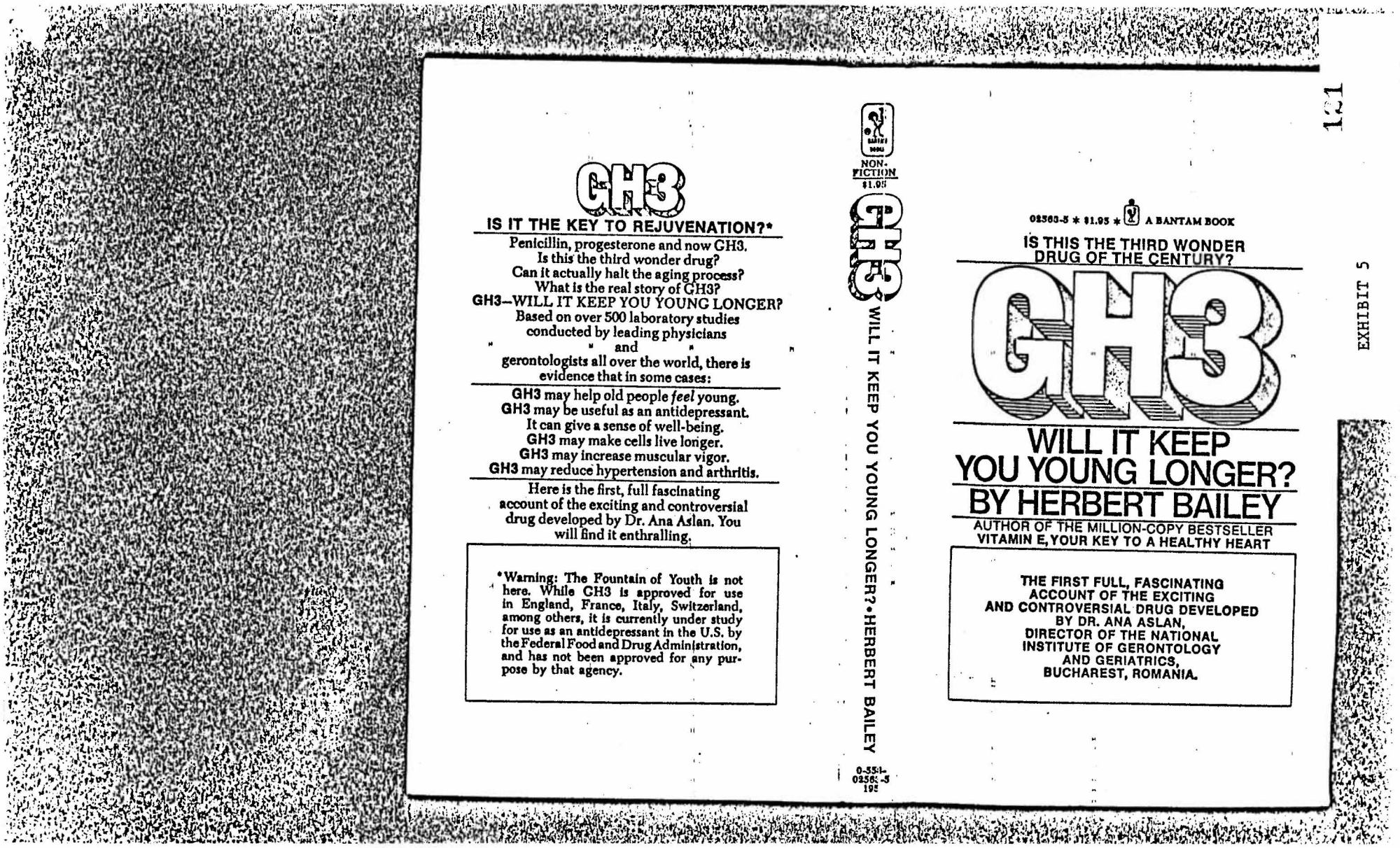

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EXHIBIT 5

Also, the conditions which GH3 benefits are related in one way at least: they are associated with the aging process. It is logical that if you have a substance which will biologically retard, or in some cases, roll back the process we call aging, it should affect every aspect of aging.

It is easier to test the effects on just one condition—which is what the present series of tests in the United States are doing. Old-age depression. This may seem too narrow to some; but according to the FDA and other medical authorities, depression is one of the most important ailments afflicting man. They claim it is easier to ascertain in a short time if a substance is efficacious than to perform an experiment on longevity or experiments with heart disease or cancer.

Furthermore, if old-age depression is benefited, so will the other accompanying maladies—if the substance is universally beneficial. And that is just what has happened in the United States experiments. Concomitant ailments have been favorably affected as well as depression.

The most effective refutation of the critics who say GH3 hasn't been studied scientifically is to examine a mammoth experiment by Dr. Aslan, her colleagues at the Institute of Geriatrics, Bucharest, and 400 other doctors in Romania. The study further refutes those who say that even if GH3 acts against old-age symptoms and diseases, you cannot prove it *prevents* aging; that if we start taking GH3 at say, 30 or 40, we won't be subject to those all-too-familiar symptoms of aging. No proponent of GH3 ever claimed it would *prevent*

aging; only the critics use these terms to obfuscate the real value of GH3.

Dr. Aslan's study on the prophylactic qualities of GH3, most carefully conceived, executed and recorded, answers all the critics' skepticism by overwhelming, incontrovertible evidence. (See Appendix 2.)

Never before has such a scientific antiaging program been conducted on such a large scale and with such scientific thoroughness. It should (and will) make her critics hang their heads in something resembling shame, or at least contrition, for not having examined the evidence before criticizing.

First, the experiment was staggering in its size and scope. Convinced by previous studies during a twenty-year period that GH3 was not only an effective antiaging factor in the aged, but would act as a preventive of aging as well, Dr. Aslan—working, or course, with the government of Romania—established 144 centers throughout Romania, in factories and other industrial sites, and in agricultural areas.

There were 15,000 people tested, ages 40 to 62. The experiment lasted two years before Dr. Aslan correlated the data and reported to the International Symposium of Gerontology (Bucharest, June 1972). The study is still continuing in many phases.

The main objective was to "prolong the active life period of workers, especially of those undergoing a temporary working incapacity, and to prevent the process of infirmity."

All these active, elderly working people received every health-saving aid known to medical science. In addition, 4121 received GH3, while 2905 did not, acting as a control group. To repeat, they all got the same medical treatment in every other respect; all underwent a battery of 11 objective physiological and biochemical tests. For the first time in medical history, a controlled study was being made on a mass scale, testing an antiaging substance. Remember, these were healthy yet aging people, active at all types of work, under all conditions, indoors and out, country and city, being tested where they worked—not in a hospital. In

short, an excellent cross-section of average, so-called normal men and women.

The tests, made at regular intervals, included weight, pulse, blood pressure, breathing frequency, muscular strength, cardiovascular tests before, during, and after exercise, blood sedimentation rate, number of red and white blood cells, total lipidemia (amount of fats, such as cholesterol in the bloodstream), spirometry (measurement of air capacity of the lungs).

Some results follow.

1. Blood pressure: those treated with GH3 showed an improvement (normalization whether high or low) of 85% compared to only 61% in the group which received the same medical care but no GH3.

There were other therapeutic effects besides normalizing of blood pressure. For example, among the elderly workers, there were naturally some who had cardiovascular problems in addition to hypertension (in some cases, caused by hypertension). Since GH3 is a vasodilator (opening the arteries) in addition to exerting a beneficent effect on each cell, heart problems were improved by 83.2% in the GH3-treated patients vs. 63.8% of the controls.

Probably the most significant findings were the *prophylactic* results. Many subjects were normotensive: they had normal blood pressure, but should, according to previous reports, gradually change for the worse (either up or down) during the two-year study. Patients treated with GH3 maintained their normal blood pressure in 97.2% of the cases, while only 2.6% showed a decrease in arterial pressure; 96% of the controls maintained normal blood pressure. (Any departure from the norm is bad—contrary to popular concept, low blood pressure, frequently seen in aging persons, is just as deleterious as high blood pressure—also frequently seen.)

2. Pulse rate: in patients with tachycardia (high pulse rate over 90 beats per minute), the pulse was normalized in 93%, while subjects with bradycardia (low pulse rate) were also normalized. Results in the control group were not as good. GH3 also intensified the

action of specific medicines (such as digitalis and strophantin) in patients with cardiac insufficiency (where the heart does not operate efficiently). In fact, all heart and blood pressure medicines could be significantly reduced with GH3 therapy.

3. Cardiovascular effect: those showing a low score of heart effort at the initial examination were improved after six months, 48.4%; 12 months, 56.0%; 24 months, 60.0%. For those patients who had a good or fairly good cardiovascular effort score to begin with, GH3 maintained most of them at the same level for two years—when it might be expected they would slowly decline because of their age.

4. Muscular strength: in clinically healthy patients under GH3 therapy there was a gradual improvement; after two years about one-fourth, or 23.9%, showed improvement while only 3.5% declined—72% were unchanged. These are remarkable figures because a gradual decline in muscular power almost always occurs in people of that age bracket (40 to 62). The improvement occurred in twice as many of the GH3-treated group as in the control group, which proves again GH3's dramatic role in preventing or reversing the age process in over 96% of the treated patients in this highly important test.

5. Respiratory capacity: after 24 months 96.1% of the GH3-treated group were unchanged in lung capacity compared to 91.2% of the control group. This may not seem much, but lung capacity goes rather quickly in late middle age. At about 70 the average person has lost over 40% of the lung capacity he had at 25. This decrease is bound to affect all other systems of the body, heart, kidneys, liver, brain—in short, the whole body; since the oxygen so vital to every cell is drastically reduced, the other systems are naturally affected too. That is why oxygen-conserving substances such as GH3 and vitamin E are essential.

Now consider another phase of the prophylactic effect of GH3, just as objectively, scientifically demonstrated as the medical test results. The number of days of medical leave due to sickness required by GH3-treated patients diminished nearly 40% compared to the pretest

years. Also, 77% performed their production norms (a standard set by calculating what the majority of workers achieve), 20% exceeded them, and only 3% of the elderly failed to achieve the norms. This is truly remarkable, since even maintenance of the norm is not expected at this age level. We must remember that every person received all the medical attention possible. Therefore, any difference between the GH3-treated group and the GH3-untreated must be attributed to the action of GH3, the only added factor.

No mention is made of any factor that cannot be objectively measured, either by physical medical tests or by mathematical computations. There is no mention of depression, mood elevation, happiness, or any of the hundred or so other psychological factors which affect the human equally as much as the physical—yet are harder to measure and correspondingly harder to convince die-hard skeptics about.

Here we have all the necessary ingredients for a truly objective, unarguable experiment. It would be hard to argue against the Romanian government that GH3 is all a grand delusion, that it's all in the workers' minds that they feel better and are able to produce better and live healthier. The Romanian government has the facts now. That is why the fact that Romania continues to support GH3 is solid testimony to the fact that it works; research costing millions of dollars would not be supported without some practical results. The government would not continue to spend millions treating its middle-aged and elderly workers with GH3 unless it paid off in the workers being healthier, more interested in their work, and expanding their effective working life.

Preface

In a book of this nature which requires years of research and writing, there are necessarily hundreds of persons to whom I am indebted. As much as I would like, I cannot list them all. (Several are listed specifically on the Acknowledgments page.)

However, the cooperation of the researchers involved in Gerovital H3 is most appreciated. Although the researchers were separated by many thousands of miles—from Massachusetts to Florida; from New York to California to Washington, D.C., to North Carolina—they were united in a common cause: to find out the truth about Gerovital H3. And these places only mark the major research locations in the United States. Extensive research on the antidepressant, anti-aging qualities of Gerovital H3 has been going on in Romania and other European countries for nearly three decades. Yet it was in the United States with testing beginning in 1973 under Federal Food and Drug Administration supervision that the controversy over GH3 appears to have been resolved in a manner which must please all true scientists. This is due to multi-phase testing on humans including several "double-blind" studies. There is also confirmation in many laboratories on animals and on their cells and tissues—all by brilliant researchers whose works cannot be contravened because the conclusions are so overwhelming when viewed in their entirety.

The rapport I established with these eminent researchers through close communication and frequent visits was most essential to the type of book I, as an independent writer, demand. The manuscript was sub-

mitted to those researchers working under the FDA-supervised project for their comments, corrections and insertions. Almost all made suggestions which I was grateful to incorporate in the book to avoid technical errors. Almost all were pleased with the book itself, which in turn, pleased me.

Several knowledgeable observers have predicted that Gerovital H3 may prove to be the third "wonder drug" of modern times—the other two being Penicillin and the Pill.

There have been many so-called "wonder drugs" in the last 30 years. Some have proved to be much less than wonderful and have been cast into the medical waste-heap. Some have proved useful for specific conditions and are included in the ever-growing list of worthwhile drugs doctors need for specific conditions —these drugs can and do save many lives.

But it is difficult to imagine a near-universal antidote for depression and even harder to stretch the imagination still further and conceive that such an agent could also be an antidote for the signs and symptoms of aging—and that it might actually be one of the long sought for substances necessary to counteract man's most ancient enemy.

As an investigative writer-reporter for many years without any real challenges to my published books or articles—I can say that I agree with the majority of GH3 researchers: that GH3 is a safe effective medication, proved clinically on thousands of people and now proved in the laboratory. It is no longer a theory. It is a fact.

Therefore, I believe that any investigative writer, after having examined the facts logically, objectively, should take a stand in defense of the truth of which he writes. He should present all sides, of course, but still have the courage to report the facts no matter what ensues. This I believe I have done in this book, and the researchers believe so, too, as they have stated.

We think we are on the eve of a great breakthrough in the history of the human race. Yet even if GH3 is only a unique antidepressant without side effects, we would still be achieving a major victory, for almost

every member of our race suffers from depression, and as we progress toward our transfer to another dimension, depression and its apocalyptic partners are almost universally with us. We are now apparently in possession of Siegfried's Magic Ring—which while not yet conferring the immortality of the Gods, will enable us to undertake our lives on this planet with lengthened and broadened understanding; therefore with greater majesty and dignity when we are eventually faced with aging, old age and death.

Herbert Bailey
Sandy Hook, Connecticut
July, 1976

95TH CONGRESS
1ST SESSION

H. R. 54

IN THE HOUSE OF REPRESENTATIVES

JANUARY 4, 1977

Mr. SYMMS (for himself, Mr. BEDELL, Ms. CHISHOLM, Mr. COCHRAN, Mr. COLLINS of Texas, Mr. CRANE, Mr. HAMMERSCHMIDT, Mr. KELLY, Mr. KETCHUM, Mr. KINDNESS, Mr. LAFALCE, Mr. LAGOMARSINO, Mr. LOTT, Mr. MCDONALD, Mr. SANTINI, Mr. TREEN, Mr. WAGGONNER, Mr. BOB WILSON, Mr. CHARLES WILSON of Texas, Mr. HALL, and Mr. MARTIN) introduced the following bill; which was referred to the Committee on Interstate and Foreign Commerce

A BILL

To expand the medical freedom of choice of consumers by amending the Federal Food, Drug, and Cosmetic Act to provide that drugs will be regulated under that Act solely to assure their safety.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That (a) sections 201(p) and 201(w) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 (p), (w)) are each amended by striking out (1) "and effectiveness" each place it occurs, and (2) "and effective" each place it occurs.

I

EXHIBIT

In a report published in MEDICAL WORLD NEWS, a McGraw Hill Publication, on April 6, 1973, Volume 14, No. 14, Dr. Elmer Gardner, the then head of the FDA's Division of Neuro-Pharmacology, was quoted with regard to Gerovital H3 as follows:

"There is no safety problem with the drug and the Rumanian producer has agreed to good standards of manufacture. Also, claims for the drug have been reduced from the ridiculously extravagant ones of several years ago. Fighting geriatric depression is a perfectly viable rationale for testing a drug, and such a limited claim makes valid testing possible."

EXHIBIT 128

STATE OF TENNESSEE
Department of Mental Health and Mental Retardation

VANDERBILT UNIVERSITY
School of Medicine

TENNESSEE NEUROPSYCHIATRIC INSTITUTE
1501 Murfreesboro Road · Nashville, Tennessee 37217
Telephone (615) 741-7431

February 28, 1977

State of Nevada
Legislature Assembly
Commerce Committee
Carson City, Nevada

Gentlemen:

My attention has been directed to the fact, that you are considering legislation to legalizing the use of Gerovitol H_3 in the State of Nevada. In this connection, I thought it might be helpful for you to have a record of some of our experiences with this medical product.

A few years ago Dr. H.E. Lehmann and I were contacted in Montreal to set up a clinical study with Gerovitol H_3. After a careful study of the literature on the drug and with consideration to Dr. Lehmann's previous experience with procaine (in a study in which he had collaborated with Dr. V.A. Kral), we designed a double-blind, placebo-controlled, clinical study with 40 depressed psychogeriatric outpatients. This study started approximately two years ago in collaboration with Dr. M. Amin and is still underway. Since the code has not been broken, we cannot make any comments on the therapeutic findings in it. On the other hand, on the basis of our experience with the 33 completed patients in this study, we can state that no serious adverse effects have occurred.

I hope you will find this information useful in your deliberations.

Yours truly,

Thomas A. Ban, M.D.
Professor of Psychiatry

TAB/sc

EXHIBIT

Feb. 22, 1977

Dear Sir:

For the past three years my Mother, Mrs Irene Kunkel, has been receiving the Gerovital H 3 injections throufhg Dr. Keith Dittman. He informed her that he is now unable to obtain the product and to check with you people. Is there anyone in the Phoenix area that is doing the trial shots.

My Mother feels so m uch better when she is on shots and would like to continue with them. If there is no one here, perhaps she gould go to the Dr. in Las Vegas or another Dr. in Beverly Hills. After all this testing, I truly hope the FDA will allow it to be put on the market. My Mother is 77 yrs old and is in so much better all round condition.

Please let me hear from you,
Lois Jones
6927 E. Glenrosa Ave
Scottsdale, Arizona 85251

EXHIBIT 130

LEONARD CAMMER, M. D.
110 EAST 82ND STREET
NEW YORK, NEW YORK 10028

TELEPHONE (212) 288-4546

February 26, 1977

The Assembly Commerce Committee
State Legislature
Carson City, Nevada

Gentlemen:

Inquiry has been made as to my experience in the investigation of Gerovital H3. I am also advised that you are considering legislation which will legalize the use of Gerovital-H3 by prescription in the State of Nevada. I would endorse such legislation.

I am a physician, specializing in psychiatry, and licensed to practice in New York and Arizona. I am a Diplomate of the American Board of Psychiatry and Neurology, a Fellow or member of numerous psychiatric, medical and scientific societies, former Clinical Associate Professor of Psychiatry at New York Medical College and the author of three books and over 50 scientific papers in clinical research and experience.

In May, 1975 I undertook a double blind study of Gerovital H3 on 40 men and women at, or past their menopausal period to evaluate the efficacy and safety of this drug in the treatment of depressive disorders. The 20 patients who received Gerovital H3 intramuscularly for a 4 week period improved notably. The 20 patients in the placebo group did not.

Evidence of efficacy was obtained from a variety of psychiatric scales that measured depression, personality function, social activity, free time activity and clinical global impressions of illness and improvement. The administration of Gerovital H3 produced significant improvement on all scales.

Evidence of Safety was measured by before-and-after blood chemistries, blood counts and urinalysis. The drug was found to be safe, with no substantial side effects or changes in body chemistry.

My studies showed that the majority of the patients who received Gerovital H3 accepted the drug with enthusiasm because of the physical and mental benefits derived. It was my strong impression that the drug has therapeutic merit as a psychic energizer with negligle, if any, risks attendant upon its proper administration.

Sincerely yours,

Leonard Cammer

LEONARD CAMMER, M.D.

LC:ic

Exhibit "D"

Max Hayman, M.D.

160 LURING DRIVE
PALM SPRINGS, CALIFORNIA 92262
(714) 327-8813

March 1, 1977

TO WHOM IT MAY CONCERN:

I have been asked to write on experiences with a procaine derivative for the treatment of depression (formerly called Gerovital H_3). We have carried on two studies, the data on one having been published in Psychosomatics 1976:Vol XVII:No. 2, called "A Procaine Derivative for the Treatment of Depression in an Outpatient Population: A Double-Blind Study." The data on this paper showed clearly that the vast majority of patients on this medication improved significantly. They included different types of depression. Since this was a carefully studied double-blind experiment and since levels of significance on the order of .001 were obtained, it indicates the great advantage of having such a medication for depression. Depression is rapidly becoming the most prominent psychiatric condition. This paper has been published and is available for investigation.

In addition to the above study, we have carried out another experiment utilizing the same medication in an open study with 55 patients. The data on this study have been collected, but not written up as yet. However, the results of this study were as significant as the above, with a level of significance on the order of .001+.

Again, a variety of different types of depression were treated in this case as well. We also found that the younger patients did equally as well as the older patients, although it had been accepted that this was a treatment for older patients.

We have carried on many other studies with different medications, and we must say that our results with this medication have been superior thus far to most of the other antidepressant medications, good as some of them have been.

We can also say that the side effects of the medication were minimal and no subject who took part in the experiment had to give up the project.

I would be happy to have the medication available for patients, and we would be happy indeed to carry on further studies with the medication in different types of patients with this condition.

Sincerely,

Max Hayman

Max Hayman, M.D.
Consultant to Desert Hospital
Mental Health Center

MH:rs

CURRICULUM VITAE

Morton L. Kurland, M. D.

PERSONAL DATA:

Clinic Office Address:	Desert Hospital Mental Health Center 1150 Indian Ave. (P.O. Box 1627) Palm Springs, California 92262 Telephone: 325-9166
Private Office Address:	160 Luring Drive Palm Springs, California 92262 Telephone: 327-2813
Birth Date:	September 29, 1932 - Richmond County, New York
Married:	June 10, 1956
Children:	Four daughters
Military Service:	1956-59 U.S. Public Health Service (including U.S.C.G. Tour)

EDUCATION:

Wagner College, Staten Island, New York - B.S. 1952
State University of New York, Downstate Medical Center - M.D. 1956

POST-GRADUATE TRAINING:

Internship - U.S. Public Health Service Hospital, New York		1956-57
1st Year Psychiatric Res.	- U.S.P.H.S. Hosp., Lexington, Ky.	1957-59
2nd Year " "	- V.A. Hospital, Bronx, New York	1959-60
3rd Year " "	- N.Y. State Psychiatric Institute	1960-61
Psychoanalytic Candidate	- William Alanson White Institute	1963-64

PROFESSIONAL EXPERIENCE:

1971-Present:	Medical Director, Desert Hospital Mental Health Center
1970-71:	Clinical Associate Professor of Psychiatry, College of Medicine of New Jersey, Newark; Director, Outpatient Clinic, East Orange, New Jersey
1964-1970:	Assistant Professor of Psychiatry, Post-Graduate Teaching, New Jersey College of Medicine & Dentistry
1963-1964:	Senior Instructor of Psychiatry, Drug Research, Seton Hall College of Medicine
1962-1963:	Instructor of Psychiatry, Psychosomatic Medicine, Seton Hall College of Medicine

CURRICULUM VITAE

Morton L. Kurland, M. D.

LICENSURE, DIPLOMATES & FELLOWSHIPS:

Medical License, State of New York, 1959
Medical License, State of New Jersey, 1960
Medical License, State of California, 1961
Diplomate, National Board of Medical Examiners, 1957
Qualified Psychiatrist (QP), State of New York, 1963
Diplomate, American Board of Psychiatry & Neurology, 1964
Fellow, American Psychiatric Association, 1970

ACADEMIC APPOINTMENTS:

Associate Clinical Professor, Department of Psychiatry,
U.S.C. School of Medicine, Los Angeles, California, 1972-Present
Adjunct Professor of Psychology, Pepperdine University, Desert Div.

HOSPITAL APPOINTMENTS:

Consultant in Psychiatry:

N.J. State Hospital, Marlboro, N.J.	1963-68
N.J. State Hospital, Trenton, N.J.	1962-67
V.A. Hospital, East Orange, N.J.	1963-71
Eisenhower Medical Center, Palm Desert, California	1972-Present
Angel View Crippled Children's Hospital, Desert Hot Springs, California	1971-Present

Attending Staff:

Desert Hospital, Palm Springs, Calif.	1971-Present

PROFESSIONAL ORGANIZATIONS:

American Psychiatric Association	1962-Present
American Medical Association	1957-
Society for Adolescent Psychiatry	1969-Present
N.J. Neuropsychiatric Association	1964-71
So. Calif. Neuropsychiatric Association	1971-Present
International Society for Existential Psychiatry	1969-72

16. Depressive Neurosis: Disease of Many Disguises - Clinical Medicine, Vol. 83, No. 9, pp 13-16, September 1976.

CURRICULUM VITAE

Morton L. Kurland, M. D.

ADDENDUM

CLINICAL RESEARCH ACTIVITIES:

1. During residency and as an associate with two other physicians, we researched and later published studies having to do with the use of Librium in the treatment of alcoholic patients. 1960

2. As a member of the faculty of Seton Hall College of Medicine, I was asked to review and comment upon certain sections of the AMA publication "New & Unofficial Drugs," specifically in relationship to psychotropic drugs and to evaluations of the research design, clinical trials, etc. 1962-63

3. Upon assuming directorship of the Palm Springs Mental Health Center, I completed a study originally undertaken and largely worked on by Max Hayman, M.D., having to do with the drug Tranxene. 1971

4. A study on the comparative use of Mellaril and Valium for the Sandoz Pharmaceutical Corporation was completed during the 1972 calendar year involving 1,296 patients, and presented as an exhibit at the AMA Convention in New York City in 1973. 1972

5. I completed a project for the use of Librium in chronic schizophrenic patients who were already on major tranquilizers. The use of Librium was an adjunct to the major tranquilizer, and we studied twelve severely disturbed patients, completing extensive reports on eight of them. 1972

6. A brief study on cardiovascular effects of anxiety and tension vis-a-vis blood pressure readings in different physical positions.

7. Two studies recently completed involved the comparative double-blind use of Mellaril, Serentil, and a placebo. One study involved 100 outpatients in the Mental Health Clinic, and the other involved 75 geriatric patients in a nursing home. The results of these studies are being evaluated presently. 1973-74

8. A study in the use of Gerovital H_3, an injectable moderate to weak monoamine-oxidase inhibitor, in the treatment of depressive patients ages 45 and older. Done in conjunction with Max Hayman, M.D., on 60 patients. 1974

CURRICULUM VITAE

Morton L. Kurland, M.D.

ADDENDUM

CLINICAL RESEARCH ACTIVITIES: (continued)

9. A study involving 100 patients in conjunction with the Schering Corporation, of Bloomfield, New Jersey, testing the chronic toxicity and possible neurological effects of the new benzodiazepam product which they have produced (Halazepam), as well as its efficacy, double-blinded, against Valium. 1974-75

10. A study involving 20 patients (with Max Hayman, M.D.) on Lenperone, a major antipsychotic agent for the A.H. Robins Company, of Richmond, Virginia. 1975

11. A follow-up study on Gerovital H_3 (procaine hydrochloride derivative) for Rom-Amer Ltd. on 100 open patients, with Max Hayman, M.D. 1975

12. A study involving 45 patients testing double-blinded a new antianxiety agent (Ketazolam) for the Upjohn Company, Kalamazoo, Michigan. 1975

13. A study on 30 patients testing h.s. doses of Librium for Hoffmann-La Roche, Inc., Nutley, New Jersey 1975

14. A study of 60 patients for the Hoechst-Roussel Company, of Somerville, New Jersey, involving a new antianxiety agent (Clobazam), double-blinded vs. placebo. 1976

15. A study of 70 patients with primary depression for Hoffmann-La Roche, Inc., Nutley, New Jersey, quadruple-blinded. 1976

16. An ongoing study of 35 depressed patients over 65 years of age for Hoechst-Roussel, Inc., Somerville, New Jersey. 1976-77

Exhibit "E" -1-

IN THIS LIFE WE ARE SOMETIMES LUCKY ENOUGH TO COME IN CONTACT WITH BRILLIANT, DEDICATED PEOPLE WHO WORK MIRACLES FOR THOSE AROUND THEM. DOCTOR HANS NEIPER IS JUST SUCH A "MIRACLE MAN". THROUGH HIS DEDICATED CARE AND THE DRUG LAETRILE I WON A GRUELLING BATTLE WITH DEATH AND OVERCAME ONE OF MAN'S WORST ENEMIES. . . . . CANCER!

