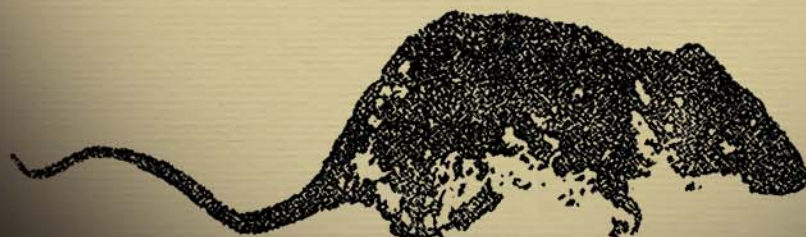


“Lying to the American people
wasn’t part of my job description.”

Ralph W. Moss, PhD

SECOND OPINION

LAETRILE AT SLOAN-KETTERING



This 4-page document contains the “Minutes” from the June 2, 1974 meeting at the Food & Drug Administration discussing conducting human clinical trials of Laetrile based on Sloan-Kettering’s positive lab studies.

Second Opinion: Laetrile At Sloan-Kettering is available on Blu-ray, DVD, and Video On Demand.
Also available is *Doctored Results*, a new book & companion guide to this documentary by Ralph W. Moss, PhD

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MEETINGATTENDANCE 3:00 P.M. July 2, 1974

B.H. Morrison	NCI
John M. Venditti	NCI
Stephen K. Carter	NCI
Robert M. Hadsell	NCI
Lewis Thomas	Sloan Kettering Memorial Institute
Robert A. Good	Sloan Kettering Memorial Institute
Dr. Chester Stock	Sloan Kettering Memorial Institute
Lloyd Old	Sloan Kettering Memorial Institute
B.T. Loftus	FDA/BD
Phil Walters, M.D.	FDA/BD
Bryant L. Jones, M.D.	HFD-150
Howard L. Walker, M.D.	HFD-150
William J. Evans, M.D.	HFD-300
Paul Sage	FDA/BD
David J. Richman, Ph.D.	HFD-150
J. Richard Crout, M.D.	FDA
Carl Leventhal	FDA
M.J. Finkel, M.D.	FDA
Barrett Scoville	FDA

1. Dr. Crout and Dr. Thomas opened the meeting with introductions.
2. Dr. Good (Sloan Kettering) reviewed the scientific question of interest to Sloan Kettering. He emphasized:
 - a. It is hard to identify Laetrile as a compound; one can only work with amygdalin.
 - b. There is immense emotion associated with this drug.
 - c. Studies of amygdalin are a small part of Sloan Kettering program.
3. Dr. Old emphasized that Laetrile is amygdalin not the glucuronid of mandelonitrile. There is a theoretical rationale for amygdalin; selective release of CN (cyanide) intracellularly. Amygdalin is one of a series of cyanogenic glycosides. (They would like to study other members of this group not just amygdalin. Sloan Kettering would like to test these drugs in spontaneous tumors not just experimentally derived tumors. B-glucosidases are found in mammalian tissues. Cancer cells are said to have high glucosidase levels. Normal cells are said to have low glucosidase levels.

The rat kidney has a high level of B-glucosidase but does not break down amygdalin to release cyanide.

The oral route of administration of amygdalin(a) is much more toxic than the parenteral because the intestinal bacteria break down amygdalin to release cyanide(CN). This is shown by use of environmentally protected raised animals who do not harbor bacteria in the intestine. The oral route in these animals is no more toxic than the parenteral.)*

Dr. Old presented some possible research approaches to study the concept that a CN donor might be an anti-tumor agent.

Dr. Old has written to several world users of Laetrile, including Drs. Contreras and Niepes and others. He found two groups (1) Those who used it and found it of value (i.e. Contreras) and (2) Those who had not used it and did not believe in it.

Dr. Old feels that amygdalin is as non-toxic as glucose, although oral administration increases toxicity due to CN release from bacterial break down.

Sloan Kettering confirmed all NCI negative studies of amygdalin. (In toxicity studies deaths following i.p. injections were found due to accidental intestinal penetration and action of mouse intestinal bacteria on amygdalin with cyanide release.)

(All tumors tested, at dosage of 250/1000 mg/k/d, were negative for effectiveness, including Lewis Lung Tumors. A Dr. _____ claimed some effect in Lewis Lung Tumors.

Sloan Kettering tested tumor bearing animals - 100 treated with amygdalin 25 showed lung metastases. 100 not treated with amygdalin 75 showed lung metastases.)*

Some preliminary data were released prematurely to the press. These were initial data only, on Mexican amygdalin. A second exp. c German amygdalin was negative.

4. The data charts show new (a third set) of experiments with Mexican amygdalin and German amygdalin all by injection. Exp. I, II, III are repeats of each other - Results:

Mexican amygdalin showed an effect in 2/3 experiments. German amygdalin showed no effect. However analysis of slopes showed that both were better than control and Mexican better than German. Both Mexican and German inhibited metastases to the lung.

(Test animals were from Dr. Martins colony. The tumors were generally less than 1 cm diam before testing.)*

(In these comparative tests there were lung metastases in 83 control animals. 20 German amygdalin treated 18 Mexican amygdalin treated.)*

The next chart shows that the results are not due to failure of amygdalin treated to grow.

Gas chromatography has shown that Mexican amygdalin is the natural R form, while German is a mixture of S & R. The Mexican form is highly purified.

Final chart shows effect on spontaneous tumor in mice.

(Parenteral amygdalin excreted unchanged; oral amygdalin excreted as the thiocyanate. It was mentioned that amygdalin may be useful in sickle cell anemia because of thiocyanate levels. The Sloan Kettering group believe their results show that amygdalin used in animals with tumors show: a decrease in lung metastases; slower tumor growth; and pain relief.

The Sloan Kettering group are thinking of a study in man on pain relief.)*

5. A discussion ensued on the sensitivity of the test systems and they were deemed to be good for the purpose.
6. There is essentially no clinical pharmacology of amygdalin in man, although thiocyanate blood levels can be followed. The thiocyanate blood level goes up after oral administration (due to bacterial break down) but not known if it does so after injection. (? see above)
7. Dr. Good expressed that the aim today is to present the data to FDA and NCI and to have us think about it.

(Sloan Kettering is not enthusiastic about studying amygdalin but would like to study CN releasing drugs.

Dr. Stock thinks studies on amygdalin should be made particularly regarding pain relief and reduction of lung metastases.

Amygdalin added to other chemo Rx agents has shown no change in effects on toxicity.

Dr. Old would like to talk to Dr. Levine FDA who found on testing amygdalin that the Mexican amygdalin was iso-amygdalin.)*

8. A discussion ensued on where should we go from here. Agreements (a) Sloan Kettering Institute and NCI will consider clinical trials aimed at treatment of Cancer and for the relief of pain and will request consultation of ACS. (b) There are no regulatory policy problems preventing the study of amygdalin in man. (c) A standard scientific approach to studying amygdalin is recommended meaning the drug should be worked up by standard approaches. (d) FDA will publicly endorse good research on amygdalin as in the public interest.

H.L. Walker MD.

* Dr. Walker's notes