CANCER OF THE TONGUE STRUCK LONG BEFORE I KNEW I HAD IT. THE FIRST SIGN WAS A TERRIBLE CRAMPING IN THE RIGHT SIDE OF MY NECK EACH TIME I SWALLOWED. THIS WENT ON FOR ABOUT SIX MONTHS BEFORE I FINALLY DECIDED TO SEE MY DOCTOR IN COLORADO.

HE FELT IT WAS CANCER. A BIOPSY CONFIRMED THE FACT. WHEN YOU STARE DEATH IN THE FACE, A LOT GOES THROUGH YOUR MIND - BUT MOST OF ALL, YOU THINK, "I DON'T WANT TO DIE".

TO L. A. AND ST. JOHN'S HOSPITAL FOR OUT-PATIENT TREATMENTS OF COBALT. AFTER NINE SUCH TREATMENTS, (3,000 RADS) I BECAME SO ILL, I LOST MOST OF MY SENSES. AFTER THAT, IT WAS DECIDED M. D. ANDERSON CANCER CLINIC IN HOUSTON, TEXAS WOULD BE BEST FOR ME. WITHIN TWO AND A HALF MONTHS I WAS SUBJECTED TO 6,000 RADS OF ALTERNATE COBALT AND BATATRON TREATMENT, WHICH MADE 9,000 RADS ALTOGETHER, ENOUGH, I AM TOLD, FOR A FULL-GROWN MAN OF 200 POUNDS.

MY MOUTH AND THROAT HAD BEEN BURNED DRY OF SALIVA. LATER, RADIATION SORES BEGAN APPEARING ON THE OUTER SKIN OF MY TONGUE. THE DOCTORS ASSURED ME THAT MY SALIVA WOULD RETURN WITHIN SIX MONTHS. TODAY, IT HAS BEEN ALMOST THREE YEARS, AND I STILL HAVE NO SALIVA.

DESPITE THE AMOUNT OF RADIATION GIVEN TO ME, (BIOPSY STILL SHOWED PERSISTIN + GROWING CANCER) THE TREATMENTS WERE UNSUCCESSFUL./ OPERATING WAS THE ONLY CHANCE LEFT, AND THAT WAS ONLY A 30% CHANCE. THIS OPERATION WOULD HAVE REMOVED MY TONGUE AND PART OF MY FACE AND NOSE. AS ANY WOMAN (WITH EVEN HALF HER SENSES) WOULD DO IN THIS SITUATION, I TOLD MY HUSBAND TO JUST LET ME DIE. HOWEVER, HE NEVER GAVE UP HOPE OR STOPPED TRYING.

HE TOOK ME BACK TO LOS ANGELES AND ST. JOHN'S AGAIN.

DUE TO INCINERATION OF MY THROAT, I WAS UNABLE TO EAT OR SWALLOW ANYTHING, SO A TUBE HAD TO BE PLACED DIRECTLY INTO MY STOMACH FOR FEEDING.

MY CHANCES OF SURVIVAL WERE ZERO, AND I WAS FINALLY SENT HOME WITH TERMINAL STAMPED ON MY CASE.

BUT, MY HUSBAND LEFT NO STONE UNTURNED. THROUGH A NUTRITION STRESS RESEARCH FOUNDATION HE BELONGED TO HE HEARD OF A SO-CALLED MIRACLE DRUG. . . . . THAT SO-CALLED MIRACLE DRUG WAS LAETRILE. HE ALSO FOUND THAT IT WAS AGAINST THE LAW IN AMERICA, AND THAT ONE OF THE FEW PLACES IT COULD BE ADMINISTERED WAS GERMANY. SO, I WAS FLOWN THERE IMMEDIATELY.

IT WAS THERE THAT I FIRST MET DOCTOR NEIPER; AND, IT WAS THERE THAT I FIRST MET LAETRILE, WHO WOULD EVER BELIEVE THAT THE SIMPLE LITTLE GOD-CREATED PIT OF AN APRICOT COULD ARREST AND DESTROY ONE OF THE MOST DREADED DISEASES OF MANKIND!

MY FIRST EXPERIENCE WITH LAETRILE WAS NOT A PLEASANT ONE. DOSES OF IT WERE INJECTED IN THE BASE OF MY TONGUE. NOT LONG AFTER, THANK GOODNESS, I GRADUATED TO LAETRILE PILLS. IT WASN'T LONG BEFORE THE

MEDICINE BEGAN WORKING, AND SOON AFTER, I FELT MY STRENGTH AND SENSES COMING BACK.

ONE OF THE WONDERFUL THINGS THAT HAPPENED WAS THAT I NO LONGER NEEDED TO TAKE PERKADIN TO EASE THE TERRIBLE PAIN. IN LOS ANGELES, I HAD BEEN TAKING PERKADIN (WHICH IS A FORM OF MORPHINE) EVERY TWO HOURS. MY HUSBAND FEARED THAT, EVEN IF THE CANCER COULD BE CURED, I WOULD REMAIN A HOPELESS DRUG ADDICT THE REST OF MY LIFE. BUT GOD PULLED ME THROUGH, AND I FOUND THAT WHEN I NO LONGER FELT PAIN, NEITHER MY MIND NOR MY BODY HAD GROWN DEPENDENT ON THE PAIN KILLER.

IN THE SIX WEEKS I SPENT IN GERMANY, LAETRILE BECAME AS MUCH A PART OF ME AS EATING, AND, DR. NEIPER BECAME AS MUCH A PART OF MY HEART AS BEATING. THANKS TO HIM, MY HUSBAND, AND THE MIRACLE OF LAETRILE, I AM ALIVE AND STRONG. MY CANCER HAS BEEN CURED.

SINCE I AM STILL VERY SUSCEPTIBLE TO CANCER, IT IS NECESSARY FOR ME TO CONTINUE TO TAKE **LAETRILE** EVERY DAY. . . . . A SMALL SACRIFICE FOR LIFE.

I STILL SUFFER FROM MANY OF THE EFFECTS OF OVER-EXPOSURE TO RADIATION. THOUGH I HAVE NOT REGAINED MY SALIVA AND AM UNABLE TO TASTE ALMOST ALL FOODS, AND, THOUGH MY NERVES ARE SENSITIVE, DUE TO BEING BURNED INTENSELY, I STILL HAVE FAITH THAT SOMEDAY I WILL RECOVER COMPLETELY.

WOULD ANYONE LIKE TO ASK ANY QUESTIONS?

Exhibit "E-1"

Ladies and gentlemen

Mr. Chairman and members of the committee, I am Michael Culbert, Editor of The Choice, the magazine for Freedom of Choice in Cancer Therapy, Inc. It is an honor for me to address this meeting of the Nevada Legislature on a matter which is a life-and-death issue and one of deep political significance to the entire United States.

For five years, our organization has been leading the fight for the restoration of the doctor-patient relationship and for the ~~unhampered~~ use of Laetrile or Vitamin B17, and for the recognition of non-toxic, metabolic and nutritional therapy in disease. We now have 500 chapters and 30,000 members, among whom are some 2,000 individuals in the health-arts field, including well over 1,200 medical doctors.

Despite all the controversy and emotion over the issue of Laetrile or Vitamin B17, the passage of Assembly Bill 121 in Nevada should perhaps be looked upon as a simple matter of justice and common sense: it would restore the freedom of choice of physician and patient -- WITH THEIR INFORMED CONSENT -- to have access to an alternative, non-toxic cancer therapy.

This therapy, while now legally available in 27 other countries--the most recent being Israel, whose government sent a medical team to the United States and to Mexico to investigate the matter -- is regarded by our medical establishment as worthless. So be it. But it is also known to be harmless. If it is harmless, then there is simply no reason for the intervention of government into the doctor-patient relationship, particularly when dealing with a disease for which the so-called establishment has neither a known cause nor a known cure.

Please bear in mind that while we are discussing this subject today alone, 1,100 Americans will be dead by midnight either of cancer or from the TREATMENT of cancer--the standard,so-called orthodox treatment, which remains surgery, chemotherapy and radiation, or all of these. Chemotherapy, now regarded as a treatment of choice, is the administration of poisonous chemicals in a desperate effort to burn through the body's new tissues and kill cancer cells before these same poisons kill the patient or, as so frequently happens, so destroy the body's natural defenses that a minor infection does the patient in. Radiation is a blow-torch approach to destroying tumors. The fact of the matter is, the success rates of these so-called orthodox therapies have increased scarcely at all since 1950, a point emphasized last year in President Ford's Environmental Quality Council report. In many cases, chemotherapy and-or radiation do not work at all; in many others, they may actually cause the SPREAD of cancer. We will agree with orthodox medicine that a small percentage of people are today relatively free of the symptoms of cancer after undergoing these standard modalities--but this percentage is so small, that, in the analysis of physiologist Dr. Hardin Jones of the University of California, statistically a person with diagnosed cancer will live longer and feel better if he does NOTHING at all to his tumors.

The opposition likes to claim that Laetrile has been tested and re-tested without a shred of efficacy ever having been found. It also claims that Laetrile constitutes a gigantic ripoff of desperate patients by money-hungry ghouls. Let me deal with these two points right away:

First, it is difficult for physicians in this country to come forward with the carefully controlled experiments the FDA likes to look at because of a "Catch-22" concerning Laetrile:

One the one hand, the government is saying, "show us your evidence;" on the other hand, doctors who step forward and announce such evidence may be arrested, as in California, or find their licenses in jeopardy, as in Oregon, Alabama and several other states. At the same time, the government officially pooh-poohs the considerable foreigh research which has developed on Laetrile. The government also issues utter falsehoods concerning the embarrassingly positive results with Laetrile and Laetrile-like compounds achieved, for example, at Sloan Kettering Memorial Cancer Center in New York--where AT LEAST eight series of experiments in animals, and some in humans, have indicated Laetrile's cancer-inhibiting effects. The impressive foreign research in the medical literature IS known to the official establishment, coming from such centers as the Pasteur Institute in Paris, the von Ardenne Research Institute in East Germany, the clinic of Dr. Hans Nieper in West Germany, and the 50 or so published papers by Dr. Manuel Navarro of the University of Santo Tomas in the Philippines. Evidence also mounts from the thousands of cases developed for the Mexican government by doctors at the Tijuana clincs--many educated, by the way, in the United States. The only genuine tests American orthodoxy points to when claiming the failure of Laetrile happen to be the very dubious 1953 California Cancer Commission report, a close reading of which should convince anyone that even the 44 terminal, non-ambulatory patients to whom low dosages of Laetrile were administered UNIFORMLY FELT BETTER. Early positive responses

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in patients were also reported in medical literature based on the experience of Dr. Morrone in New Jersey. Some of the officially sanctioned animal studies referred to by the government are so statistically cumbersome that one of them -- the 1973 National Cancer Institute--Souther Research Institute research on Lewis lung tumors in mice -- has been denounced by a City of Hope Hospital analyst as, in his words, "a textbook example of how to lie with statistics." Other officially sanctioned animal reports used to discredit Laetrile also reveal that the animals involved underwent life-extension, whether their tumors decreased or increased. In this connection, it is increasingly the opinion of a growing number of physicians and researchers that the measuring of a chemical's effect on a tumor is no genuine indication of whether cancer ITSELF is being treated. In fact, treating lumps and bumps--the tumors, or symptoms--of cancer, is somewhat like treating as orthodoxy did for hundreds of years, the skin lesions of smallpox and syphilis in the vain and ignorant belief that by so doing they were attacking these diseases.

Orthodoxy's defense of its failure to curb malignant disease which is now striking 1 our of every 4 Americans, killing 1 out of every 6 or 1,100 per day, affecting 2 out of every 3 families, and which constitutes the number one killer of children to age 14 and the second killer of adults, is that cancer is really at least 110 separate diseases with as many more possible variations. Metabolically oriented doctors say "nonsense" cancer is a systemic, chronic, metabolic disease, and treating its symptoms--the tumors--is NOT an attack on the underlying disease itself.

As to Laetrile being a ripoff.

This charge overlooks the following facts:

EVEN in the so-called black market, Laetrile carries a 10 percent markup over the prices set--not by smugglers but by the Mexican government. The alleged markup of Laetrile over production costs of 900 percent, even if true--which it is not--would pale alongside the markup of EVERY SINGLE LEGAL CHEMICAL ENTITY ON THE MARKET TODAY IN THIS COUNTRY--a markup which varies not from a paltry 900 percent but from THIRTY-TWO HUNDRED TO SEVEN <u>THOUSAND</u> PERCENT.

As to the cost of Laetrile-based cancer treatment in this country and abroad, it happens to be far less than the cost of orthodox therapy, one which may now range anywhere from $15,000 to $80,000 per patient. If you multiply such figures times the 675,000 new cases of cancer to be diagnosed in this country this year, you will have some idea of the $25 billion-dollar-per-year cancer bill. Official medicine stands scientifically and economically in opposition to the simple, natural, unmysterious and, most importantly--UNPATENTABLE--Vitamin-like Laetrile, whose synthesis and refining from any of its 1400 natural plant sources could spell a potentially INEXPENSIVE treatment for cancer and offer the brightest of all hopes: PREVENTION of the dreaded disease.

I am not here to debate the merits of metabolic and nutritional therapy in cancer, but I do wish to state that information from our B17-using physicians in the United States and abroad indicates that Laetrile, as a central factor in metabolic therapy, is far more successful than so-called orthodox agents in arresting or controlling cancer. Our figures indicate that between 65 and 70 percent of cancer patients find at least SOME palliation or improvement by using the Laetrile program, particularly in relief from pain and improvement in the quality of life. These figures may be better appreciated when it is realized that more than 90 percent of patients on the Laetrile program are already considered "terminal"--that is, without hope.

So the question for these people is very simple: IF they are regarded by orthodox therapy as terminal, if orthodox therapy has been tried and failed on them, then by WHAT CONCEIVABLE RIGHT DOES THE FEDERAL STATE INTERVENE TO TELL SUCH A PATIENT AND HIS DOCTOR THAT THEY MAY NOT HAVE ACCESS TO A HARMLESS ALTERNATIVE CANCER THERAPY?

Bear in mind that this bill does not affect orthodox modalities in cancer treatment. Not at all. What it allows is freedom of choice--NOT the open sale of Laetrile over the counter, not a license for patients to treat themselves. All this bill states is that no physician shall be punished or harassed because he and his patient have mutually agreed they should have access to vitamin therapy in cancer.

The issue IS freedom of choice, not Laetrile itself. If Laetrile is as worthless as orthodoxyclaims, its use will soon fade away. But if it is a useful analgesic, or an excellent adjuvant therapy, or has any promise whatsoever, its availability to, and use by, Nevada physicians becomes a simple matter of justice.

THANK YOU FOR YOUR ATTENTION.

Exhibit "F"

SOME FACTS OF LIFE

~~You, as a member of the~~ are exercising sixty million words of unlawful law to conspire, impair, and infringe upon the rights of the free citizens and doctors of the State of Oregon, and of the United States of America, who just happen by the foresight of our founding fathers to be protected by the lawful laws as provided by this Nation.

THE LAW OF THE LAND.....

The general misconception is that any statute passed by legislators bearing the appearance of law constitutes the "Law of the Land"..The U. S. Constitution is the supreme law of the land, and any statute, to be valid, must be in aggreement.. It is impossible for both the Constitution and a law violating it to be valid. One must prevail. This is succinctly stated as follows:

"The general rule is that an unconstitutional statute, though having the form and name of law, is in reality no law, but is wholly void, and ineffective for any purpose; since unconstitutionality dates from the time of its enactment, and not merely from the date of the decision so brandin g it. An unconstitutional law, in legal contemplation, is as inoperative as if it had never been passed.. Such a statute leaves the question that it purports to settle just as it would be had the statute not been enacted..

"Such an unconstitutional law is void, the general principles follow that it imposes no duties, confers no rights, creates no office, bestows no duties, bestows no power or authority on anyone, affords no protection, and justifies no acts performed under it.

"A void act cannot be legally consistent with a valid one. An unconstitutional law cannot operate to supersede any exsisting valid law. Indeed, insofar as a statute runs counter to the fundamental law of the land, it is superseded thereby.

"No one is bound to obey an unconstitutional law and no courts are bound to enforce it."

This being our Bicentennial Anniversary it may be worth reviewing some of the events just prior to the signing of our Constitution. During the 10 day period before the formal birth of this Nation, Dr. Benjamin Rush, a prominent physician and delegate to the Constitutional Convention that wrote the Constitution of the United States of America proposed that the Bill of Rights contain an ammendement guaranteeing freedom of medicine.

The proposal was ignored because the other delegates were of the opinion that this right was included in all the other rights. It was not, and Dr. Rush's prediction that eventually medicine in the United States would be corrupted by a huge concentration of power has for all intent and purpose been verified.

"----------all men are created equal that they are endowed by their Creator with certain unalienable Rights that among these are Life, Liberty and the pursuit of Happiness. ----------"

There is no statute, rule, law, precedence or anything else that says I can not exercise my own judgement about what is best for the preservation of my life and health so long as in so doing I do not infringe upon the rights of my fellow humans.

Further as a Doctor of Medicine there is no statute, rule, law, precedence or anything else that says I must stop learning after graduating from Medical School and that I can not share my learning, knowledge, experience and abilities with any one who asks for it so long as I make no claims or recommendations that the personal experiences I have had are not necessarily applicable to the person asking about it.

On August 22, 1965 I suddenly experienced painless uminary tract bleeding. Cystoscopy, biopsy and radiography revealed a grade IV fungating flat based adenomatous papiloma of the bladder about the size of a golf ball with two metastatic osteolytic lesions in my 4th lumbar vertebrae. The bleeding was stopped by electro cautery. My life circumstances at that time made it imperative I assume responsibility for myself and decide what course to take. I reviewed all orthodox and non orthodox theories of malignancies and their their therapies.. The Trophoblast Theory of Dr. John Beard, a Scottish Embryologist at the turn of the Century made the most sense to me and was most consistant with my own extensive studies in embryology.. At that time, being a Fellow at UCLA Los Angeles I soon had a cross file of all literature on this aspect of the subject..I promptly made a phone call to Dr. Howard Beard of Texas (no relation to John Beard). On the phone I was given an outline of the therapy program and by airmail special delivery he sent me the specific literature and the necessary information for obtaining the necessary supplies. Needless to say I followed it carefully but secretly and am alive and well today. I can't go back and try another route to see if it would have been better or worse---I'm satisfied with the course I've taken. My profession can go to Hell about this issue.

In November 1966 I began to share my experience with other cancer patients.

victims. I saw only those who had gone the gamut of orthodoxy and had been told" there is nothing more we can do for You". As of June 30, 1976 I have seen 3,588 persons afflicted with cancer of every nature and description from all over the World. Roughly 1800 were still living and two of these from 1966. Of the 1800, one hundred ninety seven are for all intent and purposes well and healthy in total remission. The remainder are functioning reasonably well in a control state. Since January 1975 I've shared my experience with 73 persons who came to me for a "second opinion". To the best of my knowledge all 73 are following this program per primum on their own volition and so far as I know they are doing well. Time will tell.

My simple conclusion about all this is that an inverse relation exists between education, degrees, authority restrictive regulations and the depth of brainwashing with its concomitant limited horizon and the stifling of any new learning. That is the more the degrees and all else the greater is the brainwashing and less learning.

E. Paul Jedel M.D.

roughly 500 new CA Patients since July 1976 to Feb 28 1977

ROLAND C. BARTLETT
Managing Editor
Former Democratic Nominee
U. S. Congressman

★★★ PUBLISHED IN THE INTEREST OF 135,000 NEVADA DEMOCRATS ★★★

DEMOCRATIC NEWS

P. O. Box 11152 • Las Vegas, Nevada 89111 • Telephone (702) 734-1291

July 26, 1976 Exhibit "G"

Hon. Senator Gaylord Nelson
United States Senate
Washington, D. C.

Dear Senator Nelson:

I am writing this communication because of the editorial in the Jack Anderson column of July 21, 1976, concerning the private letter written to you from the FDA concerning Laetrile.

I believe that the FDA is not only distorting, but mutilating, and decapitating the truth.

Under separate cover I have mailed you two sixty minute each cassette tapes titled: "The Earth Without Cancer"; and "The Miracle Drug That Keeps You Young." I believe that both of my commentaries will substantiate my former remark.

Laetrile (B17) is a compound that is part of the nitriloside family which occurs abundantly in nature in over twelve hundred edible plants, and is found virtually in every part of the world. It is particularly prevalent in the seed of fruit, but also contained in grasses, maize, sorghum, millet, cassava, linseed, apple seeds, bitter almonds, and many other foods that, generally, have been deleted from the menus of modern civilization.

In the tiny kingdom of Hunza whose people are known the world over for their longevity and good health, visiting medical teams from the outside world report that there never has been a case of cancer in Hunza. They eat foods abundant in nitrilosides. The same applies to the Eskimos, the Abkasians near the Black Sea, the Hopi and Navajo Indians of North America, and certain native populations in South Africa, and South America. In Utah, which is seventy-three percent Mormon, the cancer rate is twenty-five percent below the national average.

Enclosed is a photo-copy of a letter that I have just mailed to Honorable Lawrence P. McDonald, Democrat Congressman from Atlanta, Georgia. The Congressman is also a Doctor and has been treating his patients with Laetrile.

Of particular interest is the news release dated April 24, 1976:

"U. S. District Judge Luther Bohanon granted permission to six patients for them to import Laetrile for their own use."

UPI news release, May 16, 1975. The average American works a month each year just to pay the doctors, hospitals, and health insurance companies, and by 1980 he will be working two months to cover those costs, Governor Patrick J. Lucey of Wisconsin said.

The morays of government who are denying citizens the right to determine their own destinies can be circumvented. Recently I was informed that the Alaska Legislature had legalized Laetrile (B17). I have been assured a similar bill will be introduced in the next session of the Nevada Legislature.

I believe the years of research devoted to obtaining the editorial for the commentaries will justify the allotting of your valuable time in lestening to them.

Cordially yours,

Roland C. Bartlett

RCB;pm

Copy

Exhibit "H"

WASHOE MEDICAL CENTER

77 PRINGLE WAY • RENO, NEVADA • 785-4100/CODE 702

Over One Hundred Years of Community Service

November 5, 1973

RADIOTHERAPY CONSULTATION

DIAGNOSIS: Carcinoma of the right lung

We started Mr. on radiotherapy recently, in a semi-emergency situation. His situation, as I understand it, is as follows.

Mr. is a 71 year old white male who, in Late August and early September, began having the symptoms of cough, minor shortness of breath and some minimal hemoptysis. Six weeks earlier he had been seen by Dr. and a chest series demonstrated a small lesion in the right mid lung field without other symptomotology. Upon his repeat visit, he had the symptoms of cough, fever, and hemoptysis and a repeat chest series showed rather marked growth of the mid lung lesion with fluid at the right base. The patient was admitted to St. Mary's Hospital on 9/6/73.

Sputums were obtained, which suggested malignant cells; bronchoscopy was performed, which suggested a partial occlusion of the bronchus to the right upper lobe. Washings and biopsy were performed, the diagnosis being that of a bronchogenic carcinoma, large cell, variant. On 9/13/73, a limited thoracotomy was performed, which demonstrated a large amount of tumor extending apically into the apex of the pleura, laterally and inferiorly along the pleura down to the diaphragm and medially along the pericardium. Bone survey was done which was negative. Chest x-rays revealed rather marked density in the right mid lung field.

The patient then elected to go down to Tiajuana for cancer chemotherapy and apparently spent six weeks down in Mexico. Upon his return he was still having problems with hemoptysis, anorexia, and weight loss and was readmitted to St. Mary's Hospital because of rather marked shortness of breath and hemoptysis.

work-up during his second hospitalization revealed a white count of 15,000, hematocrit of 33%. Chemistry panel revealed a low albumin, slightly elevated alkaline phosphatase and SGOT. Normal EKG. Because of the patient's rather poor clinical situation and the fact that he was starting to get some suggestive evidence of superior vena caval obstruction, he was transferred to Washoe Medical Center and referred to me for the starting of radiotherapy, which Dr. Boyden initiated.

past medical history indicates that the patient has been in rather good health all his life. He has had two hernia operations. He has otherwise been in excellent health other than some benign prostatic hypertrophy, also mild cervical arthritis.

Physical examination revealed a somewhat obtunded, slightly short of breath white male who appears somewhat younger than his stated age. There is elevation of the external jugular vein with the patient supine and his face appears to be slightly swollen. The patient has rather distant breath sounds over his right lung field and dullness on percussion can be elicited, suggesting the presence of fluid. He is febrile. No definite cervical or paraclavicular adenopathy is demonstrated. The left lung appears clear. Heart sounds are normal with a mild tachycardia. The abdomen demonstrates no evidence of liver or spleen enlargement and no pelvic masses are noted.

Because of the patient's rather poor clinical condition and the suggestive signs of early superior vena caval obstruction, he was irradiated first fairly heavily at the midplane rate of 300 rads a day. We have since slowed down to 200 rads midplane dose and are treating the entire right lung. I would estimate that he will receive at least 3000 rads midplane dose and, depending upon his clinical response, we may go on up to 4500 or 5000 rads, if improvement is demonstrated.

We will try to keep you abreast of his clinical situation. Thank you very much for allowing us to see this patient in consultation.

Sincerely yours,

Roger D. Miercort, M.D.

RDM:lm

Exhibit "H-1"

WASHOE MEDICAL CENTER

77 PRINGLE WAY • RENO, NEVADA 89502 • 785-4100/CODE 702

TELEX NO. 354454 (WSHOMEDCTR RNO)

Over One Hundred Years of Community Service

November 2, 1976

RADIOTHERAPY CONSULTATION

DIAGNOSIS: Poorly differentiated carcinoma of the left breast, post mastectomy

Dear Dr. .:

We saw Mrs. in consultation recently. We understand that Mrs. is a 56 year old, caucasian female who approximately one year ago noticed a mass in the inferior lateral aspect of the left breast. She did nothing about it for approximately 6 months but then because of growth she went down to the Bay area where she received Laetrile. Despite being on Laetrile, continued growth of the mass occurred and she developed ulceration and draining, nipple changes and skin thickening. The patient eventually elected to see Dr. who placed her in [redacted] Hospital where, on the 20th of September a mastectomy was performed with split thickness skin graft on the chest wall.

At the time of surgery, a large mass on the left breast which had caused nipple retraction, ulceration, skin nodularity and also extended up into the axilla. Obvious extension was present high in the axilla. Pathological report was that of a poorly differentiated infiltrating ductal carcinoma with lymphnode metastases.

During her stay at [redacted] Hospital, she had a normal CBC, normal chemistry panel except for an elevated alk. phos., normal liver scan. She also had a normal chest x-ray and normal urinalysis. The patient was then transferred to Washoe Medical Center where she was seen in consultation by Dr. and multiple drug chemotherapy was initiated and I have been asked to consider chest wall irradiation, as well as ovarian ablation.

PAST MEDICAL HISTORY includes 3 Cesarean sections. She is one year post menopausal. She takes 2 grains of Thyroid daily and Pancreatin tablets for her bowels.

FAMILY HISTORY: The patient's father died at age 60 of heart attack, and the mother died at age 72 of wide spread colon cancer.

PHYSICAL EXAMINATION reveals a nervous, quite talkative, caucasian female appearing her stated age and in no distress.

head and neck: exam of the head and neck fail to reveal any evidence of lymphadenopathy. Evidence of a nicely healing graft on the left chest is noted. Above this, however, an area of mass and thickening extending into the axilla is demonstrated which in my opinion represents persistent tumor in this area. No definite tumor nodules are seen in the graft site however. The right breast feels normal. No right axillary nodes are found.

lungs: clear to percussion and ascultation.

heart: heart sounds are normal.

abdominal exam: unremarkable.

We will go ahead and start out with ovarian ablation and I estimate that approximately 1400 rads will be necessary to accomplish this. Following this, after complete healing of the graft has occurred, we will go ahead and irradiate the chest wall as I feel there is a large mass of tumor present in this area.

The rationale for radiotherapy and the rationale of the combined radiotherapy-chemothera program have been explained in detail to Mrs. including the possible problem of losing the skin graft. After a lengthy discussion, she appears to understand the above and was initiated on her ovarian ablation.

Thank you for allowing us to see this patient in consultation.

Sincerely yours,

Roger D. Miercort, M.D.

RDM:jlc
cc: hospital chart
Dr. King

Exhibit "H-2"

RADIOTHERAPY CONSULTATION

October , .

Dr. .

Reno, Nevada 89502

RE: . . . Therapy #880

Diagnosis: Adenocarcinoma of the left breast, post-radical mastectomy, - Stage T3,N0,M0.

Dear Dr. :

I saw Mrs. in consultation today, /72. The situation, as I understand it, is as follows.

Mrs. is a 54 year old gravida IV, para IV, aborta 0 white female who was in her usual state of robust health until she noted a small amount of bloody discharge issuing from her left nipple. After this had occurred for several months, she became aware of a slightly tender mass in the upper inner quadrant of the left breast. She then saw Dr. who referred her to you for further therapy. She was admitted to Washoe Medical Center and, on /72 a left radical mastectomy was performed. The pathological report was that of a 7 cm. in diameter infiltrating comedo carcinoma. 13 lymph nodes were removed, all of which were negative for metastatic disease. The tumor extended to within a few millimeters of the pectoralis musculature, according to Dr. who read the sections. The patient is now recovering nicely from her surgery and is here for consideration for possible radiotherapy post-operatively.

During her hospitalization, she had a CBC which revealed a white count of 7800, hematocrit of 44%. She had a normal urinalysis. She did not receive liver function studies or metastatic bone survey. A PA and lateral chest film was performed which was felt to be unremarkable.

The patient's past medical history is essentially unremarkable. She has never had any surgery. Her Mother and Father are both living and well. She has nine siblings, all of whom are well. The only history of cancer in her family is an Aunt who died of cancer of undetermined type or site.

It should be noted that the patient is <u>allergic to Codeine.</u>

The physical examination today revealed a well nourished, well developed cheerful white female in no distress. The examination of the neck reveals no cervical adenopathy & no palpable supraclavicular or axillary

adenopathy is felt. A healing left radical mastectomy incision is demonstrated without evidence of dermal or subcutaneous implant. The liver is normal in size, and the remainder of the abdomen is unremarkable.

I feel Mrs. is a candidate for post-operative radiotherapy for the following reasons:

1. The size of the lesion places her into a Stage T3 category. The rate of recurrence in the scarred chest wall in these patients is fairly high, and I feel that treatment to the chest wall via medial and lateral tangential fields is thus indicated.
2. In addition, the fact that this was a medial lesion indicates that statistically, despite the absence of positive nodes in the axilla, the chance of her having involved internal mammary nodes is in the range of 15%. For these reasons, I feel that radiotherapy to the nodal areas, namely, the internal mammary and paraclavicular areas is also indicated.

I would anticipate a dose of 4500 rads in a five week period. Possible complications of radiotherapy including skin reaction, scarring in the lungs, mediastinitis and esophagitis have been thoroughly explained to the patient. She is scheduled to return in one week's time. We will then evaluate her and if she is healed enough, we will go ahead with localization and plan her therapy to start shortly thereafter.

Thank you very much for allowing us to participate in the care of this patient.

Sincerely yours,

ROGER D. MIERCORT, M. D.

WASHOE MEDICAL CENTER - DEPARTMENT OF RADIATION THERAPY

1-75 Mrs. returns for a routine follow-up evaluation. She is feelin well except for the following complaints. She still has problems with dysphasia. She feels that there is a lump in her throat immediately above the suprasternal notch area. This is an episodic type of sympto wherein, after waking up in the morning, it does not appear until approximately 1 or 2 in the afternoon. She has no difficulty in swallow but just has a feeling of a lump at that area. The second conplaint i one of a small nodule in the inner aspect of her left eyelid, upper. examination today, no abnormalities are noted except for a small 3 mm nodule in the left medial upper eyelid. No evidence of recurrence is noted and the right breast remains normal. As part of her evaluation, she was seen by Dr. who felt that this was inflammatory. H treated this symptomatically and stated that if it does not disappear shortly that an excision would be indicated. The patient is scheduled for a repeat chest x-ray, esophagram on Thursday 4-3-75 and is also to have CBC, and Chem Panel at that time.

RDM:jlc

Roger [illegible]

HEMATOLOGY

OUTPATIENT USE ONLY — DATE REQUESTED 4/3 — NURSE E.C. — TECHNOLOGIST 1-3-75 LED

DIFFERENTIAL: % POLYS 57 — % STABS 3 — % LYMPHS 38 — % MONOS 3 — % EOSINO — % BASO — % META — % MYELOS — PRO % GRANULO — % BLASTS

PAT ROOM 220

☐ Hemogram ☐ Sed. Rate ☐ Reticulocytes
☒ CBC ☐ Diff ☐ Platelet Count

DATE PERFORMED 4 0 3

TEST		NORMAL VALUES	
WBC X 10³	3.7 | 0 6.0	M-4.8-10.8 F-4.8-10.8	
RBC X 10⁶	4.9 | 4.9	M-4.6-6.2 F-4.2-5.4	
Hgb gm	15.1 | 15.1	M-14-18 F-12-16	
Hct %	44.1 | 44.1	M-42-52 F-37-47	75
MCV μ³	90.0 | 90.0	M-80-94 F-79-97	
MCH μμg	30.9 | 30.9	M-27-31 F-27-31	
MCHC %	34.3 | 34.3	M-32-36 F-32-36	

R.B.C. NORMOCHROMIC NORMOCYTIC — POIKILOCYTOSIS slight — ANISOCITOSIS slight — HYPOCHROMIA — MACROCYTOSIS — MICROCYTOSIS — POLYCHROMIA — SED. RATE M.M. 1 HR. — PLATELETS /CU. MM. — RETICULOCYTES — PLATELETS: ADEQUATE NUMBER NORMAL MORPHOLOGY — Laurie Schuster 133

WASHOE MEDICAL CENTER · RENO, NEVADA
CHART COPY

653 04-04 WMCER MIERCORT 450-779 4/3 4977

*09.9	mg%	CA++	8.3-10.6
2.80	mg%	PHOS	2.4-4.5
109.	mg%	GLUC	77-113
18.5	mg%	BUN	6.0-21.0
04.2	mg%	URIC ACID	M 3.1-9.0 F 2.2-7.6
295.	mg%	CHOL	130-250
7.74	gm%	T. PROT	6.1-8.0
4.83	gm%	ALB	3.2-5.0
0.35	mg%	T. BILI	0.1-0.9
94.	mu/ml	ALK. PHOS	20-100 (Child Bone Growth: 40-290)
095.	mu/ml	LDH	44-100
085.	mu/ml	SGOT	32-100
141	meq/1	NA+	137-143
4.5	meq/1	K+	3.6-5.5
	UNITS	TEST	NORMALS

THESE NORMAL VALUES APPLY ONLY TO TESTS PERFORMED

TE WASHOE MEDICAL CENTER - DEPARTMENT OF RADIATION THERAPY
-75

The esophagram was normal. The CBC and Chem Panel were totally normal. Chest x-ray revealed what appeared to be probable areas of pulmonary metastasis in the left apex and one in the left lateral lower lobe. Views of the left shoulder were normal. Because of the probable pulmonary metastases, whole lung tomograms were obtained today which I feel confirm the presence of at least 3 lesions in the left apex and one lesion in the left lower lobe laterally. Mrs. was informed of this. She is going to , for a week to visit a seriously ill father and then will return. At that time, we will refer her to either Dr. , Dr. for consideration for either hormonal or appropriate chemotherapy.
RDM:jlc

Roger D. Miercort, M.D.

Mrs. elected to go to Tijauna for treatment by Dr. Contreras at his clinic with Leatrile. She went down there on the 21st of April had a Chem Panel, urinalysis, CBC, all of which were normal. She had films of her lumbosacral spine, pelvis and chest taken which showed essentially no change in the appearance of the pulmonary lesions with them being unchanged. She has undergone a course of enzymes and Leatr and is currently taking 3 Leatrile tablets a daily. She states that s feels extremely well. On examination today, her lungs are clear. Hea sounds are normal. The chest wall clean. The liver normal in size wi out evidence of adenopathy. What we will do is follow her along and s is to return in 1 and 1/2 month's for a repeat chest x-ray which will compared with are previous films.
RDM:jlc

Roger D. Miercort, M.D.

Mrs. returns complaining of continued problems with coughing, questionable shortness of breath and epigastric distress. She states that she had a ulcer several years ago. As part of her evaluation tod an upper G.I. series was performed which demonstrated duodenitis and a questionable duodenal ulcer. Chest x-ray showed rather marked progression of the pulmonary metastases with bilateral involvement now demonstrated. In the face of progession of her disease even on Leatrile treatment, I again suggested that hormonal or chemotheraputic management is in order although I would tend to favor chemotherapy whic multiple drugs. I contacted Dr. and the patient is goir to be seen by him today for his consideration.
RDM:jlc
cc: Dr.

Roger D. Miercort, M.D.

FRED M. ANDERSON, M. D.

275 HILL STREET
RENO. NEVADA 89501
322-2161

FRANK A. RUSSELL, M. D.

Exhibit "I"

March 2, 1977

Fred M. Anderson, M.D.

I am a general surgeon in Reno and a considerable part of my practice deals with cancer patients. For about twenty five years I was on the State Board of Directors of the Nevada Division of the American Cancer Society. For four years I was on the National Board of Directors of the American Cancer Society and served for three years on its Committee on New and Unapproved Methods of Cancer Treatment. For many years I also served as a member of the Nevada Governors Cancer Advisory Council. When I first learned of this bill I was considerably disturbed but my reaction at my age was to let the younger doctors take care of it. Two days ago however, I was called and asked if I had an opinion, and if I would testify. My reaction was that for the sake of present and future sufferers from cancer that I could not refuse.

From my own medical experience and my rather large study of the literature, I believe there is no positive evidence by animal experimentation which has been carried out by trained scientists that Laetrile has any beneficial effect in the treatment of cancer. These have been done in numerous places such as the National Cancer Institute, the world famous Sloane Kettering Cancer Institute, and the Catholic Medical Center in New York, and the Southern Research Institute in Birmingham, Alabama. A variety of tumors have been tested.

In addition it is the opinion of well trained members of the Medical Profession who have large experience with cancer treatment that Laetrile, when sought and used by some of their patients, and still followed by these doctors, adds nothing beneficial to their treatment.

There is at present in Nevada no law that prevents the use of Laetrile or the giving of it by physicians. Why then pass a law to approve it?

FRED M. ANDERSON, M. D. 275 HILL STREET RENO. NEVADA 89501 322-2161 FRANK A. RUSSELL, M. D.

Fred M. Anderson, M. D. (cont.)

The only reason I can perceive why some people want approval is to give Laetrile the support and respectability that passage of a state law would give to it. If it were worthwhile it wouldn't need such a law. This type of respectability and the publicity that would go with it could well induce many patients to seek out this useless treatment and thus pass up seeking proven methods of cancer treatment that might cure them. All that they would be encouraged by this Law to sacrifice, would be their lives.

As I mentioned earlier I served for many years as a member of the Governors Cancer Advisory Council.

This Council can investigate any substance or device used in the prevention or treatment of cancer and can request findings or studies by other organizations such as the State Health Department, Scientists within Universities or Medical Schools, the National Cancer Institute or others independent scientists. After such studies it renders an opinion regarding the value or ~~usefulness~~ lack of value of such substance or device.

This Council has functioned very effectively over the years. It has never found unfavorably on anything that was effective or useful in prevention or cure of cancer and it has in several instances determined some substances to be of no value.

After a few years of the existence of this Council, cancer fraud and quackery practically ceased to exist in Nevada. Now Assembly Bill 121 is ammended so that neither the State Health Department nor the Governors Advisory Council can do anything about this substance, even when it is, as I am sure it will be, proved to be worthless.

I sincerely hope that this Assembly Bill No. 121 will not be passed, and thus lend respectability and support to a substance that would be useless to the cancer patient and in many cases would prevent the patient from getting appropriate treatment at a time when help or cure was still possible. I don't know just who it is in Nevada that ~~wants to~~ would exploit the cancer patient in this manner, but I humbly ask that you do not permit it. Passage would undoubtedly result in a large number of unnecessary deaths.

Exhibit "J"

TESTIMONY OF THE FOOD AND DRUG ADMINISTRATION

Laetrile is the latest in a long history of alleged cancer remedies which have defrauded a vulnerable public. This drug is now derived from pulverized apricot pits and has been widely promoted for prevention, treatment, and cure of cancer. Laetrile is also known as amygdalin and vitamin B-17.

The extent of current Laetrile promotion and the continuing manipulation of the therapeutic claims made for it should be of concern to the public as well as health professionals.

Promotion Shifts to "Prevention"

When Laetrile was first promoted, it was offered as a "cure for cancer". Today, the preparation is more heavily promoted than ever before, but the statements now being featured do not refer to "cure" as often as to "prevention," "relief of pain," "slows the cancer," "stops its spread," and other unproven claims.

Laetrile's promoters are more vocal and better organized today than in the past. They are sponsoring

seminars and conventions for cancer victims and their families. They are encouraging articles in the press and appearances on radio and television talk shows to promote the drug as well as lobbying and organizing write-in campaigns to influence state legislatures and Congress.

Most of these efforts are being orchestrated by four lobbying groups promoting Laetrile use:

1. The National Health Federation, a champion of so-called health foods and other unorthodox medical treatments.

2. The International Association of Cancer Victims and Friends, which publishes the Cancer News Journal.

3. The Cancer Control Society, which publishes the Cancer Control Journal.

4. The Committee for Freedom of Choice in Cancer Therapy, an organization which treats

efforts to regulate Laetrile and similar unproven substances as an invasion of personal privacy. Committee leaders recently were indicted on charges of conspiracy to smuggle Laetrile into the United States. This Committee is now widely publicizing a film which makes false and misleading claims for Laetrile.

A direct result of the promotion of Laetrile by these groups has been:

- In 1976, Alaska passed a law prohibiting hospitals and health facilities from barring the use of Laetrile when prescribed or administered by a physician and requested by a patient.

- Bills to legalize Laetrile have been introduced in many other state legislatures.

- At least one prominent conservative journalist has condemned "know it all doctors" and

argues against the Government forbidding individuals the "freedom" to use Laetrile "merely because experts regard it as worthless."

- Newspapers such as The New York Times and Detroit Free Press editorially question why Laetrile should not be made available to those who want it.

- A number of lawsuits are active in many areas of the United States in which individual citizens are seeking legal access to Laetrile.

- FDA is receiving 50 inquiries or more each month from congressmen on behalf of constituents interested in Laetrile.

- A Federal judge in Oklahoma recently ruled that numerous victims of cancer wishing to import Laetrile for their own use should be allowed to do so without Government intervention.

The FDA Position on Laetrile

The FDA position on Laetrile remains clear and unchanged:

- Laetrile is a "new drug" under the Federal Food, Drug, and Cosmetic Act because it is not generally recognized by qualified experts as safe and effective for the recommended use.

- Federal law prohibits the interstate distribution of a "new drug" unless FDA has approved a New Drug Application (NDA) submitted by the sponsor and containing full reports of clinical investigations establishing the safety and effectiveness of such drug.

- While Laetrile (also known as amygdalin) has been marketed and promoted as a vitamin (BEE 17 or B-17), there is no scientific basis for accepting the claim that Laetrile is a vitamin and not a drug. It is of no value as a factor in human nutrition. This view has been supported by most courts. It is,

therefore, illegal to market Laetrile as a "vitamin" or as a nutritional supplement and all attempts to market the product as such are thinly veiled efforts to avoid the drug labeling provisions of the Food, Drug, and Cosmetic Act.

On December 16, 1976, the National Nutritional Consortium, Inc., with its reputable member societies including the American Dietetic Association, American Institute of Nutrition, American Society of Clinical Nutrition, Institute of Food Technologists, Society for Nutrition Education, American Academy of Pediatrics, and Food and Nutritional Board of the National Academy of Sciences-National Research Council, issued a formal statement which said, in part: ". . .there is no recognized vitamin B-17 or any possible need for the substance so named."

FDA contends that it would not only be illegal but also contrary to the public interest to exempt Laetrile, as some propose, from the efficacy requirements of Federal law (the Kefauver-Harris amendments). Such an exemption would set an unacceptable precedent for other unproven drugs. The drug provisions of the Food, Drug, and Cosmetic Act do not permit FDA to arbitrarily exclude

some drugs from complying with the law because of emotions, popularity, etc.

FDA believes there are serious faults in the "freedom of choice" argument. No worthless drug is without harm; a patient's choice of Laetrile to the extent that such choice delays or interferes with swift diagnosis and prompt effective treatment is potentially suicidal.

The "evidence" of efficacy presented by Laetrile promoters consists entirely of anecdotes, hearsay arguments and patients' testimonials. FDA and the National Cancer Institute have reviewed "success stories" submitted by the most prominent promoter of Laetrile, a Mexican physician and failed to find evidence of therapeutic effect.

History of Laetrile and FDA Actions

Despite the fact that it has been known, tested, and used for more than a quarter of a century, no valid scientific evidence which indicates that Laetrile has any potential value in cancer management has ever been found.

Despite confused and misleading reports from Laetrile promoters, the FDA has found no study which provides any evidence that Laetrile is active against any cancer.

No other reputable organization has found any evidence to support the use of Laetrile in the treatment or prevention of cancer.

The only investigational new drug application (IND) ever received by the FDA was in 1970.

In 1971, the Department of Health, Education, and Welfare completed a five-month review of the Laetrile issue. The review included reevaluation by the Food and Drug Administration of submissions by the McNaughton Foundation of California, Laetrile's most recent sponsor, and statements made on behalf of Laetrile by its various proponents, including Dean Burk, Ph.D., a chemist then employed by the National Cancer Institute; Dr. Ernesto Contreras of Mexico; and Dr. Hans Nieper of Germany.

A separate review was made by an independent special advisory committee of cancer experts from all over the

country. These experts were members of the academic research community and specialists in oncology. All of the McNaughton Foundation submissions, including the statement of the Laetrile supporters, also were made available to the committee.

Both the advisory committee and the Department found there is no acceptable scientific evidence that Laetrile has any anti-cancer effect.

Repeated requests, as recently as 1975, have been made by the Food and Drug Administration to the McNaughton Foundation that it submit whatever scientific data it might have to correct the serious deficiencies in its animal tests and plans for clinical investigation. To date, the Government has not received any scientific data which would justify clinical trial under proposed conditions of use as an anti-cancer drug.

Over the past 20 years, a number of scientists have tried to demonstrate the alleged anti-cancer effect of Laetrile by seeking to control animal tumors known to respond to anti-cancer drugs shown to be useful in man. The largest series of tests have been sponsored by the National Cancer Institute and conducted in a

number of independent laboratories, including the Sloan Kettering Institute and Southern Research Institute, throughout the country. Laetrile shows no anti-cancer activity in the ten different model tumor systems tested. The FDA has no scientific reports that contradict these findings.

Over the past 25 years, a number of medical scientists have reviewed the case histories of cancer patients who allegedly benefited from taking Laetrile. Among the organizations sponsoring these reviews have been the California Cancer Advisory Council, the American Cancer Society, the Food and Drug Administration, the Canadian Drug's Directorate, and the Australian Drug Evaluation Committee. The cases reviewed were usually furnished by those who claim that Laetrile has an anti-cancer effect. The cases the FDA reviewed were submitted by Dr. Ernesto Contreras of Tijuana, Mexico. After a thorough review of the submitted cases, the universal conclusion was that there was no scientific evidence that Laetrile has any demonstrable anti-cancer effect in man.

Based on all of the above, FDA has considered Laetrile a "new drug" within the meaning of Section 201(p) of

the Federal Food, Drug, and Cosmetic Act, in that it is not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs as safe and effective for use in the cure, mitigation, treatment, or prevention of cancer in man.

The FDA has initiated numerous enforcement proceedings under the Act, many of which have been successful. We intend to continue initiation of enforcement proceedings against distribution of Laetrile. These enforcement actions are in the form of (1) seizures, (2) injunctions, and (3) criminal prosecutions. Some cases instituted against the FDA in the Federal District Courts have resulted in the granting of relief to the plaintiffs. To date, there have been approximately 15 such suits. Only four have been successful. All others have been finally decided in favor of FDA.

In cases where court has permitted Laetrile to be used, relief has been limited solely for the personal use of an individual cancer patient. No court has authorized commercial sale or distribution of Laetrile.

FDA Ordered to Conduct an Administrative Hearing by Federal Court: Rutherford Vs. United States

The Rutherford case commenced in Oklahoma City in March of 1975 when a terminal cancer patient and her husband sought to have an alleged FDA order prohibiting the use of Laetrile voided so that she could obtain the drug for her own use. The district judge denied the requested relief on the grounds that the FDA has not issued any order regarding Laetrile. In June, 1975, another cancer patient, Glen Rutherford, intervened in the case seeking the same relief sought by the above patient. District Judge Bohannon heard the case in August 14, 1975, issued a preliminary injunction allowing Mr. Rutherford to purchase and transport a six-month supply of Laetrile solely for his personal use. On appeal, the 10th Circuit, in October 1976 affirmed the injunction, but held that judicial review of two issues, i.e., (1) the new drug, and (2) grandfather clause must await development of an adequate administrative record, and remanded the case to the District Court. Thereafter, Judge Bohannon remanded the case to FDA on January 4, 1977 to compile within 120 days an administrative record on the issues set forth. The details of the administrative proceedings are fully detailed in the Federal Register Notice of February 18, 1977.

The administrative record to be compiled must deal with whether or not Laetrile is exempt from the new drug application requirements (by having "grandfathered" status) and whether or not Laetrile is considered safe and effective (generally recognized to be so by experts qualified by scientific training and experience to evaluate these issues). In short, FDA must reiterate for the record why it believes Laetrile is a "new drug" and, thus, violative in not having approval.

It should be emphasized that FDA is undertaking this rule-making proceeding solely because the Agency was directed to do so by the Court. It is well established that the FDA has primary jurisdiction to determine the status of products under the Act, including the two issues set forth above. The Agency also has the discretion, if it wishes to exercise it, of initiating enforcement proceedings to have the issues decided in the District Court.

We would expect that the rule-making procedure will be very important for FDA because this will uphold our right to act as we have under the law and should discourage the marketing and attempted distribution of other "quack" remedies. We hope that the publicity

surrounding this process will counteract some of the current propaganda in the lay press and show, in an open record, the true issues. Interested and knowledgeable professionsls are invited to submit information and evidence in response to the rule-making notice.

Laetrile and the Medical Profession

Physicians have encountered many cases of patients who are curious about Laetrile and many are presented with anecdotal reports of "cures" which patients have heard about.

At its meeting in Philadelphia in December, 1976, the House of Delegates of the American Medical Association adopted the following resolution:

> 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 beneficiant 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 of palliation of malignancies is unproven and that the use of amydalin 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.

FDA is aware of state medical board disciplinary actions in California, Ohio and elsewhere involving physicians who deal in Laetrile. We are assisting those medical boards in any way possible in connection with these actions.

FDA is honoring official requests from state legislatures to provide expert medical testimony on our knowledge of Laetrile in any hearings held on pro-Laetrile legislation. The Agency is also working with Congress and the press to counteract misstatements and misinformation diseminated by Laetrile promoters.

FDA asks that health professionals be alert to the kinds of claims now being made by Laetrile promoters. Examples include the following excerpts from the televised film "World Without Cancer":

". . .vitamin B-17 does control cancer in human beings with an effectiveness approaching 100 per cent."

"Unfortunately, most cancer victims start taking Laetrile only after the disease is so far advanced that they've been given up as hopeless by routine medical channels."

". . .a patient can have his cancer destroyed by vitamin B-17 and still die from the irreversible damage already done to his vital organs."

"Of those with early diagnosed cancer, at least eighty per cent will be saved by vitamin therapy. And, of those who presently are healthy with no clinical cancer to begin with, close to one hundred per cent can expect to be free from cancer as long as they routinely obtain adequate amounts of vitamin B-17."

"Once vitamin B-17 is as widely understood and available as other vitamins, cancer then will be as rare as scurvy or pellagra today."

FDA has prepared a brochure on Laetrile which sets forth, for the layman, the history of this substance. This brochure may be helpful to physicians who treat cancer patients and whose patients ask about Laetrile. [redacted] multiple copies of the brochure, called "Laetrile: The Making of a Myth," by writing to Consumer Inquiries, Food and Drug Administration, HFG-20, 5600 Fishers Lane, Rockville, Maryland 20857.

Roland D. Wuesow
NCI

Exhibit "K"

TESTIMONY BEFORE NEVADA

LEGISLATURE, MARCH 2, 1977

MR. CHAIRMAN, COMMITTEE MEMBERS, LADIES AND GENTLEMEN. MY ROLE HERE TODAY IS TO STRIKE A ~~BALANCE~~ DIFFERENT PERSPECTIVE, IF YOU WILL, ABOUT ~~A~~ THE VERY SIGNIFICANT ISSUE CONFRONTING ALL OF US, ~~AND IN PARTICULAR,~~ AS CONSUMERS OF AMERICAN AND NEVADA CANCER MEDICINE TODAY - THAT ISSUE IS LAETRILE: VITAMIN B 17, AMYGDALIN, AND APRIKERN.

I AM A HEALTH COMMUNICATIONS SPECIALIST. I AM NOT A PHYSICIAN OR A SCIENTIST. BUT I AM UNIQUELY QUALIFIED TO SHARE WITH YOU SOME OBSERVATIONS AND FACTS ABOUT THE ISSUE AND THE PUBLIC -- PATIENTS AND FAMILY, FOR AMONG OTHER THINGS I FREQUENTLY FIND MYSELF IN A ROLE OF SERVING AS AN ABSORBER OF THOUGHT AND OPINION ABOUT MEDICAL AND SCIENTIFIC SUBJECTS. ONE OF THOSE SUBJECTS IS LAETRILE, A SUBJECT OF INTEREST TO ME SINCE 1971, WHEN I WAS A MEMBER OF THE ADMINISTRATIVE STAFF OF THE MAYO CLINIC. ADMITTEDLY, I AM AS WERE MANY OF THE PREVIOUS SPEAKERS, INFLUENCED IN MY OBSERVATIONS FOR MANY REASONS. AMONG THEM IS THE FACT THAT I AM PART OF THE MEDICAL ESTABLISHMENT - THE 'SYSTEM' IF YOU WILL. I READ MEDICAL/SCIENTIFIC LITERATURE: ATTEND MEDICAL/SCIENTIFIC MEETINGS: SOCIALIZE WITH PHYSICIANS AND SCIENTISTS. WE ARE, AFTER ALL, CREATURES OF OUR ENVIRONMENT. SIGNIFICANTLY, BECAUSE OF MY ENVIRONMENT, I HAVE COME TO TRUST THE JUDGMENT OF THOSE MEDICAL/SCIENTIFIC TYPES WHO HAVE EDUCATION AND TRAINING IN THOSE NOBLE FIELDS.

WHY INDEED, IS THERE A LAETRILE MOVEMENT AFTER ALL? MANY REASONS. CANCER IS BOTH A POLITICAL AND AN EMOTIONAL ISSUE. IT IS A MEDICAL AND A SOCIAL SCIENCE. I'M NOT TOO SURE MANY OF US - UNTIL RECENTLY, DEFINITELY RECOGNIZED THAT.

A SIGNIFICANT NUMBER OF PEOPLE STRICKEN WITH CANCER - ABOUT 110,000 EACH YEAR - ARE DYING UNNECESSARILY OR PREMATURELY. USUALLY DUE TO LACK OF EARLY DETECTION AND DIAGNOSTIC EFFICIENCY, MORE AND MORE, PEOPLE ARE ASKING "WHY"?

FROM THE POINT OF VIEW OF MANY OF US, AN ALREADY LARGE, AND WIDENING GAP BETWEEN MEDICAL KNOWLEDGE AND ACTUAL PRACTICE EXISTS. OUR HEALTH CARE DELIVERY SYSTEMS,

ARE BY MANY STANDARDS, INEFFECTIVE. MANY COMMUNITIES ARE INCREASINGLY UNABLE TO PROVIDE TOP-FLIGHT MEDICAL SERVICES OR TRAINED MEDICAL PERSONNEL IN SPECIALITY AREAS, AND THE LACK OF KNOWLEDGE ON THE PART OF THE GENERAL PUBLIC IS TOO CONSIDERABLE AS IS, SURPRISINGLY, THAT OF MUCH OF THE MEDICAL PROFESSION - AS TO HOW AND WHERE TO OBTAIN THE BEST MEDICAL CARE WHEN CANCER STRIKES. THAT FACT ALONE IS ILLUSTRATED DAILY BY WE AT THE NCI. THE PUBLIC SEEKS KNOWLEDGE AND INFORMATION. BETWEEN JUNE 1975 AND MAY 1976, NCI RESPONDED BY MAIL TO SOME 55,000 INQUIRIES FROM THE PUBLIC HAVING QUESTIONS ABOUT SOME ASPECT OF CANCER. ABOUT 1/5 OF THOSE - 11,000 - DEALT WITH QUESTIONS ABOUT UNPROVED METHODS OF TREATMENT - PRIMARILY LAETRILE.

NOW, CONSIDERING THAT ABOUT 675,000 NEW CANCER CASES WERE DIAGNOSED BETWEEN THAT BLOCK OF TIME IN THE U.S.; AND ASSUMING THAT THE MAJORITY OF PEOPLE ARE CONCERNED ABOUT THEIR DIAGNOSIS, AND IN SOME PART, HAVE QUESTIONS ABOUT THEIR CANCER - WHERE, IN FACT, DO THEY GO FOR ANSWERS? OR BETTER YET, DO THEY EVEN ASK THE QUESTIONS? 55,000 QUESTIONS CAME TO NCI; UNDOCUMENTED THOUSANDS MOST ASSUREDLY WENT TO THE ACS; SOME WENT TO PHYSICIANS, BUT THE VAST MAJORITY OF THOSE DIAGNOSED APPARENTLY DON'T GET THEIR QUESTIONS ANSWERED. DON'T RECEIVE THE INFORMATION AND EDUCATION THEY SEEK - YET PERHAPS CAN'T ARTICULATE THERIN, LIES A KEY. THERIN IS AN OPPORTUNITY FOR GROUPS SUCH AS THE COMMITTEE FOR FREEDOM OF CHOICE IN CANCER THERAPY AND THE INTERNATIONAL SOCIETY OF CANCER VICTIMS AND FRIENDS TO APPEAL TO THE EMOTIONS OF PEOPLE DESPARATELY IN NEED OF EXPRESSIONS OF HOPE IN THE FACE OF THEIR PERSONAL BATTLE WITH CANCER. TO THOSE WITH THE DISEASE, THEIR RELATIVES AND FRIENDS, CONTACTS WITH LAETRILE ADVOCATES HAVE SERVED AS A FORM OF "EDUCATION" AND "INFORMATION". ~~THAT ALONE IS ONE MAJOR REASON WHY ESTIMATES RANGE IN THE U.S. THAT BETWEEN 100,000 AND 5 MILLION PEOPLE HAVE BECOME INFLUENCED BY THE LAETRILE MOVEMENT~~. 1976 ESTIMATES ALONE APPROXIMATEBY THAT ABOUT 20,000 AMERICANS - MANY FROM NEVADA - TRAVELED TO MEXICAN LAETRILE CLINICS FOR TREATMENT.

WHY?

DESPARATION. MISINFORMATION. MOST OF THOSE DESPARATE ATTEMPTS - AS WE ALL KNOW TOO WELL - END IN DESPAIR - AND DEATH.

UNPROVED REMEDIES FOR CANCER TREATMENT ARE AS OLD AS THE DISEASE ITSELF. SOME PEOPLE HAVE MADE MILLIONS OF DOLLARS OVER THE YEARS FROM FEAR-STRICKEN CANCER PATIENTS WHO GAMBLE THEIR LIVES ON MAGICAL CURES AND TREATMENT. THE LAETRILE MOVEMENT HAS BEEN LIKENED TO A SUPERSTITION; AND I SUBMIT IT IS EXTREMELY DIFFICULT TO FIGHT A SUPERSTITION WITH SCIENTIFIC AND MEDICAL FACTS. ONE OF THE MOST EFFECTIVE WAYS TO COMBAT LAETRILE IS THROUGH PUBLIC EDUCATION. THIS FORUM IS A STEP IN THAT DIRECTION. PUBLIC EDUCATION ON ANY HEALTH SUBJECT TAKES TIME. AND THERE IS NO GUARANTEE OF SUCCESS. ~~WITNESS THE HEAVY INVESTMENTS OF FUNDS IN ANTI-SMOKING, ALCOHOL, AND DRUG ABUSE PROGRAMS. BEFORE SUCH NATIONAL PROGRAMS ARE UNDERTAKEN, OFFICIALS IN WASHINGTON MUST BE CONVINCED THAT THE SUBJECT OF THE PUBLIC EDUCATION PROGRAM MUST BE OF EPIDEMIC PROPORTIONS TO WARRANT HUGE INVESTMENTS OF RESOURCES. WELL, CANCER IS CERTAINLY EPIDEMIC. IT STRIKES ONE OF EVERY FOUR OF US. PRACTICALLY EVERYONE KNOWS SOMEONE WITH IT, HAS HAD IT, OR HAS DIED OF IT. PEOPLE FEAR IT MORE THAN ANY OTHER KILLER DISEASE.~~

THIS NATION IS NOW WELL INTO WHAT IS THE FIRST NATIONAL, COORDINATED EFFORT TO TACKLE THE COMPLEXITIES OF CANCER. THIS EFFORT IS SPURRING HOPE. WHILE STILL TOO MANY PEOPLE BELIEVE THAT WE ARE ON THE VERGE OF A "BREAKTHROUGH" - CANCER SCIENTISTS AND ONCOLOGISTS CERTAINLY CAUTION AGAINST OVERPROMISE.

ONE OF THE MOST EXCITING THINGS THAT HAS HAPPENED IN CANCER - AND IS VITALLY IMPORTANT TO COMMUNICATE IN A PUBLIC EDUCATION FASHION - IS THAT DURING THE LAST FEW YEARS SCIENTISTS HAVE FOUND WAYS OF CURING AND/OR CONTROLLING SOME FORMS OF THE DISEASE. DOCTORS BELIEVE THAT ABOUT TEN KNOWN TYPES OF CANCER CAN NOW BE CONTROLLED OR CURED. NOW, CONSIDERING THE FACT THAT THERE ARE AN ESTIMATED 110 DIFFERENT VARIETIES OF CANCER, THAT MAY NOT SOUND LIKE MANY

TO THE PUBLIC AT RISK, ~~TO COIN A FASHIONABLE CANCER CONTROL TERM~~, PARTICULARLY TO THOSE ACCEPTING THE RHETORIC OF THE LAETRILE MOVEMENT. BUT DOES ASPIRIN CURE ALL HEADACHES? IS THE SAME INSULIN DOSE ACCEPTABLE FOR ALL DIABETICS? PROGRESS IN CURING THESE 10 CANCERS HAS DEVELOPED IN THE PAST DECADE OR SO! !

IN MOST CASES, THE JOB IS DONE WITH A BATTERY OF FAIRLY NEW DRUGS THAT, WHEN USED IN COMBINATIONS WITH EACH OTHER, CAN WIPE OUT TUMOR CELLS. THE CANCERS INVOLVED INCLUDE SEVERAL OF THE FORMS OF LEUKEMIA AND LYMPHOMA THAT STRIKE LITTLE CHILDREN, HODGKINS DISEASE WHICH IS LIKELY TO AFFLICT YOUNG ADULTS, CHORIOCARCINOMA (CANCER OF THE PLACENTA) AND A COUPLE OF OTHER FAIRLY RARE BUT DEADLY TUMORS, CANCER OF THE CERVIX AND SKIN CANCER.

THE TRAGIC ELEMENT IN THIS OTHERWISE HAPPY SITUATION IS THAT TREATING THESE CANCERS IS A TRICKY BUSINESS. THIS TOO, THE PUBLIC DOESN'T BUT SHOULD - GENERALLY KNOW AND UNDERSTAND. SO TRICKY, IN FACT, THAT COMBINATION DRUG THERAPY SEEMS TO WORK BEST ONLY IN THE HANDS OF A BROADENING NUMBER, BUT STILL YET TOO FEW SPECIALISTS WORKING AT CANCER CENTERS WHERE THEY AND THEIR CO-WORKERS, INCLUDING NURSES AND OTHER MEDICAL PERSONNEL, HAVE REAL EXPERTISE.

PRACTICING PHYSICIANS AT COMMUNITY LEVELS NEED TO KNOW MORE ABOUT WHO THE EXPERTS ARE. CENTERS FOR CANCER TREATMENT ARE BEING GEOGRAPHICALLY SPREAD ACROSS THE COUNTRY SO MORE PEOPLE WILL HAVE ACCESS TO THE BEST THERAPY THERE IS. NEVADA'S MEDICAL COMMUNITY IS BEING ENCOURAGED AND INFLUENCED TO BECOME AN INTEGRAL PART OF THE SOPHISTICATED CANCER CENTERS. THE PUBLIC NEEDS TO KNOW THAT EFFORTS ARE BEING MADE TO ENSURE THAT THEIR COMMUNITY PHYSICIANS ARE BEING GIVEN THE OPPORTUNITY TO LEARN MORE ABOUT NEW METHODS OF CANCER TREATMENT THRU CONTINUING MEDICAL EDUCATION - CME - AS ITS CALLED.

WE FREQUENTLY HEAR FROM LAETRILE PROPONENTS THAT THE SUBSTANCE IS PROCLAIMED "LEGAL" IN MORE THAN 20 COUNTRIES. ACTUALLY, IT IS NOT ILLEGAL IN THOSE COUNTRIES - AND MANY MORE - FOR THE SIMPLE FACT THAT THE U.S. AND CANADA ARE

LEADERS IN THE WORLD WITH LAWS PROTECTING THE CONSUMERS OF MEDICAL GOODS AND SERVICES.

SOME TIME AGO, DR. SHERWOOD LAWRENCE OF THE ACS IN CALIFORNIA WROTE TO OFFICIAL AGENCIES IN A NUMBER OF COUNTRIES PROCLAIMED BY LAETRILE ADVOCATES THAT LAETRILE WAS "LEGALIZED", ASKING ABOUT THE STATUS OF THE COMPOUND WITHIN THEIR BORDERS. I HAVE REPLIES WHICH WILL SURPRISE YOU. I WOULD BE HAPPY TO SUBMIT THESE FOR THE RECORD.

SOME REPLIES:

FROM MEXICO, BASTION OF U.S. LAETRILE SUPPORTERS:

"HAVING UNDERGONE THOROUGH STUDIES BY THE CHEMISTS AND DOCTORS OF THE TECHNICAL DRUG DEPARTMENT, IT WAS FREQUENTLY REJECTED,

BECAUSE THE THERAPEUTIC PROPERTIES ATTRIBUTED TO IT (TO CURE ALL FORMS OF CANCER) HAD NEVER BEEN PROVEN. AFTER SEVERAL YEARS OF RESEARCH AND STUDIES, HOWEVER, THE PROPONENTS WERE ABLE TO PROVE THAT THE AGENT AMIGDALINA HAD A CERTAIN ANALGESIC EFFECT IN CERTAIN TYPES OF CANCER OF THE BRONCHI. THIS FACT, COUPLED WITH THE RESULT OF PREVIOUS STUDIES (WHERE IT HAD BEEN ESTABLISHED THAT THE PRODUCT WAS HARMLESS AND ITS PROLONGED USE DID NOT LEAD TO ADDICTION), LED TO THE AUTHORIZATION OF MANUFACTURING THE PRODUCT AND TO RESUME SCIENTIFIC RESEARCH.

AFTER ANOTHER YEAR OF EXPERIMENTATION, REGISTRATION OF THE PRODUCT WAS GRANTED. THIS REGISTRATION, HOWEVER, IS RESTRICTIVE, FOR ITS OVER-THE-COUNTER SALE IS PROHIBITED. THE SALE OF THE PRODUCT IS LIMITED TO RESEARCHERS, HOSPITALS, AND CLINICS, AND ADVERTISING IS RESTRICTED TO 'ANALGESIC FOR CERTAIN TYPES OF CANCER OF THE BRONCHI'.

FROM THE PHILLIPINES:

" 'LAETRILE' HAS NEVER BEEN REGISTERED WITH THE PHILLIPINE FOOD AND DRUG ADMINISTRATION. I HAVE PERSONAL KNOWLEDGE OF THIS DRUG BECAUSE OF MY FREQUENT COMMUNICATION WITH U.S. FDA, AND BECAUSE OF THIS, I DO NOT THINK WE SHALL

EVER RECOGNIZE OR ACCEPT THIS DRUG FOR INTRODUCTION IN THE LOCAL MARKET,"

FROM AUSTRALIA:

"LAETRILE IS NOT BEING MANUFACTURED IN AUSTRALIA; NEITHER IS IT APPROVED FOR GENERAL MARKETING OR FOR USE IN CLINICAL TRIALS, AND THERE IS AT PRESENT NO AUTHORIZED IMPORTER/DISTRIBUTOR."

FROM INDIA:

"WE HAVE RECEIVED NO APPLICATION FOR REGISTRATION OF AMYGDALIN FOR USE IN THE TREATMENT OF CANCER IN THE COUNTRY. THIS DRUG IS NOT BEING MARKETED IN INDIA."

FROM BELGIUM:

"ANSWERING YOUR LETTER OF JUNE 19 CONCERNING THE LEGAL AND MEDICAL STATUS IN OUR COUNTRY OF THE COMPOUND CALLED 'AMYGDALIN', I ONLY CAN AFFIRM YOU THAT THIS DRUG IS UNKNOWN HERE IN BELGIUM."

FROM GREECE:

"IN REPLY TO YOUR LETTER DATED JUNE 19, 1975 WE WOULD LIKE TO INFORM YOU THAT IN GREECE IT DOES NOT CIRCULATE PHARMACEUTICAL SPECIALTY CALLED VITAMIN B17 OR LAETRILE CONTAINING THE DRASTIC SUBSTANCE AMYGDALIN."

THE RHETORIC OF LAETRILE PROPONENTS IS ENDLESS. THE RESULTS OF THE RHETORIC- IF CLEAR, CONCISE, REALISTIC AND ACCURATE INPUT OF THOSE OF US IN LEGITIMATE PUBLIC HEALTH TRUST POSITIONS IS NOT BALANCED TO AN INTERESTED PUBLIC - MAY BE DEVASTING.

THIS YEAR, MORE THAN 15 STATE LEGISLATURES - INCLUDING NEVADA - WILL AND ARE BEING APPROACHED BY LAETRILE SUPPORTERS TO OFFER VARIOUS FORMS OF "LEGALIZATION" OF LAETRILE LEGISLATION. LEGISLATORS MUST NOT BE MISINFORMED OR MISEDUCATED ABOUT LAETRILE. LADIES AND GENTLEMEN, YOU MUST ASSESS YOUR POSITION OF RESPONSIBILITY VERY CRITICALLY. YOUR JUDGMENT IN CONSIDERING THE LEGISLATION BEFORE YOU MUST BE CLEAR. I URGE YOU NOT TO YIELD TO EMOTIONS AND RHETORIC BUT WEIGH SCIENTIFIC FACTS AND REASONED JUDGMENTS.

Exhibit "L"

BACKGROUND STATEMENT ON LAETRILE

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service National Institutes of Health

Prepared by:

Office of Cancer Communications
National Cancer Institute
Bethesda, Maryland 20014

October 1975

NCI TESTING OF LAETRILE (AMYGDALIN)

The National Cancer Institute has conducted several series of tests of Laetrile in the animal tumor systems used to screen drugs for anti-cancer activity. Laetrile is variously described as a form of Amygdalin, a nitriloside, Vitamin B_{17}, or l-mandelo-nitrile-beta-glucuronide. Amygdalin is a cyanogenic glucoside that occurs in many plants. Supporters of the drug have used the names Laetrile and Amygdalin synonymously. The compound actually used in all tests at NCI and elsewhere (including clinical studies) has been Amygdalin. The compound was tested alone or in combination with an enzyme, beta-glucosidase. In each of the tests, summarized below, the compound failed to produce a reproducible antitumor effect.

1957: Amygdalin was tested with three transplanted mouse tumor systems used at the time by the NCI Cancer Chemotherapy National Service Center (CCNSC) to screen compounds for anti-cancer activity. Amygdalin produced no significant inhibition or growth of the carcinoma 775 or sarcoma 180 tumors, and produced no significant increase in the lifespan of mice with leukemia L1210 tumors.

1960: Material from a different source was tested against the same three mouse tumors. The compound failed to show antitumor activity.

1969: Amygdalin was tested alone and in combination with beta-glucosidase against leukemia L1210 in mice. Amygdalin was inactive against the tumor, alone and in combination with the enzyme. Toxic side effects increased when the drug and enzyme were given together.

1973: Amygdalin was tested alone and in combination with beta-glucosidase against the Walker 256 carcinoma in rats and against the following 4-tumor mouse screen currently in use by NCI: leukemia L1210, lymphoid leukemia P388, B16 melanoma, and Lewis lung carcinoma. Amygdalin was completely inactive against the four tumors, alone or in combination with the enzyme.

1975: Amygdalin was tested alone and in combination with beta-glucosidase against three transplanted mouse tumors; lymphoid leukemia P388, Lewis lung carcinoma, and Ridgway osteogenic sarcoma. In these tests, Amygdalin had no antitumor activity.

Tests of Amygdalin are continuing at the Memorial Sloan-Kettering Cancer Center, New York City, with spontaneous, naturally-occurring mammary (breast) tumors in two strains of mice: Swiss and CD8F1 hybrid. To date, Amygdalin has shown no reproducible effect on either growth of the original tumors or development of subsequent metastases. Scientists at the Memorial Sloan-Kettering Cancer Center are also testing the effects of Amygdalin against a spontaneous, naturally-occurring leukemia in AKR mice.

The National Cancer Institute is conducting additional tests of Amygdalin against a metastatic mouse tumor, the Lewis lung carcinoma. The current tests are directed toward assessing the effect of Amygdalin on development of metastases from the tumor. Previous tests showed conclusively that Amygdalin did not inhibit growth of the primary tumor, nor did it reproducibly increase the lifespan of the mice.

Chemically, Amygdalin is a derivative of a molecule called mandelonitrile. Specifically, it is mandelonitrile-beta-gentiobioside, in which mandelonitrile is linked with a chain of two glucose units. The enzyme beta-glucosidase, used in some of the tests, can break the link between mandelonitrile and the one or more sugar derivatives. Mandelonitrile may decompose further, releasing highly toxic cyanide.

Ernst T. Krebs, Jr., who claimed the synthesis of Laetrile in 1952, proposed that the compound acted through the release of cyanide in cancer cells. He suggested that normal cells contain an enzyme called rhodanese that detoxifies cyanide by coverting it to thiocyanate.

Past NCI tests of Laetrile in many rodent tumor systems have failed to produce evidence of anticancer activity. Because there is no basis for predicting that Amygdalin might act against cancer in humans, the National Cancer Institute does not intend to test Amygdalin in cancer patients. Nevertheless, the National Cancer Institute is committed to pursuing any evidence that might provide a basis for clinical trials with cancer patients.

# # #

Antitumor Activity of Amygdalin MF (NSC-15700) as a Single Agent and With β-Glucosidase (NSC-120953) on a Spectrum of Transplantable Rodent Tumors[1,2,3]

Isidore Wodinsky and Joseph K. Swiniarski[4,5]

SUMMARY

Experiments are described in which four transplantable rodent tumors (L1210 lymphoid leukemia, P388 lymphocytic leukemia, B16 melanoma, and Walker 256 carcinosarcoma) were used to investigate the antitumor activity of amygdalin MF. Amygdalin MF was given alone and in combination with β-glucosidase which was administered ½ hour prior to amygdalin MF, starting 24 hours after tumor implantation. No antitumor activity was observed in any of the four tumor systems tested with the drug alone or in combined therapy. The combined therapy showed potentiation of toxicity with doses of amygdalin MF greater than or equal to 100 mg/kg.

[Cancer Chemother Rep 59:939-950, 1975]

Amygdalin MF, found in the kernels of bitter almonds, peaches, and apricots, has been reported to have been used in cancer chemotherapy since 1845 (1). In spite of its availability for 130 years, there is a striking paucity of published data on the antitumor effects of amygdalin MF on experimental tumor systems. The mechanism proposed to explain the activity of amygdalin MF is that sufficient amounts of hydrogen cyanide (HCN) are released in the presence of β-glucosidase to stop tumor respiration which is lethal for the tumor cells (fig 1) (2). HCN is reported to be less lethal for normal tissues because they contain the enzyme thiosulfate sulfurtransferase EC 2.8.1.1 (rhodanese) which converts the HCN in the presence of thiosulfate to thiocyanate (3). Burk et al (4,5) reported that Ehrlich ascites cells, treated in vitro, are sensitive to combined treatment with amygdalin MF and β-glucosidase because of the synergistic effects of the HCN-benzaldehyde mixture which produces a decreased respiration and an increased aerobic glycolysis, whereas Levi et al (6) have reported that the samples of amygdalin MF they tested on human tumor tissues and Ehrlich ascites cells had no significant effect on respiration or on aerobic and anaerobic glycolysis. Levi et al also found no significant inhibition of DNA, RNA, or protein synthesis.

The lack of in vivo experimental data prompted the DR&DP, DCT, NCI to initiate a series of experiments on a spectrum of transplantable rodent neoplasms with amygdalin MF alone and in combination with β-glucosidase at our laboratory. The results of these tests are reported herein.

MATERIALS AND METHODS

Compounds

Amygdalin MF solutions were prepared fresh daily in physiologic saline. A volume of 0.4 ml was administered intraperitoneally (ip) each day for 9 days starting 24 hours after tumor implantation.

β-Glucosidase was dissolved in cold saline each day and injected ip ½ hour prior to the amygdalin MF treatment daily for 9 days. According to the DR&DP, the β-glucosidase was obtained from Calbiochem catalog No. 346801 which contained approximately 800 IU/mg. The mice received a maximum of 160 IU/mouse/injection and the rats received a maximum of 400 IU/rat/injection.

[1]Received Apr 11, 1975; revised June 18, 1975; accepted July 3, 1975.

[2]Supported by contract NO1-CM-33727 from the Division of Cancer Treatment (DCT), National Cancer Institute (NCI), National Institutes of Health, Department of Health, Education, and Welfare.

[3]Amygdalin MF (NSC-B900540; lot No. 7209): CAS reg. No. 672-72-0; D-mandelonitrile, gentiobioside; Laetrile. Obtained by Drug Research and Development Program (DR&DP), DCT, NCI from the Food and Drug Administration, and prepared by the McNaughton Foundation, Montreal, Canada.

β-Glucosidase (batch MB) was obtained from Calbiochem, San Diego, Calif, by DR&DP, DCT, NCI.

[4]Arthur D. Little, Inc., Cambridge, Mass.

[5]*Reprint requests to:* Mr. Isidore Wodinsky, Arthur D. Little, Inc., Acorn Park, Cambridge, Mass 02140.

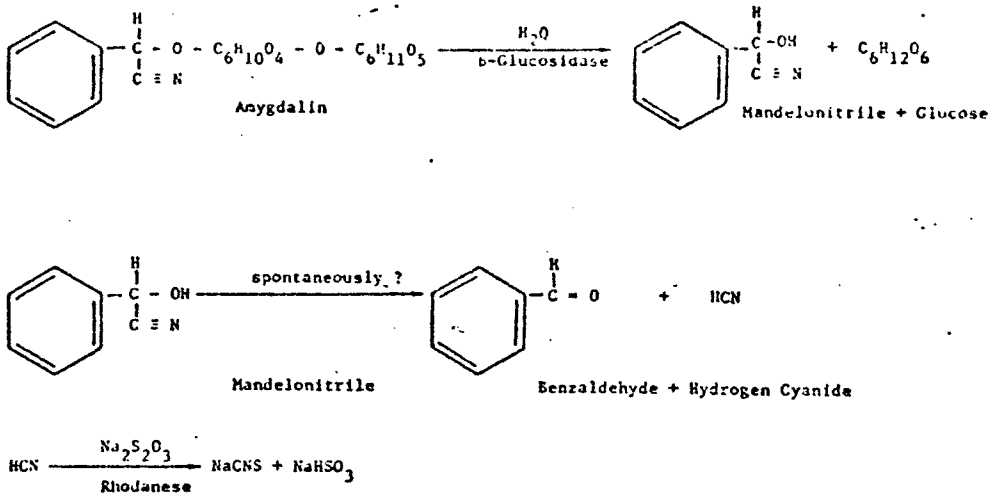

FIGURE 1.—Amygdalin metabolism.

Neoplasms

The L1210 and P388 leukemias, B16 melanoma, and Walker 256 carcinosarcoma test systems used in these studies are described elsewhere (7). These transplantable rodent-tumor systems have, in retrospective studies, detected most of the currently active clinical drugs (8).[6]

Briefly, in the L1210 leukemia test system, CDF_1 mice were inoculated ip with 10^5 tumor cells from the ascitic fluid of donor DBA/2 mice. Daily injections of amygdalin MF and β-glucosidase alone and in combination were given starting 24 hours after tumor implantation. The β-glucosidase was administered ½ hour prior to the amygdalin MF injection. The test was evaluated by determining the mean survival times of test groups of ten mice as a percentage of the mean survival time of the control group of 30 mice (T/C). It is also reported as percent increase in lifespan (%ILS) or T/C − 100. (Significant activity is ≥ 25% ILS. Significant toxicity is ≤ −15%).

In the P388 leukemia test system, CDF_1 mice were inoculated ip with 10^6 cells from the ascitic fluid of donor mice and the same procedure used in the L1210 leukemia test system was employed with the exception that an increase in median survival time was the criterion for activity.

In the B16 melanoma test system, 0.5 ml of a 1:10 g/ml tumor brei was inoculated ip or subcutaneously (sc) into BDF_1 mice; treatment began 24 hours after tumor implantation and was administered daily for 9 days. The parameter for presumptive activity is an ILS of 25%, which is considered to warrant further study.

In the Walker 256 carcinosarcoma studies, 10^6 ascites cells were implanted intramuscularly (im) in the hind leg muscle of Sprague Dawley rats and drug treatments of single 0.4-ml daily doses were given on Days 1, 3, and 6 after tumor implantation. The parameter for activity was an increase in median survival time of a treated group of ten rats, compared with the control group of 30 rats.

RESULTS

L1210 Leukemia Test System

Amygdalin MF did not increase the lifespan of CDF_1 mice bearing ip implanted L1210 leukemia when administered as a single daily dose for 9 days at dose levels of 6.25-800 mg/kg, and toxicity was not observed as evidenced by the changes on Day 5 in mean body weight and death of the mice. β-Glucosidase (10 mg/kg) was also ineffective and nontoxic. There was no increase in lifespan noted for any group treated with β-glucosidase ½ hour prior to the amygdalin MF injection. Early deaths (due to the drug) were noted in combined therapy with amygdalin MF (100 mg/kg) and β-glucosidase (10 mg/kg) (table 1).

Amygdalin MF was tested in a second experiment at dose levels from 25 to 3200 mg/kg. The results showed that the mice gained weight with amygdalin MF alone at the higher doses but no antitumor effect was noted. The mice died at the same time as the controls. β-Glucosidase was inactive and nontoxic at 10 mg/kg. Combinations of 200-800 mg/kg of amygdalin MF and 10 mg/kg of β-glucosidase were toxic; all

[6] Venditti JM. Plan for antitumor screening in animals and selection of new agents as candidates for clinical trial. *In* Report of the Division of Cancer Treatment, NCI, 1973. Bethesda, Md, NCI, 1973, vol 2, pp 2.27-2.75.

TABLE 1.—Effect of combination chemotherapy with amygdalin MF and β-glucosidase on the survival time of CDF_1 mice bearing L1210 leukemia*

Drug	Dose** mg/kg/inj.	Δ $\bar{X}$ Body Weight Grams (Day 5)	Mortality Distribution (Day) 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	Mean Survival Time (Days)
Control	0	+1.0								6	12	7	5										9.4
β-glucosidase	10	+1.5								3	4	3											9.0
Amygdalin MF	800	+2.9								1	5	4											9.3
	400	+0.9		1						3	4	3											9.0
	200	+1.0									6	2	1										9.4
	100	+0.9								3	3	3	1										9.2
	50	+1.4								1	3	5	1										9.6
	25	+0.9								4	3	3											9.2
	12.5	+0.9								4	4	1	1										8.9
	6.25	+0.7									2	6				2							10.6
β-glucosidase and Amygdalin MF	10 + 100	-				2	4			1	3												6.3
	10 + 50	+1.7								3	4	2	1										9.1
	10 + 25	+1.1								5	3	2											8.7
	10 + 12.5	+1.4								2	5	3											9.1
	10 + 6.25	+1.0								3	3	4											9.1

* L1210 - 10^5 cells in 0.1 ml i.p.
** β-glucosidase - administered i.p. on days 1-9 1xday/1/2 hr prior to amygdalin
Amygdalin - administered i.p. on days 1-9 1xday

Exp. L6381

mice died after the first injection. At 100 mg/kg of amygdalin MF and 10 mg/kg of β-glucosidase, the toxicity was evidenced by the lower increased mean lifespan (table 2).

P388 Leukemia Test System

The results were similar to the L1210 leukemia test system. In the first experiment, amygdalin MF alone or β-glucosidase alone was not effective and was nontoxic for mice bearing P388 lymphocytic leukemia. Amygdalin MF (6.25-100 mg/kg) and β-glucosidase (5 or 10 mg/kg) in combination therapy were neither active or toxic (table 3).

These same doses of β-glucosidase were employed in a second experiment but the dose levels of amygdalin MF were higher (100-400 mg/kg). The results (table 4) showed no toxicity or activity with either drug alone but when the drugs were combined, the 200- and 400-mg/kg doses of amygdalin MF were toxic with both the 5- and the 10-mg/kg dose levels of β-glucosidase. At the highest nontoxic combined treatment dose levels, no antitumor activity was noted.

Ip B16 Melanoma Test System

The results using this test system were similar to those noted with the L1210 and P388 leukemia test systems. Amygdalin MF and β-glucosidase used as single agents showed no antitumor activity, as evidenced by the parameter of increased survival time, and no toxicity, as evidenced by drug-related deaths and mean change in body weight. There is some evidence, again, that the combination of 100 mg/kg of amygdalin MF and 10 mg/kg of β-glucosidase was toxic for the BDF_1 mice. Three of the ten mice died by Day 9. The median lifespan of the group, however, was 19.5 days compared with 20 days for the control groups of mice (table 5).

Sc B16 Melanoma Test System

The results in the sc B16 melanoma assay demonstrated that both compounds were well tolerated at the highest dose level tested and, in general, the mean weight gain for the treated groups was on the positive side. Death in the control group occurred between 17 and 39 days with a median of 26.0 days, and one mouse lived past Day 45. We noted that almost all of the deaths in the treated groups fell within this range and no group survived long enough to produce a 25% ILS. There were eight mice with large ulcerated tumors alive at the end of the experiment (Day 45). Only the combination of 100 mg/kg of amygdalin MF and 10 mg/kg of β-glucosidase was toxic for the mice (table 6).

Im Walker 256 Carcinosarcoma Test System

The median survival time for a group of 30 control rats was 14.0 days with a mean weight gain of 18 g on Day 5. There were two of 30 survivors on Day 45 in which the tumor had regressed completely by Day 18. Regressions with the im implanted Walker 256 carcinosarcoma have been observed previously (9,-10).

Table 7 shows that neither amygdalin MF nor β-glucosidase administered as single agents at dose levels up to 1000 and 10 mg/kg, respectively, increased the median survival time of the tumor-bearing rats. The drugs, given in combination, were toxic for the rats at both the 250-mg/kg amygdalin MF and the 5- and 10-mg/kg β-glucosidase dose levels. The maximal ILS (21%) was noted in this experiment at a combined dose of 31.3 mg/kg of amygdalin MF and 10 mg/kg of β-glucosidase.

Because of this observation, a second experiment was initiated (table 8) using an overlapping range of amygdalin MF (1.95-62.5 mg/kg) with β-glucosidase (1.25-10 mg/kg) administered as single agents and in combination. The results of this experiment showed no antitumor activity and no toxicity for the tumor-bearing rats with all combinations or with the drugs alone.

CONCLUSION

The pioneer study by Skipper et al (11) demonstrated a positive correlation between the drug kill of leukemic cells and an increase in the survival time of the tumor-bearing hosts. The results of our experiments showed that the neoplastic cells of L1210 lymphoid leukemia, P388 lymphocytic leukemia, ip and sc implanted B16 melanoma, and im implanted Walker 256 carcinosarcoma were not sensitive to amygdalin MF or to β-glucosidase when administered as single agents or in combination. There was no significant increase in the mean or the median lifespan of tumor-bearing groups of animals at the highest nontoxic tolerated dose levels. If a significant percentage of the hosts' tumor cells had been killed by the treatment, an increase in survival time would have been expected; however, this was not observed.

Amygdalin MF was not toxic for tumor-bearing mice when injected ip at a level of 64 mg/mouse/day for 9 days, and β-glucosidase could be administered safely at a dose level of 0.2 mg/mouse. Toxicity was noted only when β-glucosidase was administered

TABLE 2.—Effect of combination chemotherapy with amygdalin MF and β-glucosidase on the survival time of CDF_1 mice bearing L1210 leukemia*

Drug	Dose** mg/kg/inj.	Δ $\bar{X}$ Body Weight Grams (Day 5)	Mortality Distribution (Day) 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	Mean Survival Time (Days)
Control	0	+1.1								1	16	12	1										9.4
β-glucosidase	10	+0.9								4	6												8.6
Amygdalin MF	3200	+1.4			1					2	2	4	1										8.8
	1600	+0.7								1	6	3											9.2
	800	+0.9								3	3	3	1										9.2
	400	+1.2								2	3	5											9.3
	200	+1.2								2	7	1											8.9
	100	+1.9								4	3	2	1										9.0
	50	+1.0								4	3	2	1										9.0
	25	+0.8								1	5	4											9.3
β-glucosidase and Amygdalin MF	10 + 800	-		10																			2.0
	10 + 400	-		10																			2.0
	10 + 200	-		10																			2.0
	10 + 100	+1.2			1					7	2												7.7
	10 + 50	+0.8								4	2	4											9.0
	10 + 25	+1.4								6	2	2											8.6

* L1210 - 10^5 cells in 0.1 ml i.p.

** β-glucosidase - administered i.p. on days 1-9 1xday 1/2 hr prior to amygdalin
Amygdalin - administered i.p. on days 1-9 1xday

Exp. L6397

TABLE 3.—Effect of combination chemotherapy with amygdalin MF and β-glucosidase on the survival time of CDF_1 mice bearing P388 lymphocytic leukemia*

Drug	Dose** mg/kg/inj.	Δ $\bar{X}$ Body Weight Grams (Day 5)	Mortality Distribution (Day) 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	Median Survival Time (Days)
Control	0	+0.5										3	15	10	1	1							11.0
β-glucosidase	10	0.0											5	3	2								11.5
	5	-0.3											4	5	1								12.0
Amygdalin MF	800	-0.1				1						1	6	2									11.0
	400	-0.9											6	4									11.0
	200	-0.2										2	3	4	1								11.5
	100	-0.2									1	.	3	3	3								12.0
	50	-1.5										3	3	3	1								11.0
	25	-1.4									1	1	3	4		1							11.5
	12.5	-0.8									1		6	3									11.0
	6.25	+0.5										1	3	3	2	1							12.0
β-glucosidase and Amygdalin	10 + 100	-0.7		1								1	2	3	2	1							12.0
	10 + 50	-0.6											6	3	1								11.0
	10 + 25	0.0											5	5									11.5
	10 + 12.5	-0.7											5	4	1								11.5
	10 + 6.25	-1.0									2		2	6									12.0
	5 + 100	-1.0										1	6	2									11.0
	5 + 50	-0.6									1		3	4	2								12.0
	5 + 25	-0.7									1	2	2	5									11.5
	5 + 12.5	-0.2									2		4	4									11.0
	5 + 6.25	-0.5									3		3	3	1								11.0

* P388 - 10^6 cells in 0.1 ml i.p.
** β-glucosidase - administered i.p. on days 1-9 1xday 1/2 hr prior to amygdalin
amygdalin - administered i.p. on days 1-9 1xday

Exp. PS1974

TABLE 4.—Effect of combination chemotherapy with amygdalin MF and β-glucosidase on the survival time of CDF_1 mice bearing P388 lymphocytic leukemia*

Drug	Dose** mg/kg/inj.	Δ $\bar{X}$ Body Weight Grams (Day 5)	Mortality Distribution (Day) 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	Median Survival Time (Days)
Control	0	+1.7										2	9	15	3	1							12.0
β-glucosidase	10	+1.2									1	3	3	3									11.0
	5	+1.6										3		5	1	1							11.0
Amygdalin MF	400	+0.9											3	6	1								12.0
	200	+0.7									1	2	5	1	1								11.0
	100	+1.2										3	5	2									11.0
β-glucosidase	10 + 400	-		10																			2.0
and	10 + 200	-		10																			2.0
Amygdalin	10 + 100	+1.1									2	4	3	1									10.0
	5 + 400	-		8	1	1																	2.0
	5 + 200	-		6		1						2	1										2.0
	5 + 100	+1.5									1	6	2	1									10.0

* P388 - 10^6 cells in 0.1 ml i.p.
** β-glucosidase - administered i.p. on days 1-9 1xday 1/2 hr prior to amygdalin
Amygdalin - administered i.p. on days 1-9 1xday

Exp. PS2052

TABLE 5.—Effect of combination chemotherapy with amygdalin MF and β-glucosidase on the survival time of BDF_1 mice bearing ip implanted B16 melanoma *

Drug	Dose** mg/kg/inj.	Δ $\bar{X}$ Body Weight Grams (Day 5)	Mortality Distribution (Day) 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30	Median Survival Times (Days)
Control	0	+1.8	1 1 4 7 7 9 1	20
β-glucosidase	10	+2.3	1 4 4 1	19.5
	5	-0.4	1 2 7	21.0
Amygdalin MF	800	+2.6	1 1 2 2 2 1 1	20.0
	400	+1.9	1 2 4 2 1	20.0
	200	+2.2	1 4 3 2	19.5
	100	+2.4	1 1 2 4 2	21.0
	50	+2.1	1 3 1 3 1 1	20.5
	25	+2.1	2 2 3 3	20.0
	12.5	+1.8	1 4 1 1 1 1 1	18.5
	6.25	-0.9	1 2 3 2 1 1	20.0
β-glucosidase and Amygdalin	10 + 100	+1.6	1 2 1 1 2 1 1 1	19.5
	10 + 50	+2.0	2 1 3 1 1 2	19.0
	10 + 25	+1.8	3 2 4 1	18.5
	10 + 12.5	+0.7	1 1 3 3 1 1	18.5
	10 + 6.25	+1.0	1 1 1 2 3 1 1	20.5
	5 + 100	+1.2	2 1 1 1 4	21.5
	5 + 50	+0.9	1 2 1 6	21.0
	5 + 25	+1.8	1 2 2 1 4	19.5
	5 + 12.5	+1.7	2 2 2 2 2	18.0
	5 + 6.25	+2.8	1 4 5	20.0

* B16 melanoma - 0.5 ml of 1:10 (gm/ml) brei implanted i.p.
** β-glucosidase - administered i.p. on days 1-9 1xday 1/2 hr prior to amygdalin
Amygdalin - administered i.p. on days 1-9 1xday

Exp. B258

TABLE 6.—Effect of combination chemotherapy with amygdalin MF and β-glucosidase on the survival time of BDF_1 mice bearing sc implanted B16 melanoma *

Drug	Dose** mg/kg/inj.	Δ X̄ Body Weight Grams (Day 5)	Mortality Distribution (Day) 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45	Median Survival Time (Days)	Survivors (Day 45)
Control	0	+1.4	1 2 2 2 3 1 1 2 1 3 2 2 3 1 1 1 1	26.0	1/30
β-glucosidase	10	+1.2	2 2 1 1 1	24.5	1/10
	5	+1.7	1 1 1 1 1 1 1 1 1	25.5	1/10
Amygdalin MF	800	+1.3	1 2 3 2 1 1 1	24.0	0/10
	400	+1.4	1 1 2 3 2 1	26.5	0/10
	200	+1.9	1 2 1 2 1 1 1	25.0	0/10
	100	+0.9	1 2 2 2 1 1 2 1	22.5	0/10
	50	+1.2	1 1 1 1 1 1 1 1 1 1 1	27.0	1/10
	25	+0.8	1 1 1 3 1 1 1 1 1	24.0	0/10
	12.5	+1.6	2 3 2 1 2 1	22.0	0/10
	6.25	+1.3	1 1 1 1 1 1 1 1 3	24.5	0/10
β-glucosidase and Amygdalin MF	10 + 100	+1.0	1 3 3 1 1 1	9.0	1/10
	10 + 50	+0.7	3 1 1 1 1 1 1 1 1 1	25.5	0/10
	10 + 25	+0.7	1 2 1 2 1 1 1 1 1 1	23.0	1/10
	10 + 12.5	+0.9	1 1 1 1 2 1 1 1 1 1	25.0	1/10
	10 + 6.25	+1.2	1 2 1 2 1 1 1 1 1 1	27.0	0/10
	5 + 100	+1.8	1 1 1 1 2 1 2 1	26.0	1/10
	5 + 50	+0.9	1 1 1 1 1 1 2 2	26.5	0/10
	5 + 25	+1.3	1 1 1 2 1 2 1 1 1	26.5	0/10
	5 + 12.5	+1.0	1 1 1 2 1 1 1 1 1	25.0	1/10
	5 + 6.25	+1.6	1 2 1 4 1 1	29.0	0/10

* B16 Melanoma - 0.5 ml of 1:10 (gm/ml) brei implanted subcutaneously
** β-glucosidase - administered i.p. on days 1-9 1xday 1/2 hr. prior to amygdalin
Amygdalin - administered i.p. on days 1-9 1xday

Exp. 8003

TABLE 7.—Influence of combination chemotherapy with amygdalin MF and β-glucosidase on the survival time of Sprague Dawley rats implanted im with Walker 256 carcinosarcoma *

Drug	Dose** mg/kg/inj.	$\bar{X}$ Body Weight Grams (Day 5)	Mortality Distribution (Day) 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45	Median Survival Time (Days)	Survivors (Day 45)
Control	0	+18	4 2 3 2 6 4 2 1 1 1 1	14.0	2/30
β-glucosidase	10	+18	2 1 1 2 1 1 1	12.0	1/10
	5	+20	3 1 2 2 1 1	14.0	0/10
Amygdalin MF	1000	+20	1 1 3 1 1 1 1	13.5	1/10
	500	+19	1 1 4 1 3	12.0	0/10
	250	+19	1 1 1 2 3 1 1 1 1	12.5	0/10
	125	+18	1 3 1 2 2 1	13.5	0/10
	62.5	+20	2 2 1 3 1 1	12.5	0/10
	31.3	+18	1 1 3 2 1 1 1	12.5	0/10
β-glucosidase and Amygdalin MF	10 + 500	-	8 2	2.0	0/10
	10 + 250	-	8 2	2.0	0/10
	10 + 125	+15	1 1 1 3 2 1	14.0	0/10
	10 + 62.5	+13	1 1 2 1 2 1 1 1	12.5	0/10
Amygdalin MF	10 + 31.3	+16	2 1 1 2 1 1	17.0	1/10
	5 + 500	-	9 1	2.0	0/10
	5 + 250	-	5 2 1 1 1	3.0	0/10
	5 + 125	+14	2 2 1 2 1 2	11.5	0/10
	5 + 62.5	+18	1 1 1 1 1 2 1 1 1 1	14.0	0/10
	5 + 31.3	+16	1 2 2 1 1 1 1	15.5	0/10

* Walker 256 - 10^6 cells in 0.1 ml intramuscularly
** β-glucosidase - administered i.p. on days 1, 3 and 6 1xday 1/2 hr prior to amygdalin
Amygdalin - administered i.p. on days 1, 3 and 6 1xday

Exp. WA610

TABLE 8.—Influence of combination chemotherapy with amygdalin MF and β-glucosidase on the survival time of Sprague Dawley rats bearing im implanted Walker 256 carcinosarcoma*

Drug	Dose** mg/kg/inj.	Δ $\bar{X}$ Body Weight Grams (Day 5)	Mortality Distribution (Day) 8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	Median Survival Time (Days)	Survivors (Day 45)
Control	0	+14	1		6	9	3	3	4	2												11.0	0/30
β-glucosidase	10	+16			5	3	1			1												10.5	0/10
	5	+16			4	4		1		1												11.0	0/10
	2.5	+17			2	6	1	1														11.0	0/10
	1.25	+15			5	2	1	1				1										10.5	0/10
Amygdalin MF	62.5	+17			4	3	1	1														11.0	1/10
	31.3	+16			4	1		2		1		1									1	12.0	0/10
	15.6	+15		1	4	4	1															10.5	0/10
	7.8	+15			5	4	1															10.5	0/10
	3.9	+15			3	3	2	1								1						11.0	0/10
	1.95	+17			2	3	1	1			1											11.5	2/10
β-glucosidase and Amygdalin MF	10 + 62.5	+15			6	4																10.0	0/10
	10 + 31.3	+15			6	2	1		1													10.0	0/10
	10 + 15.6	+10			1	5	2	1		1												11.0	0/10
	10 + 7.8	+15		1	2	5	1	1														11.0	0/10
	10 + 3.9	+13			4	2	1	1		2												11.0	0/10
	10 + 1.95	+16			3	5	1	1														11.0	0/10
	5 + 62.5	+14			5	1	3			1												10.5	0/10
	5 + 31.3	+17			2	4	1	1		1					1							11.0	0/10
	5 + 15.6	+18			1	5		2	2													11.0	0/10
	5 + 7.8	+17		1	3	3	2	1														11.0	0/10
	5 + 3.9	+18			3	7																11.0	0/10
	5 + 1.95	+15		1	2	2	4	1														11.5	0/10
	2.5 + 62.5	+15			6	3	1															10.0	0/10
	2.5 + 31.3	+16			1	5	1	2	1													11.0	0/10
	2.5 + 15.6	+17			3	4	1	1		1												11.0	0/10
	2.5 + 7.8	+21			4	2	2	2														11.0	0/10
	2.5 + 3.9	+16		1	3	3	1				2											11.0	0/10
	2.5 + 1.95	+16		1	2	3	1	1	1													11.0	1/10
	1.25 + 62.5	+15			4	2	1		1				1									11.0	1/10
	1.25 + 31.3	+15			5	1	2	2														10.5	0/10
	1.25 + 15.6	+15			3	4	2				1											11.0	0/10
	1.25 + 7.8	+16		1	6	2				1												10.0	0/10
	1.25 + 3.9	+17			5	3	1				1											10.5	0/10
	1.25 + 1.95	-3			7	1	1	1														10.0	0/10

* Walker 256 - 10^6 cells in 0.1 ml intramuscularly

** β-glucosidase - administered i.p. on days 1, 3, and 6 1xday 1/2 hr prior to amygdalin
Amygdalin - administered i.p. on days 1, 3, and 6 1xday

Exp. WA611

prior to doses greater than or equal to 100 mg/kg of amygdalin MF. Thus, it would appear that no differential tumor-cell/normal-cell sensitivity existed in these tumor systems and hence no successful chemotherapy resulted.

ADDENDUM

Since this paper was submitted, Hill et al have reported on the lack of therapeutic effect of amygdalin in B16 melanoma and BW5147 leukemia (12).

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Experimental Studies of the Antitumor Activity of Amygdalin MF (NSC-15780) Alone and in Combination With β-Glucosidase (NSC-128056)[1,2,3]

W. R. Laster, Jr. and F. M. Schabel, Jr.[4,5]

SUMMARY

Amygdalin MF was evaluated alone and in combination with an activating agent, β-glucosidase, against three transplantable rodent tumors: Ridgway osteogenic sarcoma, Lewis lung carcinoma, and P388 leukemia. In dose-response studies up to the LD20 in normal mice, amygdalin MF alone did not demonstrate significant antitumor activity against any of these three tumor systems. Similarly, at doses not exceeding the LD10 in normal mice, amygdalin MF plus β-glucosidase did not demonstrate antitumor activity against any of these three tumor systems. Potentiation of the lethal toxicity of amygdalin MF by β-glucosidase was observed in all studies where the two agents were given in simultaneous combination.

[Cancer Chemother Rep 59:951-965, 1975]

One of the objectives of the National Cancer Program is to discover and develop new anticancer drugs. During recent years, numerous reports have appeared in both the lay press and the news sections of scientific journals reporting the undocumented anticancer activity of amygdalin MF in man. To our knowledge, the only report of possible activity of this drug against cancer in experimental animals appeared in an undocumented "News and Comment" report in *Science*, in which it was stated that "the results clearly show that amygdalin significantly inhibits the appearance of lung metastases in mice bearing spontaneous mammary tumors and significantly increases the inhibition of the growth of the primary tumors over the appearance of inhibition in untreated animals" (1).

The DCT, NCI recognizes the need to establish the validity of any material considered to have antineoplastic properties against any tumor system, in animal or man. In an attempt to establish the anticancer properties of amygdalin MF, the DCT requested Southern Research Institute to evaluate this compound against a variety of animal tumor systems. This report will describe the results of this study.

MATERIALS AND METHODS

The material to be evaluated was identified as amygdalin MF and was considered to be a clinical sample. The analytic data on amygdalin MF, as supplied by Dr. Harry Wood (DCT), are as follows: DL-mandelonitrile-β-D-glucosido-6-β-D-glucoside, also known as isomygdalin (DL on the nitrile position).

87.4% Isoamygdalin
6.9% water
5.7% Isopropanol
100%

Krebs and Bouziane[6] have proposed that nitrilosides (Laetriles) exert their anticancer activity by the release of nascent hydrogen cyanide (HCN) from nitrilosides (Laetriles) by enzymatic hydrolysis with β-glucuronidase or β-glucosidase. They further propose that normal cells are not destroyed by the released HCN because the enzyme rhodanese, present in normal cells but not in tumor cells, detoxifies HCN

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[2]Supported by contract NO1-CM-43756 from the Division of Cancer Treatment (DCT), National Cancer Institute (NCI), National Institutes of Health, Department of Health, Education, and Welfare.

[3]Amygdalin MF (NSC-B900540; lot No. 7209): CAS reg. No. 672-72-0; D-mandelonitrile, gentiobioside; Laetrile. Obtained by Drug Research and Development Program (DR&DP), DCT, NCI, from the Food and Drug Administration, and prepared by the McNaughton Foundation, Montreal, Canada.

β-Glucosidase was obtained from Calbiochem, San Diego, Calif, by DR&DP, DCT, NCI.

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[6]Krebs ET, Jr, and Bouziane NR. Nitrilosides (Laetriles). Their rationale and clinical utilization in human cancer. *In* The Laetriles-Nitrilosides in the Prevention and Control of Cancer. Montreal, Canada, the McNaughton Foundation.

to harmless thiocynates (2). Based on these observations and interpretations, we tested amygdalin MF against three murine tumor systems, either alone or in combination with β-glucosidase. The enzyme, β-glucosidase, is known to catalyze the hydrolysis of amygdalin to yield glucose, benzaldehyde, and HCN (2). β-Glucosidase was given simultaneously with amygdalin MF in order to insure hydrolysis, which produces HCN. The activity of this lot of β-glucosidase was 1010 IU/mg (activity is expressed in international units per milligram and signifies the number of micromoles of substrate converted per minute at 30°C by 1 mg of enzyme preparation).

An extensive survey of the world medical literature on nitrilosides (Laetriles) by Krebs and Bouziane[6] has considered the theoretical, experimental, and clinical data. Based on this report, the decision was made to evaluate amygdalin MF against three transplantable rodent tumors: two solid tumors and one leukemia.

The Ridgway osteogenic sarcoma (ROS) was selected as one of the two rodent solid tumors for study. The ROS is a uniformly fatal solid tumor that is markedly sensitive to representatives of the major chemical and biologically active classes of anticancer drugs used in effective, but usually noncurative, treatment of a wide variety of malignant neoplasms in man, including many solid tumors.

Established tumors (approximately 500 mg) regress under treatment with actinomycin D, adriamycin, daunorubicin, bleomycin, cyclophosphamide, melphalan, 5-fluorouracil, arabinosylcytosine, 6-mercaptopurine, vincristine, and *cis*-dichlorodiammineplatinum(II) (3). This group includes many of the anticancer drugs of greatest current clinical usefulness. Because of this wide range of drug sensitivity, the ROS was considered to be the ideal solid tumor in experimental animals to detect the antitumor activity of amygdalin MF.

The other rodent solid tumor selected for this study was the Lewis lung carcinoma. This uniformly fatal, metastasizing solid tumor was selected because it is resistant to most agents useful in man except the alkylating agents such as cyclophosphamide and the nitrosoureas. Thus, should amygdalin MF show antitumor properties against this resistant tumor, its potential value in human oncology would be enhanced.

The third rodent tumor selected to evaluate the antitumor properties of amygdalin MF was a methylcholanthrene-induced leukemia of DBA/2 mice, the P388 leukemia. This tumor has marked utility as a model animal leukemia system because of its sensitivity to a variety of anticancer agents in use in man today. The P388 leukemia is reproducibly sensitive to (*a*) alkylating agents (BCNU, CCNU, methyl-CCNU, melphalan, cyclophosphamide), (*b*) compounds that bind to or intercalate with DNA (actinomycin D, adriamycin, bleomycin), and (*c*) vincristine, a mitotic inhibitor. In addition, the P388 leukemia is the tumor system presently being used by the DCT to screen for natural product anticancer agents.

Ridgway Osteogenic Sarcoma (ROS)

In the study designed to determine the antitumor activity of amygdalin MF against ROS, AKD_2F_1 mice (AKR × DBA/2) were implanted subcutaneously (sc) with ROS tumor fragments weighing approximately 100 mg (± 20 mg). Treatment with amygdalin MF alone and in combination with β-glucosidase was started 24 hours after tumor-cell implant. This was done to begin treatment when the tumor-cell burden was lowest, to assure a maximum likelihood of detecting any antitumor activity of the agent or the combination.

Doses of 500, 335, and 220 mg/kg of amygdalin MF alone were used. In addition, doses of 120, 80, 53, 35, and 23 mg/kg of amygdalin MF were given in simultaneous combination with 10 mg/kg/dose of β-glucosidase. All treatments (single-agent and combination therapy) were given by the intraperitoneal (ip) route using ten mice per dose.

In addition to the tumor-bearing mice, normal (nontumor-bearing) AKD_2F_1 mice of the same sex and source were treated with the same doses of amygdalin MF alone and in combination with β-glucosidase. These mice were observed for lethal toxicity (drug toxicity controls).

The mice were identified individually, were housed in stainless steel cages, and were given Wayne Lab Blox (Allied Mills, Inc.) and water ad libitum. The mice were observed daily for deaths, and two-dimensional tumor measurements were made every 3rd or 4th day from the time of first tumor appearance until termination of the experiment. Tumor measurements were converted to weight using the formula:

$$w = \frac{a \times b^2}{2},$$

where a = length in mm, b = width in mm, and w = weight in mg.

Lewis Lung Carcinoma

Amygdalin MF alone and in combination with β-glucosidase was evaluated against both the sc and the intravenously (iv) implanted Lewis lung carcinoma. In the sc group, BDF_1 mice (C57Bl/6 × DBA/2) were implanted with 40-mg tumor fragments. In the

iv group, BDF_1 mice were given 10^6 counted tumor cells via the tail vein. The same schedule and doses used in the ROS group were used in the sc and iv Lewis lung carcinoma evaluation. Normal (nontumor-bearing) BDF_1 mice were treated with the same doses of amygdalin MF alone and in combination with β-glucosidase. These mice were observed for lethal toxicity and mean body weight changes (drug toxicity controls).

P388 Leukemia

BDF_1 mice were implanted ip with either 10^6 or 10^4 P388 leukemia cells. The same schedule and doses used in the ROS and Lewis lung carcinoma groups were used in this study. Since the strain, sex, and source of BDF_1 mice, and the day of treatment and compound preparation were identical to the Lewis lung carcinoma group, the drug toxicity controls in the Lewis lung carcinoma group were used for the P388 leukemia chemotherapy trials.

RESULTS

The results of the evaluation of amygdalin MF alone and in combination with β-glucosidase against ROS are shown in table 1 and in figures 1-3. As seen in table 1 (the days of death and the weight change data), amygdalin MF alone was less toxic than when given with the activating agent, β-glucosidase. When given alone, amygdalin MF produced 10% deaths at a dose of 500 mg/kg, 30% deaths at 335 mg/kg, and no deaths at 220 mg/kg given daily for 9 days. However, when β-glucosidase was given at 10 mg/kg/dose in combination with amygdalin MF, the highest level of amygdalin MF that could be given without exceeding the LD10 in normal mice was 53 mg/kg/dose.

Cumulative mortality plots of the ROS tumor-bearing mice treated with amygdalin MF and amygdalin MF plus β-glucosidase are shown in figure 1.

Individual tumor measurements in the untreated control and treated groups are shown in figures 2 and 3. As can be seen, no significant increase in lifespan (ILS) was observed in any of the treated groups based on median survival time. In the untreated control group, the median lifespan was 40.0 days with a range of deaths from 24 to 45 days. At doses equal to or less than the LD10 in normal mice, the maximum ILS was +10% with a range of deaths from 31 to 50 days.

Examination of the individual tumor measurements (figs 2 and 3) reveals essentially no tumor inhibition at any nonlethally toxic doses.

These data indicate that amygdalin MF alone and in combination with the activating agent, β-glucosidase (at doses ≤ LD10 in normal mice), was not significantly active in inhibiting the growth of ROS in AKD_2F_1 mice.

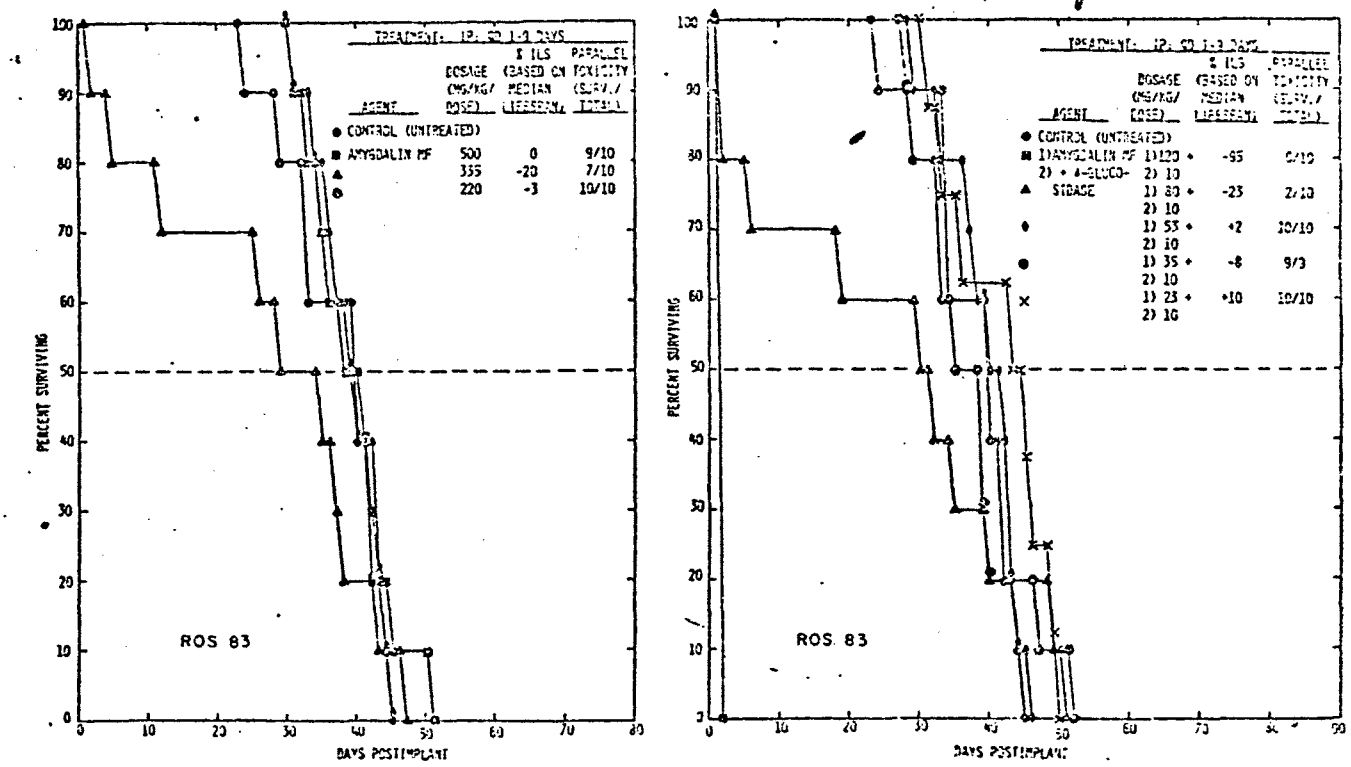


FIGURE 1.—Cumulative mortality plots of ROS treated with amygdalin MF and amygdalin MF plus β-glucosidase.

TABLE 1.—Therapy for ROS with amygdalin MF alone and in combination with β-glucosidase

Treatment; IP; qd 1-9 days Name & NSC No.	Dosage (mg/kg/dose)	Day of Death (Number of Deaths)	55th-Day Survivors/ Total	Median Life Span (days)	% ILS
Control (untreated)		24(1),29(1),33(2),40(2),42(2),44(1),45(1)	0/10	40.0	
B-900540 (Amygdalin MF)	500	31(1),33(1),35(1),36(1),39(1),41(1),42(1),43(1),45(1),51(1)	0/10	40.0	0(*)
	335	2(1),5(1),12(1),26(1),29(1),35(1),37(1),38(1),43(1),47(1)	0/10	32.0	-20
	220	31(1),34(1),36(1),37(1),38(1),40(1),43(2),44(1),45(1)	0/10	39.0	-3
1)B-900540 2)128056 (β-Glucosidase)	1)120 2) 10	2(9)	0/9	2.0	-95
	1) 80 2) 10	2(2),6(1),19(1),30(1),32(1),35(1),40(1),49(1),51(1)	0/10	31.0	-23
	1) 53 2) 10	29(1),33(1),37(1),38(1),40(1),42(1),43(2),44(1),46(1)	0/10	41.0	+2(*)
	1) 35 2) 10	28(1),34(3),35(1),39(2),40(1),47(1),52(1)	0/10	37.0	-8
	1) 23 2) 10	31(1),33(1),36(1),43(1),45(1),46(1),49(1),50(1)	0/8	44.0	+10

Drug Toxicity Control

				Maximum Wt. Loss (gms)	Day Occurred
B-900540	500	9(1)	9/10	0	-
	335	6(1),7(1),36(1)	7/10	-1	12
	220		10/10	-1	5
1)B-900540 2)128056	1)120 2) 10	2(10)	0/10	-	-
	1) 80 2) 10	2(2),3(2),5(2),7(2)	2/10	-3	5
	1) 53 2) 10		10/10	-2	5
	1) 35 2) 10		9/9	-2	5
	1) 23 2) 10		10/10	-2	5

*Highest nontoxic dose.

Experiment No. ROS 83.

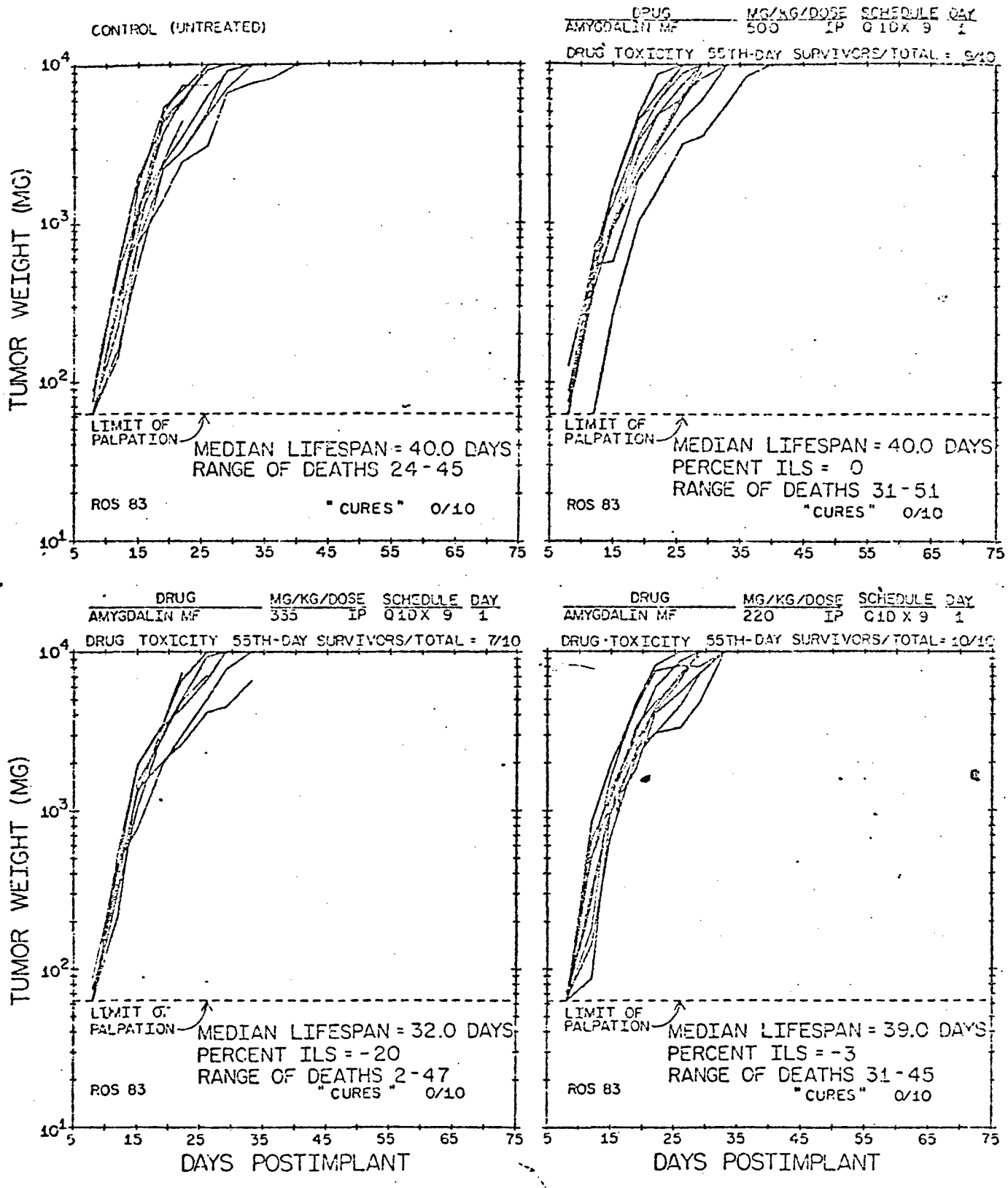


FIGURE 2.—Individual ROS tumor measurements in AKD$_2$F$_1$ mice treated with amygdalin MF alone.

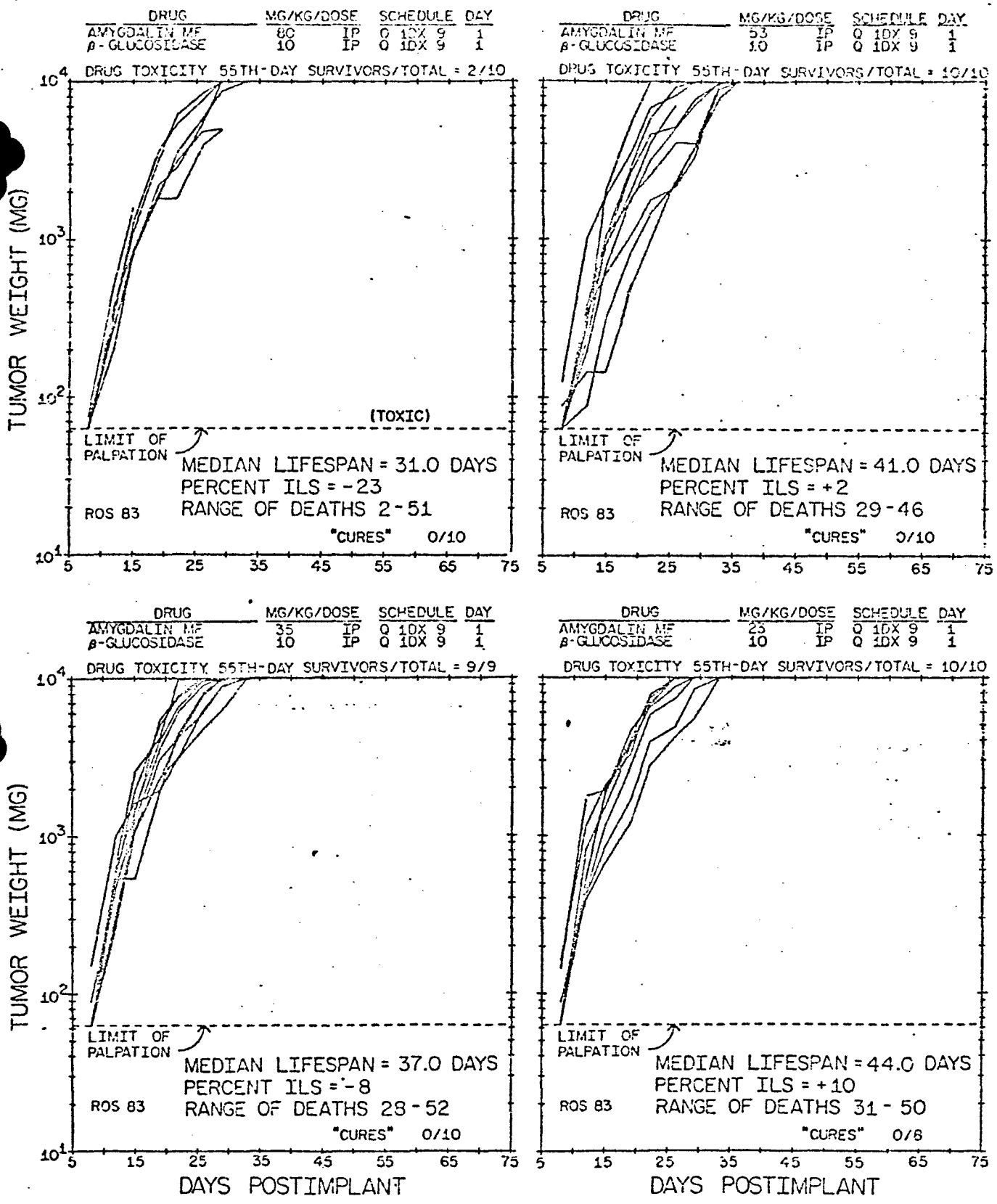
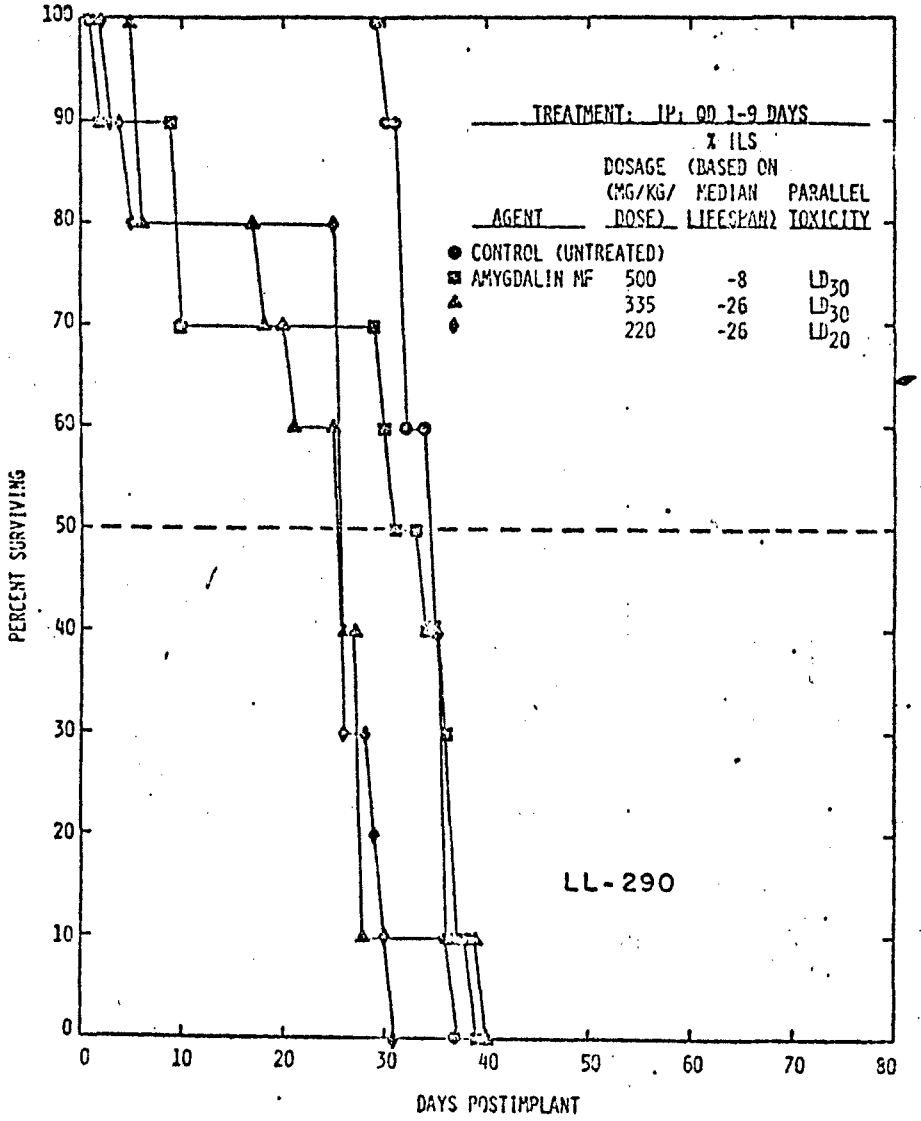


FIGURE 3.—Individual ROS tumor measurements in AKD$_2$F$_1$ mice treated with amygdalin MF plus β-glucosidase.



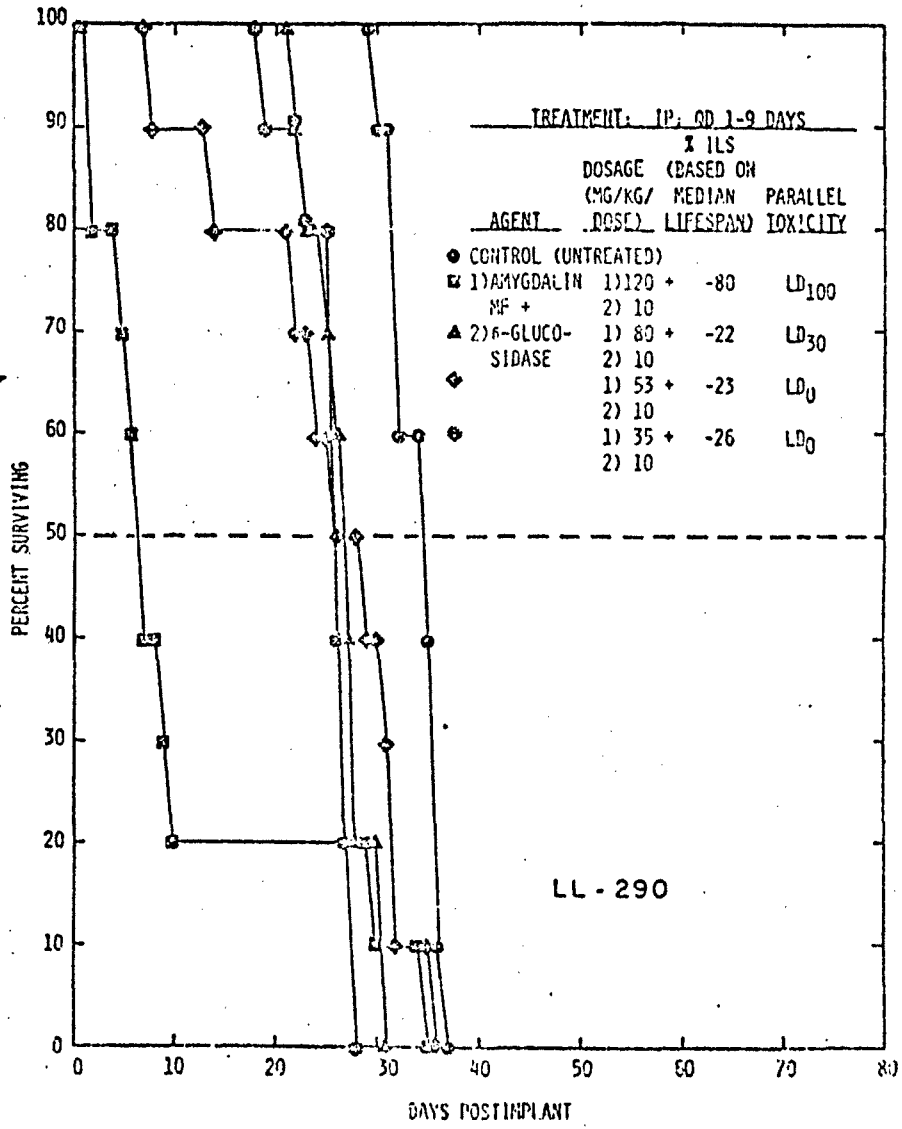
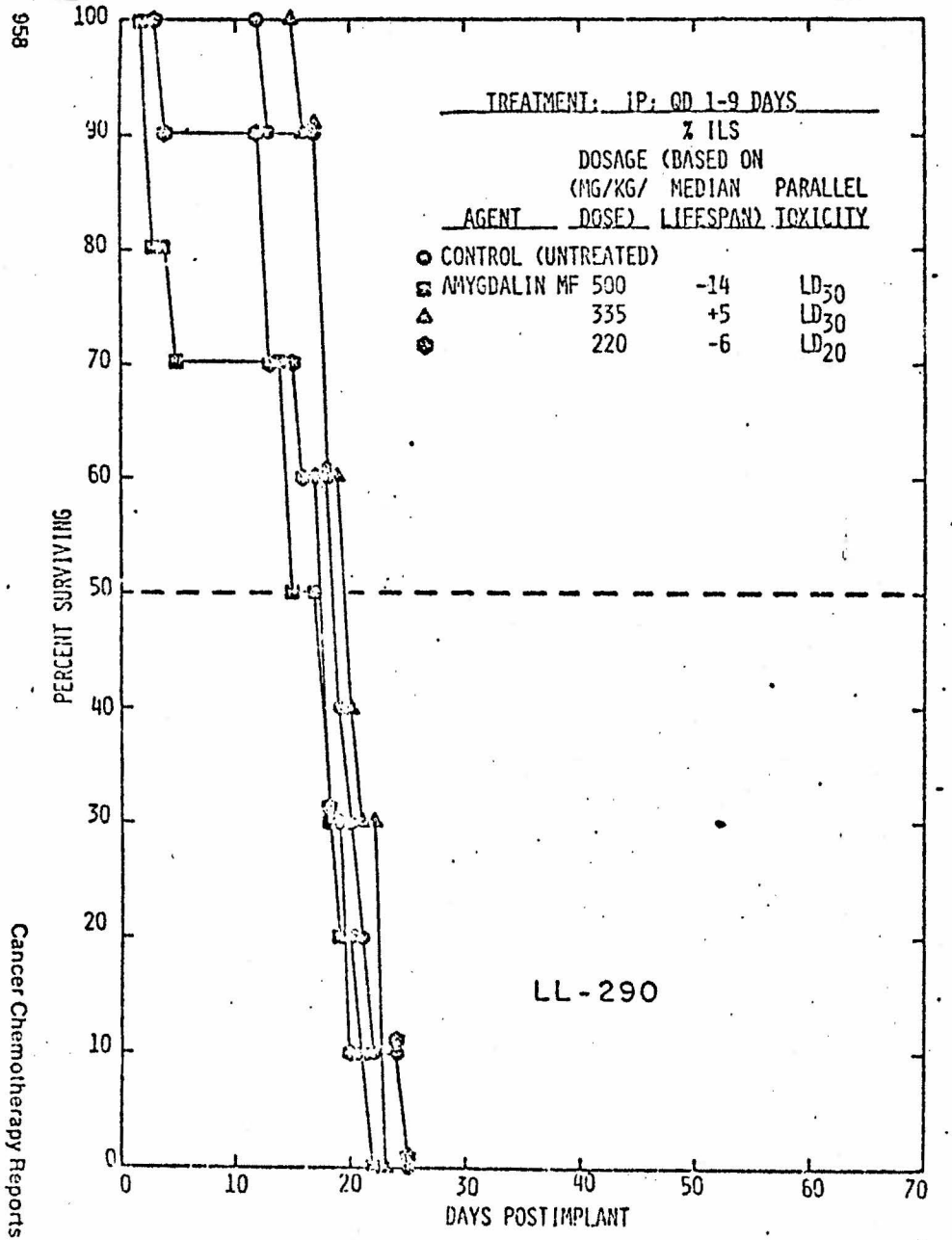


FIGURE 4.—Cumulative mortality plots of the implanted Lewis lung carcinoma treated with amygdalin MF and amygdalin MF plus β-glucosidase.



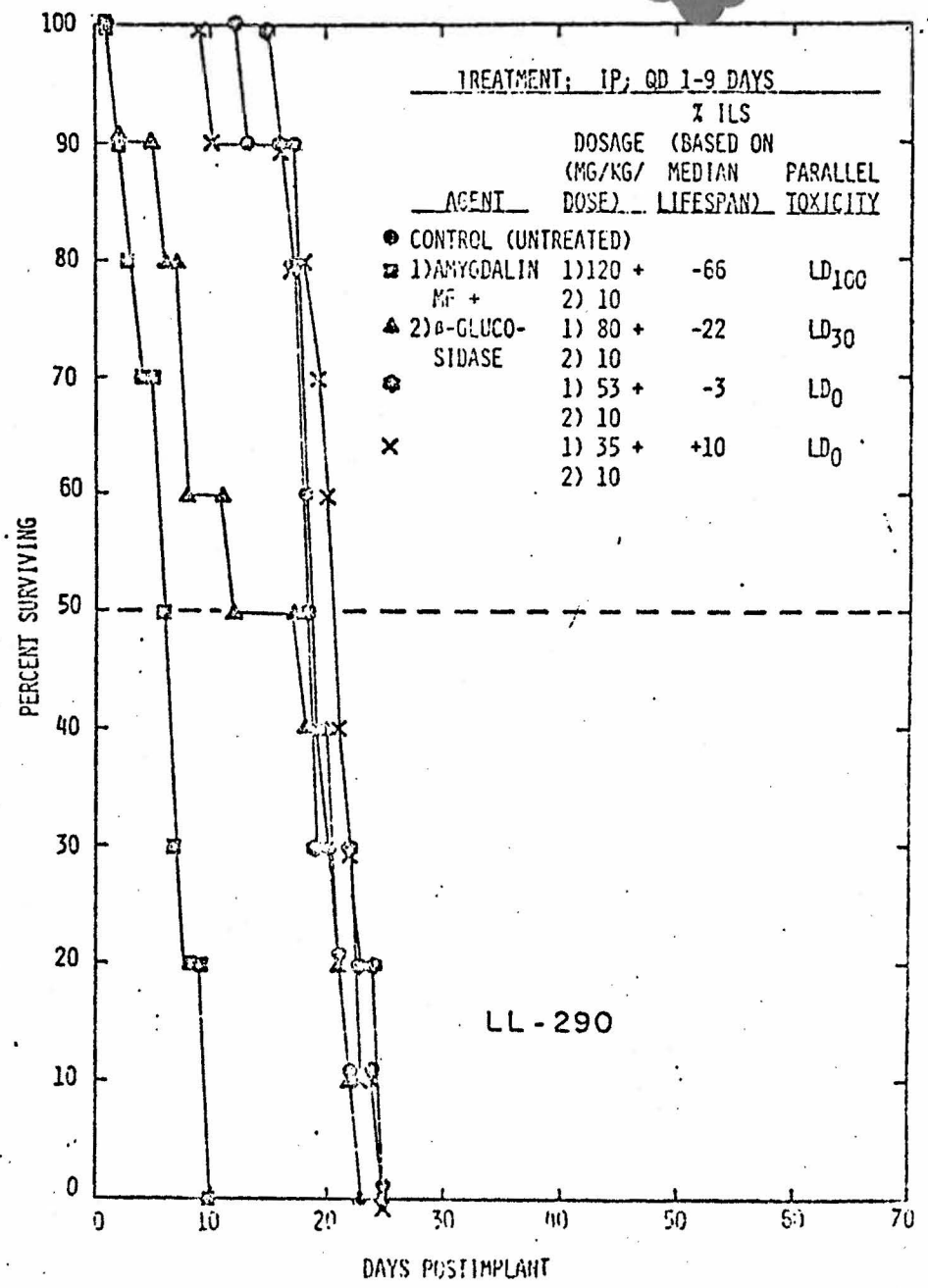


FIGURE 5.—Cumulative mortality plots of iv implanted Lewis lung carcinoma treated with amygdalin MF and amygdalin MF plus β-glucosidase.

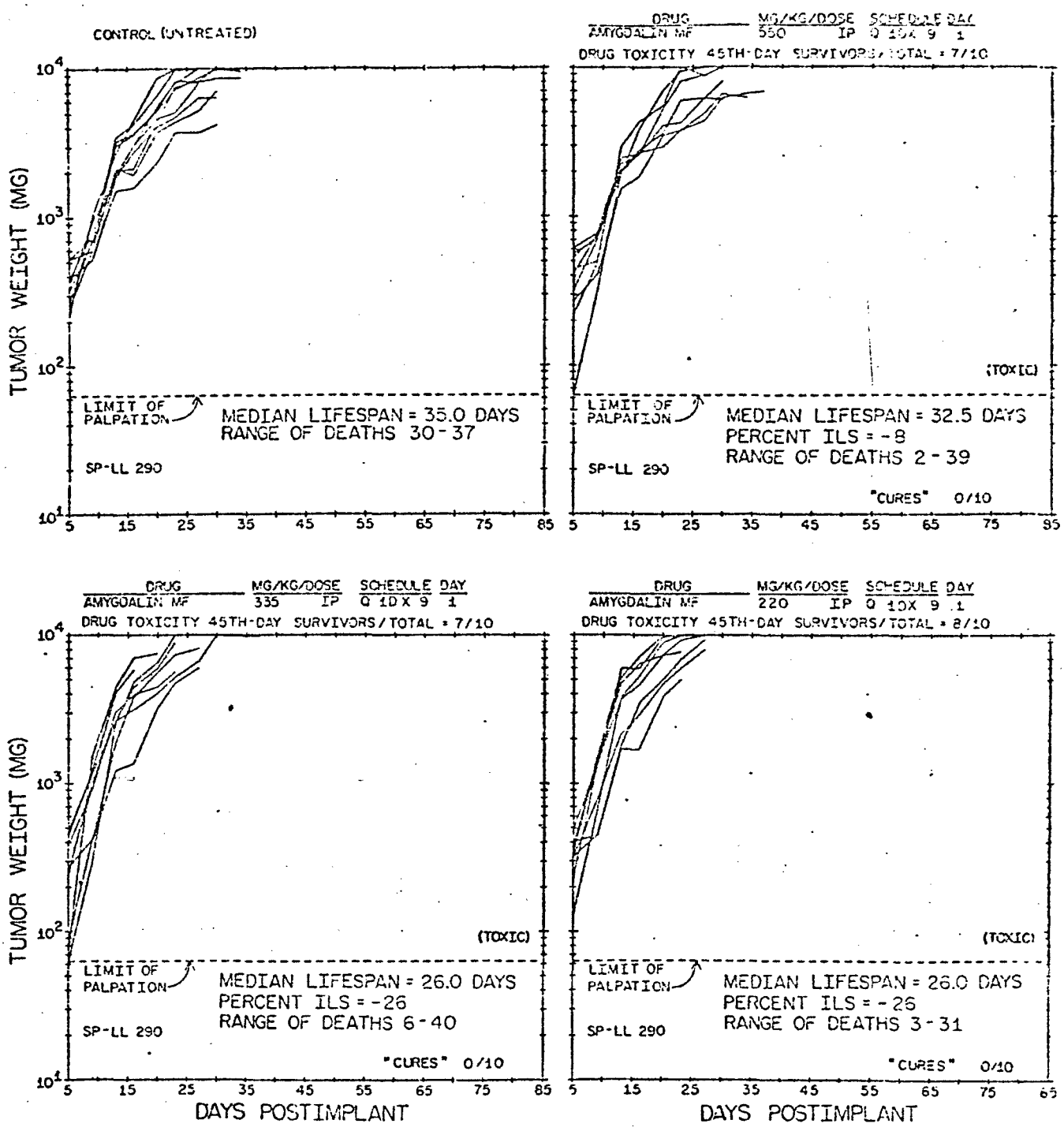


FIGURE 6.—Individual Lewis lung carcinoma measurements in BDF_1 mice treated with amygdalin MF alone.

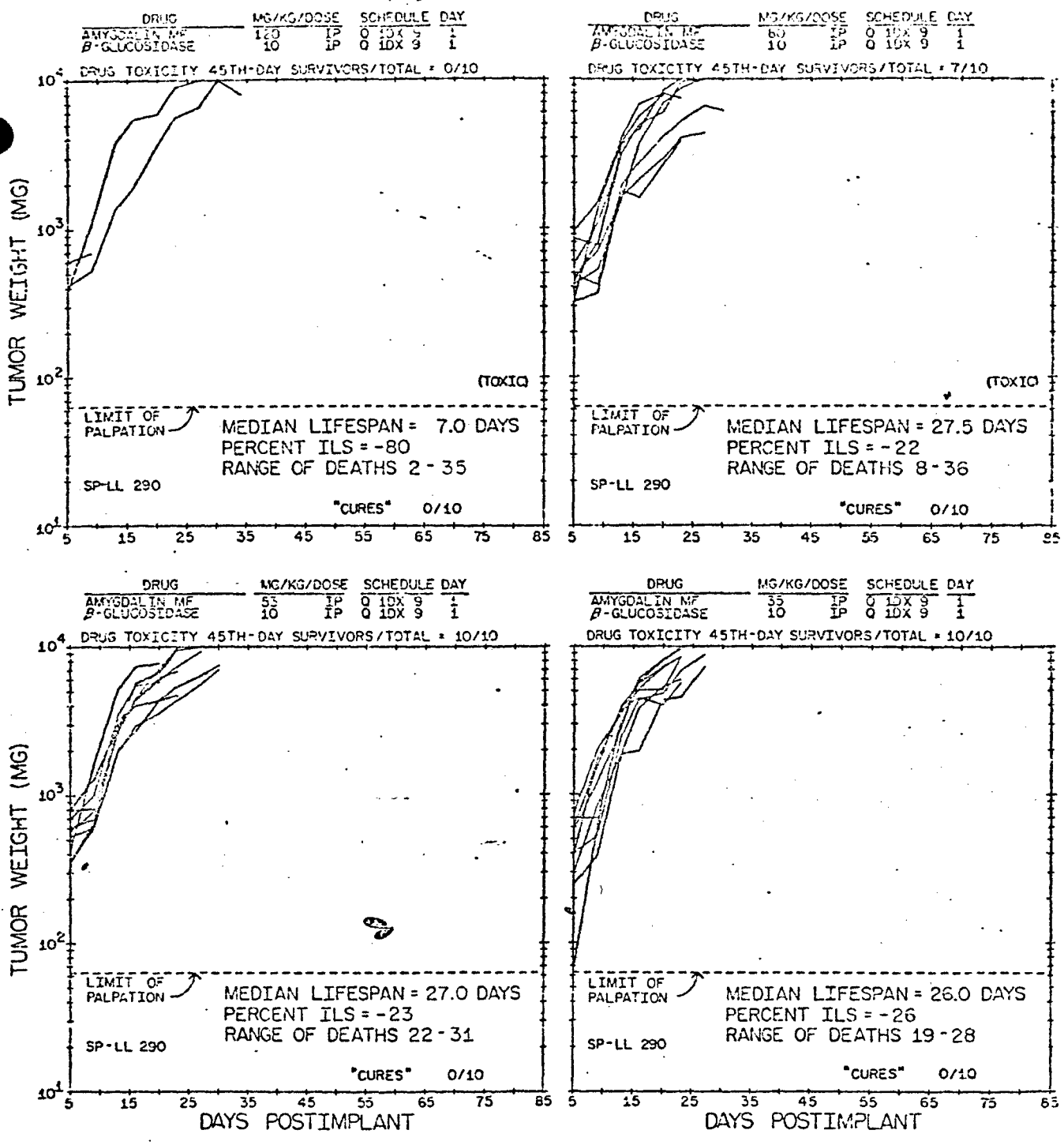


FIGURE 7.—Individual Lewis lung carcinoma measurements in BDF_1 mice treated with amygdalin MF plus β-glucosidase.

TABLE 2.—Evaluation of amygdalin MF and amygdalin MF plus β-glucosidase against sc and iv implanted Lewis lung carcinoma in BDF_1 mice

Treatment: IP; qd 1–9 days Name & NSC No.	Dosage (mg/kg/dose)	Day of Deaths (Number of Deaths)	45th-Day Survivors/ Total	Median Life Span (days)	% ILS
Implant: SC Fragments of Lewis Lung Carcinoma					
Control (untreated)		30(1),32(2),35(2),36(3),37(1)	0/10	35.0	
B-900540	500	2(1),10(2),30(1),31(1),34(1),36(2),37(2),39(1)	0/10	32.5	-8
(Amygdalin	335	6(2),18(1),21(1),26(2),28(3),40(1)	0/10	26.0	-26
MF)	220	3(1),5(1),26(5),29(1),30(1),31(1)	0/10	26.0	-26(>*)
1)B-900540	1) 120	2(2),5(1),6(1),7(2),9(1),10(1),30(1),35(1)	0/10	7.0	-80
2)128056	2) 10				
(β-Glucosidase)	1) 80	8(1),14(1),22(1),24(1),26(1),29(1),31(1),32(2),36(1)	0/10	27.5	-22
	2) 10				
	1) 53	22(1),23(1),25(1),26(1),27(2),28(2),31(2)	0/10	27.0	-23(*)
	2) 10				
	1) 35	19(1),23(1),26(4),27(2),28(2)	0/10	26.0	-26
	2) 10				
Implant: IV; 10^6 Lewis Lung Carcinoma Cells					
Control (untreated)		13(1),18(3),19(2),20(1),21(1),22(1),25(1)	0/10	19.0	
B-900540	500	3(2),5(1),15(2),18(2),19(1),21(1),22(1)	0/10	16.5	-14
	335	16(1),18(3),20(2),21(1),23(3)	0/10	20.0	+5
	220	4(1),13(2),16(1),18(3),20(2),25(1)	0/10	18.0	-6
1)B-900540	1) 120	2(1),3(1),4(1),6(2),7(2),8(1),10(2)	0/10	6.5	-66
2)128056	2) 10				
	1) 80	2(1),6(1),8(2),12(1),18(1),21(2),22(1),23(1)	0/10	15.0	-22
	2) 10				
	1) 53	16(1),17(1),18(3),19(2),23(1),25(2)	0/10	18.5	-3(*)
	2) 10				
	1) 35	10(1),17(1),19(1),20(1),21(2),22(1),23(2),25(1)	0/10	21.0	+10
	2) 10				
Drug Toxicity Control					
				Maximum Wt. Loss (gms)	Day Occurred
B-900540	2000	5(5),8(1),10(1)	3/10	1	5
	1000	3(2),4(1),5(1),6(2)	4/10	0	-
	500	3(2),6(1)	7/10	0	-
	335	6(3)	7/10	0	-
	220	5(1),7(1)	8/10	0	-
1)B-900540	1) 120	2(3),3(1),5(1),6(2),7(2),8(1)	0/10	1	5
2)128056	2) 10				
	1) 80	8(3)	7/10	0	-
	2) 10				
	1) 53		10/10	0	-
	2) 10				
	1) 35		10/10	0	-
	2) 10				

*Highest nontoxic dose.

Experiment No. Special LL No. 290.

TABLE 3.—Evaluation of amygdalin MF and amygdalin MF plus β-glucosidase against P388 leukemia in BDF_1 mice

Implant Cells	Route	Treatment: IP; qd 1-9 days Name & NSC No.	(mg/kg/dose)	Day of Death (Number of Deaths)	41st-Day Surv./ Total	Mean Life Span (days)	Mean % ILS	Median Day of Death (dying)	Median % ILS	*Approx. % Cell Kill/Dose (Logs)	*Approx. No. of Cells Alive at End of Rx
10^6	IP	Titration		10(1),11(3),12(2),13(4),14(6),15(1),16(2),17(1)	0/20	13.4		13.5			
10^5		(Doubling time		14(2),15(3),16(1),17(2),18(1),19(1)	0/10	16.0		15.5			
10^4		≈ 0.51 day)		14(1),15(3),16(2),17(4),18(5),19(1),20(1),22(1),24(1),25(1)	0/20	18.0		17.5			
10^3				16(1),17(2),18(3),19(1),20(1),21(1),22(1)	0/10	18.6		18.0			
10^2				18(1),19(1),20(2),21(1),22(2),24(2)	1/10	21.1		21.0			
10^1				18(1),22(1),38(1)	7/10	26.0		22.0			
1 Cell				20(1),21(1),23(1)	7/10	21.3		21.0			
10^6	IP	B-900540	500	12(3),13(1),14(1),15(2),16(1),17(1),18(1)		14.4	+7	14.5	+7		
		(Amygdalin	335	5(2),14(4),15(2),16(1),19(1)		15.1	+12	14.0	+3		
		MF)	270	3(1),5(1),12(1),13(1),15(2),16(2),17(1),18(1)		15.3	+14	15.0	+11(**LD20)	<0.1	7.0×10^8
		1)B-900540	1) 120	5(1),6(3),7(1),8(1),9(1),13(1),15(1),16(1)		9.6	-29	7.5	-45		
		2)126056	2) 10								
		(β-Gluco-	1) 80	15(4),16(2),17(2),18(2)		16.2	+20	16.0	+18		
		sidase)	2) 10								
			1) 53	13(2),14(2),15(2),16(2),18(2)		15.2	+13	15.0	+11(**)	<0.1	7.0×10^8
			2) 10								
			1) 35	13(1),14(3),15(2),16(2),17(1),18(1)		15.2	+13	15.0	+11	<0.1	7.0×10^8
			2) 10								
10^4	IP	B-900540	500	5(1),17(1),18(2),19(1),20(1),21(3),24(1)		19.9	+10	19.5	+11		
			335	3(1),6(1),18(2),19(1),20(2),21(2),22(1)		18.3	+1	19.5	+11		
			200	18(2),19(1),20(1),21(3),22(2),23(1)		20.9	+13	21.0	+20(**LD20)	0.2	1.7×10^7
		1)B-900540	1) 120	2(2),5(5),6(2),10(1)		10.0	-45	5.0	-72		
		2)126056	2) 10								
			1) 80	5(1),18(2),19(1),20(2),21(2),24(2)		20.6	+14	20.0	+14		
			2) 10								
			1) 53	6(2),17(1),18(1),20(3),21(1),22(2)		17.2	-5	20.0	+14(**)	0.2	6.7×10^7
			2) 10								
			1) 35	5(1),15(1),19(2),20(1),21(2),22(3)		20.1	+11	20.5	+17	0.2	3.3×10^7
			2) 10								

*Based on percent survivors (if 20% or greater); otherwise, based on median day of death (dying).
**Highest nontoxic dose (toxicity data taken from Lewis Lung No. 290).
41st-Day survivors in the titration not used in calculations. Mean life span calculated by using survivors on day 5. Median day of death calculated by using all deaths.

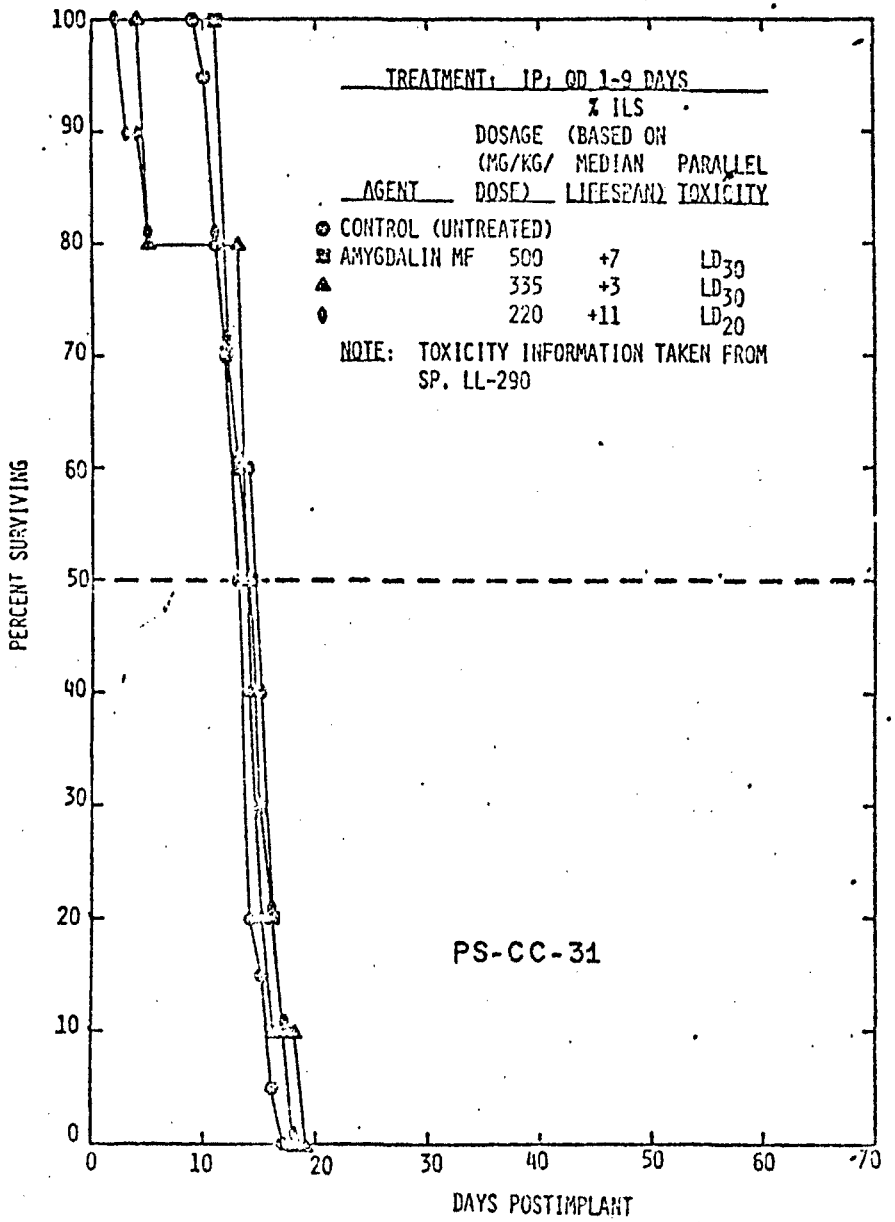
Experiment Nos. PS-CC 31 and 32.

TABLE 3.—Evaluation of amygdalin MF and amygdalin MF plus β-glucosidase against P388 leukemia in BDF_1 mice

Implant Cells	Route	Treatment: IP; qd 1-9 days Name & NSC No.	(mg/kg/dose)	Day of Death (Number of Deaths)	41st-Day Surv./ *Total	Mean Life Span (day)	Mean % ILS	Median Day of Death (dying)	Median % ILS	*Approx. % Cell Kill/Dose (Logs)	*Approx. No. of Cells Alive At End of Rx
10^6	IP	Titration		10(1),11(3),12(2),13(4),14(6),15(1),16(2),17(1)	0/20	13.4		13.5			
10^5		(Doubling time		14(2),15(3),16(1),17(2),18(1),19(1)	0/10	16.0		15.5			
10^4		= 0.51 day)		14(1),15(3),16(2),17(4),18(5),19(1),20(1),22(1),24(1),25(1)	0/20	18.0		17.5			
10^3				16(1),17(2),18(3),19(1),20(1),21(1),22(1)	0/10	18.6		18.0			
10^2				18(1),19(1),20(2),21(1),22(2),24(2)	1/10	21.1		21.0			
10^1				18(1),22(1),38(1)	7/10	26.0		22.0			
1 Cell				20(1),21(1),21(2)	7/10	21.3		21.0			
10^6	IP	B-900540	500	12(3),13(1),14(1),15(2),16(1),17(1),18(1)		14.4	+7	14.5	+7		
		(Amygdalin	335	5(2),14(4),15(2),16(1),19(1)		15.1	+12	14.0	+3		
		MF)	220	3(1),5(1),12(1),13(1),15(2),16(2),17(1),18(1)		15.3	+14	15.0	+11(**LD20)	0.1	7.0×10^8
		1)B-900540	1)120	5(3),6(3),7(1),8(1),9(1),13(1),15(1),16(1)		9.6	-29	7.5	-45		
		2)128056	2) 10								
		(β-Gluco-	1) 80	15(4),16(2),17(2),18(2)		16.2	+20	16.0	+18		
		sidase)	2) 10								
			1) 53	13(2),14(2),15(2),16(2),18(2)		15.2	+13	15.0	+11(**)	<0.1	7.0×10^8
			2) 10								
			1) 35	13(1),14(3),15(2),16(2),17(1),18(1)		15.2	+13	15.0	+11	<0.1	7.0×10^8
			2) 10								
10^4	IP	B-900540	500	5(1),17(1),18(2),19(1),20(1),21(3),24(1)		19.9	+10	19.5	+11		
			335	3(1),6(1),18(2),19(1),20(2),21(2),22(1)		18.3	+1	19.5	+11		
			200	18(2),19(1),20(1),21(3),22(2),23(1)		20.5	+13	21.0	+20(**LD20)	0.2	1.7×10^7
		1)B-900540	1)120	2(2),5(5),6(2),18(1)		10.0	-45	5.0	-72		
		2)128056	2) 10								
			1) 80	5(1),18(2),19(1),20(2),21(2),24(2)		20.6	+14	20.0	+14		
			2) 10								
			1) 53	6(2),17(1),18(1),20(3),21(1),22(2)		17.2	-5	20.0	+14(**)	0.2	6.7×10^7
			2) 10								
			1) 35	5(1),15(1),19(2),20(1),21(2),22(3)		20.1	+11	20.5	+17	0.2	3.3×10^7
			2) 10								

*Based on percent survivors (if 20% or greater); otherwise, based on median day of death (dying).
**Highest nontoxic dose (toxicity data taken from Lewis Lung No. 290).
41st-Day survivors in the titration not used in calculations. Mean life span calculated by using survivors on day 5. Median day of death calculated by using all deaths.

Experiment Nos. PS-CC 31 and 32.



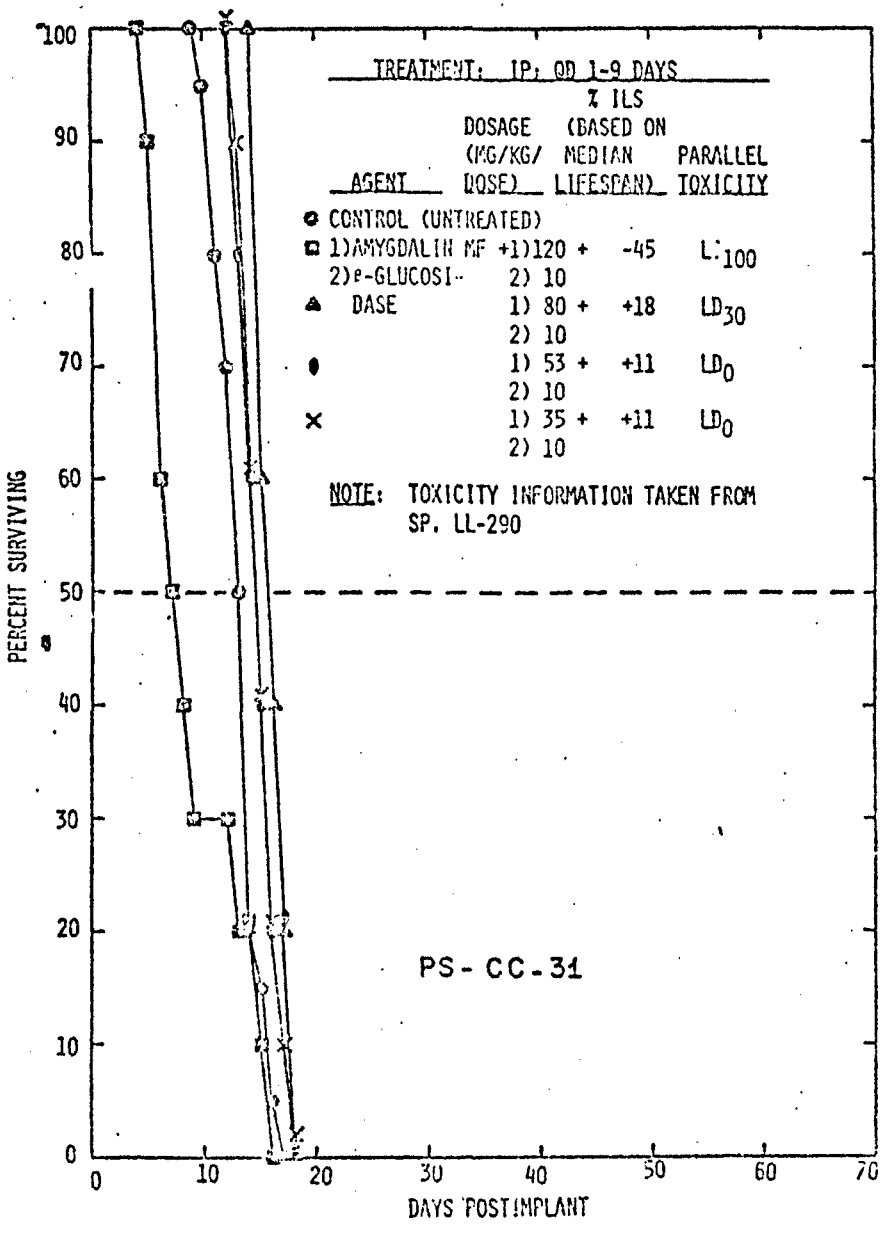
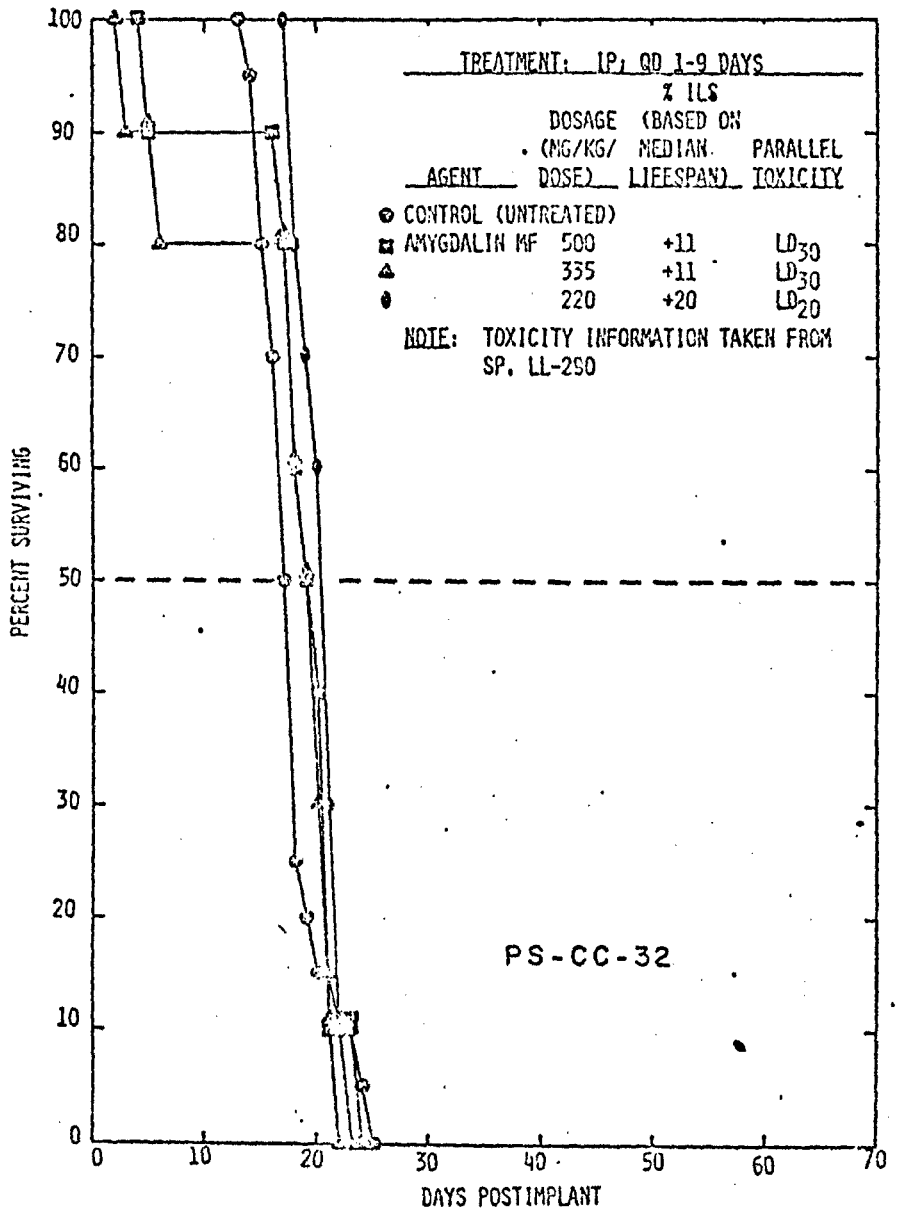


FIGURE 8.—Cumulative mortality plots of P388 leukemia (ip, 10^6 cells) treated with amygdalin MF and amygdalin MF plus β-glucosidase.



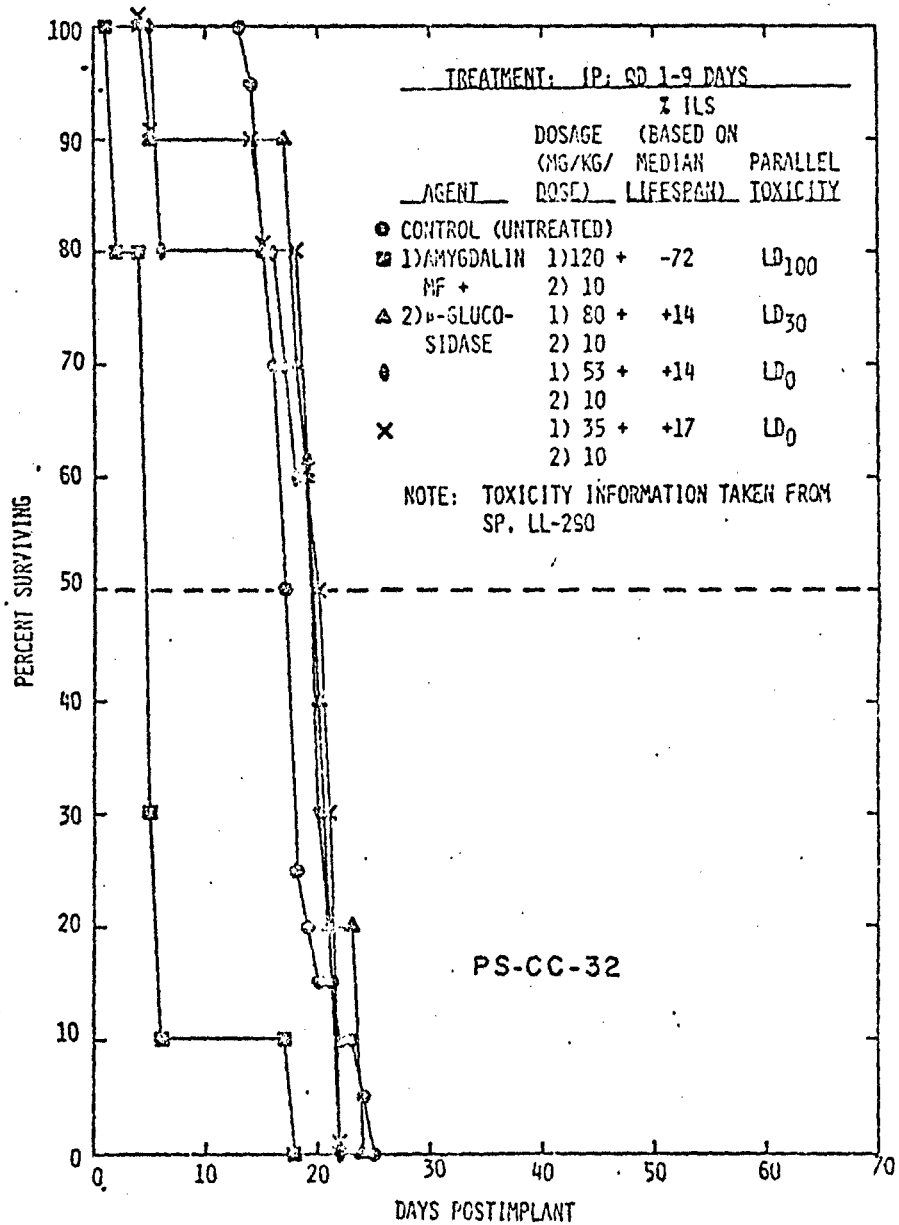


FIGURE 9.—Cumulative mortality plots of P388 leukemia (ip, 10^4 cells) treated with amygdalin MF and amygdalin MF plus β-glucosidase.

The results of the evaluation of amygdalin MF alone and in combination with β-glucosidase against the Lewis lung carcinoma are shown in table 2 and figures 4-7.

Table 2 presents the days of death for both the sc and iv implanted tumor groups and the weight change data for the drug toxicity group. At doses equal to or less than the LD20 in normal mice, there was no significant increase in median lifespan in the sc implanted group when treated with the single agent or the combination. In the iv implanted group, a 10% increase in median lifespan was observed in the group receiving 35 mg/kg of amygdalin MF plus 10 mg/kg of β-glucosidase; however, the range of deaths of the treated group (10-25 days) was essentially the same as for the untreated control group (13-25 days).

Figures 4 and 5 show the cumulative mortality of the sc and iv implanted Lewis lung groups.

Individual tumor measurements in the untreated controls and treated groups are shown in figures 6 and 7. Examination of these individual tumor measurements reveals no inhibition of tumor growth with either amygdalin MF alone or in combination with β-glucosidase.

The results of the evaluation of amygdalin MF alone and in combination with β-glucosidase against the P388 leukemia are shown in table 3 and figures 8 and 9.

Table 3 presents the days of death of mice implanted with either 10^6 or 10^4 P388 leukemia cells. In the group implanted with 10^6 cells, the greatest percent increase in median survival time (at doses ≤ LD20) was +11%, with only a 1-day increase in range of deaths over that seen in the untreated control group (an insignificant difference). In the 10^4 cell-implant group, the greatest increase in median lifespan was +17% with no increase in range of deaths over that seen in the untreated control group. Figures 8 and 9 show the cumulative mortality of the 10^6 and 10^4 P388 leukemia cell implanted mice treated with the single agent and the combination.

These data indicate that amygdalin MF alone and in combination with β-glucosidase was inactive against the P388 leukemia in BDF_1 mice.

REFERENCES

1. Cullitон BJ. Sloan-Kettering: the trials of an apricot pit—1973. Science 182:1000-1003, 1973.
2. White A, Handler P, and Smith EL. Principles of Biochemistry (5th ed). New York, McGraw-Hill, 1973, p 45.
3. Schabel FM, Jr. Animal models as predictive systems. *In* Cancer Chemotherapy—Fundamental Concepts and Recent Advances. Year Book Medical Publishers, Inc., 1975, pp 323-355.

Exhibit "L"

DEAN BURK FOUNDATION, Inc.
4719 Forty-Fourth Street · Washington, D.C. 20016
Telephone (202) 363-6279 March 2, 1977.

Hon. Daniel Demers,
Nevada Legislature,
Carson City, Nevada.

Dear Mr. Demers:

I am writing you in support of Nevada Bill 121 because of my long experience in the U. S. National Cancer Institute (35 years) and my qualifications in the field of non-toxic treatments for human cancer.

My views concerning the "legalization" of laetrile (amygdalin) as already carried out by the Legislature of the State of Alaska, and now being projected to some twenty other states - and with the aim of eliminating harrassment of medical doctors and their patients using laetrile, by government agencies and medical societies, are well supported by the herewith attached enclosures.

The accompanying "Laetrile Fact Sheet" (Item 1) points out that laetrile is indeed on the HEW-FDA GRAS List (<u>foods Generally Recognized as Safe</u>); contains <u>no</u> prussic acid (syn. hydrogen cyanide, hydrocyanic acid, HCN); and therefore cannot be classed as a Food <u>Additive</u> (cf. Federal Food, Drug, and Cosmetic Act, Chapter II - Definitions - Sec. 201(321)(s) or a New Drug, which classifications still fail of any FDA "administrative record" such as called for by the Federal 10th Circuit Court of Appeals decision of October 12, 1976 (No. 75-1725); is "doubly greandfathered" for use in the treatment of cancer prior to both the Kefauver and Copeland Amendments to the F.D.C. Act of respectively 1962 and 1938; and is currently used by at least 50,000 Americans who are able to obtain it by telephone or in appropriate food stores. Item 2 is a copy of the appropriate and pertaining section of the GRAS List set up by the FDA; Item 3 sets forth the prime evidence that, as required by the GRAS List, laetrile (amygdalin), as an <u>extractive</u> of bitter almonds (peaches, apricots) contains no prussic acid; and Item 4 is a news item issued by the San Francisco Examiner-Associated Press on "Alaska allows use of laetrile." A decision of the U.S. Court of Appeals, 4th District (No. 71-1243, May 23, 1972), confirmed by the U.S. Supreme Court, gave

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the opinion that

"The FDA has neither primary jurisdiction - nor concurrent jurisdiction - to adjudicat whether a product is an old drug or a new drug."

We understand the decision in toto to hold that the FDA cannot, under any conditions, bind industry or any of its members by a decision that a drug is new, and that nothing said or done by the FDA of itself can affect the grandfathering status of a product. Thus, the various orders and regulations which are being used by the FDA to turn old drugs into new ones have, under this decision, no legal force.

Accompanying Item 5, a Brief on Foods and Vitamins, lists on pp. 3-7 some of the legal and definitory aspects of the problem; on pp. 7-11 that laetrile is a member of the Vitamin B complex, as a feed used by man and animals for past millenia; on pp. 11-17 some of the extensive evidence that laetrile is efficacious in the treatment of some forms of cancer in man and animals, any and all statements to the contrary notwithstanding; pp 18-21 briefly summarizes the mass of evidence that laetrile at any reasonable and commonly employed dosage is harmless and non-toxic to man and animals, any and all statements to the contrary notwithstanding; and pp. 22-23 briefly summarizes my experience and qualifications credentials.

I hope that you can see your way to endorsing Nevada Bill 121.

Sincerely,

Dean Burk

Dean Burk, PhD (U.S. National Cancer Institute, 1939-1974, Ret.).

Attachments: No. 1 - 5.

Item 1.

LAETRILE IS ON THE HEW-FDA GRAS LIST
(*Generally Recognized as Safe" Food List)

On GRAS List. Page 320 of the 1976 edition of the FDA Code Regulations, Title 21 CFR 121.101(e)(2) , and earlier editions, place amygdalin (laetrile) on the GRAS list, under the heading of natural extractive from bitter almond, apricot, or peach kernels (syn. seeds, nuts), with the only specified proviso that it be " free from prussic acid."

No Prussic Acid. Amygdalin itself contains no ordinarily measurable quantity of prussic acid (syn. hydrocyanic acid, hydrogen cyanide, HCN), and indeed no quantity of acid greater than 1 part in 10,000,000 when amygdalin is dissolved in neutral water (pH 7), as has been established by many chemists. Opinions of a limited number of affiants testifying in recent court cases that amygdalin is not generally recognized as safe are rendered moot and inexpert by the FDA GRAS listing with respect to this prussic acid-free extractive, as well as by many more informed sources going back over 100 year

Not Food Additive. Being on the GRAS list prevents amygdalin from being classified as a food additive, and also provides a strong deterrent to classification as a "new drug", in addition to its being in any event simply a food universally acknowledged as such, even by the FDA, as well as by Federal statute definition. The FDA regulations for marketing a food additive or a new drug are, of course, far more stringent than for marketing a food.

"New Drug" Issue Remanded by Court to FDA. The Federal 10th Circuit Court of Appeals on October 12, 1976 remanded the question of amygdalin being also a new drug back to the FDA for preparation of a necessary "administrative record" of support for such new drug status, which it has so far failed to do

Amygdalin in any event "Grandfathered" as "Old Drug." Even if the FDA were able to establish some sort of new drug status for amygdalin, nevertheless amygdalin could still, without IND/NDA procedure intervention, be marketed in interstate commerce legally as a "drug" ("old drug") under either of two "grandfather clauses" in the Congressional Food, Drug, and Cosmetic Act of 1938 as further amended in 1962 by the Harris-Kefauver Act. Even FDA publicationsconcede that amygdalin was sold for the treatment of cancer prior to 1962 (cf. DHEW Publication No. (FDA) 76-3007).

Amygdalin as a Vitamin Therefore not a Drug. Amygdalin has further been shown to be a vitamin (B-17), as summarized in the well-known monograph, " A Brief on Foods and Vitamins," by Dean Burk, and published by the McNaughton Foundation in June 1975. Recent contrary opinion advanced by David Greenberg (West Jour. Medicine, 122, 345-348, April 1975) and by Thomas H. Jukes(JAMA, 236, September 13, 1976)can be defaulted scientifically as not addressing the specific lines of positive evidence adduced in this monograph. As a vitamin, amygdalin cannot be classed as a new drug in view of the new congressional law 94-278 (Proxmire Amendment) signed by the President April 22, 1976, and also in view of the August 74 decision of the 2nd Circuit Court of Appeals upheld by the U.S. Supreme Courtby virtue of denial of certiorari).

Current Supply and Usage of Amygdalin . Amygdalin will thus almost certainly remain a food chosen for such purposes by the user, of whom there are now son 50,000 Americans consuming over 1000 kilograms a month, as obtained from a wide variety of sources foreign and domestic.

FDA GRAS List

(1) Spices and Other Natural Seasonings and Flavorings (Leaves, Roots, Barks, Berries, etc.)—Continued

Common name	Botanical name of plant source
Pot marjoram	Majorana onites (L.) Benth.
Rosemary	Rosmarinus officinalis L.
Rue	Ruta graveolens L.
Saffron	Crocus sativus L.
Sage	Salvia officinalis L.
Sage, Greek	Salvia triloba L.
Savory, summer	Satureia hortensis L. (Satureja).
Savory, winter	Satureia montana L. (Satureja).
Sesame	Sesamum indicum L.
Spearmint	Mentha spicata L.
Star anise	Illicium verum Hook. f.
Tarragon	Artemisia dracunculus L.
Thyme	Thymus vulgaris L.
Thyme, wild or creeping	Thymus serpyllum L.
Turmeric	Curcuma longa L.
Vanilla	Vanilla planifolia Andr. or Vanilla tahitensis J. W. Moore
Zedoary	Curcuma zedoaria Rosc.

(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.
Bois de rose	Aniba rosaeodora Ducke.
Cacao	Theobroma cacao L.
Camomile (chamomile) flowers, Hungarian.	Matricaria chamomilla L.
Camomile (chamomile) flowers, Roman or English.	Anthemis nobilis L.
Cananga	Cananga odorata Hook. f. and Thoms.
Capsicum	Capsicum frutescens L. and Capsicum annuum L
Caraway	Carum carvi L.
Cardamom seed (cardamon)	Elettaria cardamomum Maton.
Carob bean	Ceratonia siliqua L.
Carrot	Daucus carota L.
Cascarilla bark	Croton eluteria Benn.
Cassia bark, Chinese	Cinnamomum cassia Blume.
Cassia bark, Padang or Batavia	Cinnamomum burmanni Blume
Cassia bark, Saigon	Cinnamomum loureirii Nees.

Item 2

22.1

(2) Essential Oils, Oleoresins (Solvent-Free), and Natural Extractives (Including Distillates)—Continued

Common name	Botanical name of plant source
Celery seed	Apium graveolens L.
Cherry, wild, bark	Prunus serotina Ehrh.
Chervil	Anthriscus cerefolium (L.) Hoffm.
Chicory	Cichorium intybus L.
Cinnamon bark, Ceylon	Cinnamomum zeylanicum Nees.
Cinnamon bark, Chinese	Cinnamomum cassia Blume.
Cinnamon bark, Saigon	Cinnamomum loureirii Nees.
Cinnamon leaf, Ceylon	Cinnamomum zeylanicum Nees.
Cinnamon leaf, Chinese	Cinnamomum cassia Blume.
Cinnamon leaf, Saigon	Cinnamomum loureirii Nees.
Citronella	Cymbopogon nardus Rendle.
Citrus peels	Citrus spp.
Clary (clary sage)	Salvia sclarea L.
Clove bud	Eugenia caryophyllata Thunb.
Clove leaf	Do.
Clove stem	Do.
Clover	Trifolium spp.
Coca (decocainized)	Erythroxylum coca Lam. and other spp. of Erythroxylum.
Coffee	Coffea spp.
Cola nut	Cola acuminata Schott and Endl., and other spp. of Cola.
Coriander	Coriandrum sativum L.
Corn silk	Zea mays L.
Cumin (cummin)	Cuminum cyminum L.
Curacao orange peel (orange, bitter peel).	Citrus aurantium L.
Cusparia bark	Galipea officinalis Hancock.
Dandelion	Taraxacum officinale Weber and T. laevigatum DC.
Dandelion root	Do.
Dill	Anethum graveolens L.
Dog grass (quackgrass, triticum)	Agropyron repens (L.) Beauv.
Elder flowers	Sambucus canadensis L. and S. nigra L.
Estragole (esdragol, esdragon, tarragon).	Artemisia dracunculus L.
Estragon (tarragon)	Do.
Fennel, sweet	Foeniculum vulgare Mill.
Fenugreek	Trigonella foenum-graecum L.
Galanga (galangal)	Alpinia officinarum Hance.
Garlic	Allium sativum L.
Geranium	Pelargonium spp.
Geranium, East Indian	Cymbopogon martini Stapf.
Geranium, rose	Pelargonium graveolens L'Her.
Ginger	Zingiber officinale Rosc.
Glycyrrhiza	Glycyrrhiza glabra L. and other spp. of Glycyrrhiza.
Glycyrrhizin, ammoniated	Do
Grapefruit	Citrus paradisi Macf.
Guava	Psidium spp.
Hickory bark	Carya spp.
Horehound (hoarhound)	Marrubium vulgare L.
Hops	Humulus lupulus L.
Horsemint	Monarda punctata L.
Hyssop	Hyssopus officinalis L.
Immortelle	Helichrysum augustifolium DC.
Jasmine	Jasminum officinale L. and other spp. of Jasminum.
Juniper (berries)	Juniperus communis L.
Kola nut	Cola acuminata Schott and Endl., and other spp. of Cola.
Laurel berries	Laurus nobilis L.

February 16, 1977.

DECLARATION

Item 3

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.)

Item 4

The Nation SF Examiner June 23 76 front page

LAETRILE has been legalized for use in treatment of cancer patients in Alaska, despite misgivings by federal officials and a ban on interstate use by the Food and Drug Administration. Page 11.

GENETIC RESEARCH was placed under restrictive guidelines to protect against the unleashing of new diseases or new strains of drug-resistant germs. Page 11.

SF Examiner June 23 76 p 11.

Alaska allows use of laetrile

Associated Press

JUNEAU, Alaska — Alaska Gov. Jay Hammond, ignoring federal misgivings, has opened the door to the use of laetrile to treat cancer patients in Alaska.

Legislation allowing Alaska doctors to administer the drug passed the legislature Mar. 28 and became law Monday because the governor neither vetoed nor signed the bill.

Laetrile is banned by the Food and Drug Administration, which says the drug is not a proven treatment or cure for cancer.

FDA spokesman Paul Sage said Dr. Alexander Schmidt, head of the agency sent a telegram to Hammond June 8 expressing fear the drug would lure cancer patients away from standard treatment. He also said the drug will continue to be illegal in interstate commerce.

But Hammond said yesterday, "The main question in my mind is how far do you go in protecting people from themselves." He said people he knew were taking laetrile and recommended that the bill became law.

The drug still could be banned in Alaska if the Alaska Medical Board rules that it is harmful.

The FDA prohibition affects only interstate use. The individual states can regulate the use of drugs within their own borders as long as neither the drug nor the materials from which it is made have moved in interstate commerce.

The new law provides that hospitals and health centers may not prevent doctors from prescribing the drug when requested by a patient unless the state medical board tests it and rules it harmful.

item 5a (replacing item 5 pp 22-23)

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, Md. 20014, 1974-1976.

(REPRINTED WITH ADOPTED AMENDMENTS)

FIRST REPRINT **A. B. 121**

ASSEMBLY BILL NO. 121—ASSEMBLYMEN DEMERS, SCHOFIELD, VERGIELS, HAYES, GOMES AND HARMON

JANUARY 21, 1977

Referred to Committee on Commerce

SUMMARY—Requires public hearing for disqualification of laetrile in cancer treatment. (BDR 40-362)

FISCAL NOTE: Local Government Impact: No.
State or Industrial Insurance Impact: No.

EXPLANATION—Matter in *italics* is new; matter in brackets [ ] is material to be omitted.

AN ACT relating to substances; permitting the use of amygdalin (laetrile) or Gerovital H3 under certain conditions; providing for the inspection of manufacturers; and providing other matters properly relating thereto.

The People of the State of Nevada, represented in Senate and Assembly, do enact as follows:

SECTION 1. Chapter 585 of NRS is hereby amended by adding thereto a new section which shall read as follows:

1. The commissioner shall:

(a) Adopt regulations which prescribe minimum standards for manufacturers in preparing, compounding, processing or packaging amygdalin (laetrile) or Gerovital H3.

(b) Conduct inspections of manufacturers of amygdalin (laetrile) and Gerovital H3.

(c) Establish fees, to be collected from the manufacturer, for the purpose of paying the costs of the inspections.

SEC. 2. Chapter 630 of NRS is hereby amended by adding thereto a new section which shall read as follows:

No physician is subject to disciplinary action solely for prescribing or administering amygdalin (laetrile) or Gerovital H3 to a patient under his care who has requested the substance.

SEC. 3. Chapter 633 of NRS is hereby amended by adding thereto a new section which shall read as follows:

No osteopathic physician or osteopathic physician and surgeon is subject to disciplinary action solely for prescribing or administering amygdalin (laetrile) or Gerovital H3 to a patient under his care who has requested the substance.

SEC. 4. Chapter 639 of NRS is hereby amended by adding thereto a new section which shall read as follows: