P U B L I C H E A R I N G

before

SENATE INSTITUTIONS, HEALTH AND WELFARE COMMITTEE

on

S-3289, S-3354, A-3295

(Legislation to remove restrictions on the use of Laetrile)

Held:
July 19, 1977
Bergen County Administration Building
Hackensack, New Jersey

MEMBERS OF COMMITTEE PRESENT:

Senator Anthony Scardino, Jr. (Acting Chairman)
Senator Alexander J. Menza
Senator Garrett W. Hagedorn

ALSO:

Michael A. Bruinooge, Research Associate
Legislative Services Agency
Aide, Senate Institutions, Health and Welfare Committee

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I N D E X

SENATOR ANTHONY SCARDINO, JR. (Acting Chairman): I have been joined by Senator Garrett Hagedorn from Bergen County on my right, and with us this morning we have members of the Senate Institutions, Health and Welfare Committee staff. I expect other members of the Committee, Senator Menza, the Chairman, to join us momentarily. I am the Vice-Chairman of the Committee.

We are here to deal with a subject that is obviously paramount in the minds of the public and the media over the last several weeks, a subject concerning the worth, the efficacy, the value, of a substance called Laetrile. It has become, I guess, a household word by this time, and people are discussing, arguing, debating, the pros and cons of whether or not this particular substance is in fact safe and will help an individual who has been diagnosed to have cancer, and quite frankly I think we are at a point whereby most or the majority of people are probably in a state of limbo regarding an opinion one way or the other. I think that any of the polls we have seen as of late indicate that very vividly. So, I don't believe, if I may be bold enough to suggest this, that those of us sitting here on the Committee are really for the most part decided one way or the other firmly as to just how we feel.

I think that the hearing we are conducting here today will hopefully shed greater light on the subject and give us an opportunity to respond responsibly. You know, as I do, that the testimony being offered on both sides of the spectrum is very forceful and very emotional. Yet, both cases raise a considerable number of questions. If I were to take the middle of the road position, and I would certainly like to do that, and I always try to do that, and I know my Committee members share the same attitude, it is very difficult to disregard the testimony of people who honestly and truly believe that the substance Laetrile has helped them in one way or another. On the other hand, it is difficult to dispute the opinions and the scientific advancements that have been made by the people who represent the Cancer Associations, by people who represent the medical profession, by people who represent the various scientific fields who say that in every case - at least that is how I read it - where the substance has been tested on animals it has not been proven effective.

I can go on and on, but I am sure many of you are already familiar with the points of view and the testimony that has been raised on both sides of the aisle. I hope that today this hearing will provide the forum whereby this Committee can responsibly debate and discuss the merits or demerits of the legislation that is before us, and hopefully very shortly we can act one way or the other on this legislation. You know that there have been twelve states that have passed laws concerning Laetrile. I understand that seven have been signed into law by the Governors of those states. Wisconsin went as far as to pass a law which not only legalizes the use of Laetrile but one is not required, as I understand it, to have a prescription to obtain the substance. There are other states, of course, that have been less liberal in their approach.

With that, I would like at this time to allow those of you who have been gracious enough to join us to testify. I will ask that you try to keep your testimony to a minimum. I would hope that whatever you have to say, whether it is given from a written statement or verbatim, that you limit your comments to ten minutes at the most. If your statement exceeds more than that time, please condense it so that you will give everyone an opportunity to speak. At the outset we have

twenty people who wish to testify and we only have this one day to hear you. We would like you to limit your comments to ten minutes and then allow the Committee to ask questions if there are any to be asked.

Senator Hagedorn, do you have anything to add to my comments?

SENATOR HAGEDORN: Not at this time, thank you.

SENATOR SCARDINO: We have with us to testify at the outset our Commissioner of Health, Dr. Joanne Finley. We welcome you to Bergen County, and we are happy that you have been able to join with us today, and we welcome your testimony.

D R. J O A N N E E. F I N L E Y: Thank you very much, Senator Scardino, and members of the Committee. My basic position is going to be to commend you for the way you are going about things, but also to urge you not to take hasty or premature action. My reasons for taking this position, asking you to wait a bit are based on both a problem we would have in the State, in the Health Department, with administering any one of the three bills, and also some national events I see possibly answering some of your questions.

Now, let's dive right into the problem in the State of New Jersey for which we would try to do a good job if the statute were passed, but with which we would have difficulty. A-3295, which is the bill sponsored by Assemblyman Gregorio, which, as we recognize has passed the Assembly, and as I know you are aware, has three sections that do refer not only to prescribing and distributing laetrile, but also would relieve manufacturers of liability providing that the manufacture is conducted pursuant to Chapter 6A and 6B of Title 24 of the New Jersey Statutes. I am aware that Senator Russo's piece of legislation does not cover manufacture, but I will come back to that catch twenty-two in a moment.

Now, if we will examine Title 24 and the sections referred to of the New Jersey statutes, we would find that the State of New Jersey's responsibility over manufacture and distribution of drugs obviously intended only for intra-state commerce, is confined to the single concern of safety. The law permits or speaks to only a review of the safety. In other words, is the drug safe to take? Is the drug safe if ingested by unsuspecting children? Is it being manufactured in a clean environment absent from contaminants? In other words, the Health Department would have the responsibility for checking that aspect if manufacture were to be conducted.

Nowhere in the New Jersey Statute does it call for testing for the efficacy. What is efficacy? Very simple. Let's use the dictionary definition, the power to produce a result - in this case, a good or favorable result. New Jersey does not now - although the statute permits it to - review any new drug applications. Although we have this responsibility for drugs sold exclusively for intra-state commerce, on a few very rare occasions we have been called upon to use this statutory authority and because we do not have the staff or capability, we have always contracted with the Federal Food and Drug Administration to carry out both safety and efficacy testing.

Let me tell you how small and underfunded the staff is, If we had a bill in New Jersey in which we were required to check on the manufacture of every new drug for the public, the budget for the entire unit, which is called the Cosmetic and Drug Unit in the Department,is only $251,000. It pays for a staff of twelve persons who are involved in the inspection of all of the plants in New Jersey that manufacture, process or distribute cosmetics, devices and drugs. Two of those twelve staff members

are presently on loan to the Attorney General's Office to do the accountability work over pharmacies connected with the controlled dangerous substances aspect. In actuality, if in New Jersey we were to do the proper job of protecting the public, if any new substance were to be manufactureed and covered by these parts of the law, we would have to have a considerable addition to the staff and a large appropriation to do the work properly.

Further questions must be raised about testing limited only to safety, and in this respect I think New Jersey's law is rather archaic. If we are to assume testing responsibility for a drug or a substance, cosmetic device, whatever, we could not in good conscience exclude testing for efficacy - the power to produce a result. As far as I am concerned, human health and peace of mind make this a necessity. Someone is taking something in the belief that it will help them. I think they need to know the truth, will it help them, or will it harm them? Perhaps we could live with the Laetrile law in New Jersey if N.J.S.A. 26, 6A and 6B were amended to include a responsibility for review in both safety and efficacy, and if the programs were properly funded to hire the expertise to do these complicated jobs.

I would like to skip to the national scene. I have tried to make the argument that if we were presented with the administration of particularly the Gregorio bill, or to some extent some aspects of the Senate bills before you, we would frankly not be capable of doing the job to protect the public in New Jersey, both because the State law is archaic, and we do not have the staffing funds to do it. Now, let me say what I think is happening on the national level that may be positive for all sides and gives an argument as a reason for waiting. As you are well aware, currently the Senate Subcommittee on Health and Scientific Research Chaired by Senator Ted Kennedy is seeking - and I think has won - an accomodation with the proponents of Laetrile. Under his leadership the Committee has evolved a position in which Senator Kennedy has assured proper national support for immediate, well-organized, national research on the effectiveness and the safety of Laetrile. He appears to have persuaded the proponents to wait for this, and if Laetrile is not proven effective, to withdraw their pressures for legalization.

Who better than Senator Kennedy can know first-hand how vulnerable people are when searching for a cure to save the life of a loved one, and how willing they are to grasp at straws or try any approach? I believe that it makes sense to allow this matter to be researched thoroughly at the federal level where there is the capacity for the appropriate kind of investigation and later if the drug is proven, or the substance is proven effective and safe, the FDA can regulate it against these proven safety and efficacy standards. So answering one of the questions that the Committee itself has passed on to us, I personally urge you to wait until the necessary national action, which is now committed, will take place.

Now I am going to address some of the bills before you, and particularly the Gregorio bill which has passed the Assembly. You are all aware that U. S. District Judge Luther Bohanon in the U. S. District Court for the Western District of Oklahoma issued a class action order on April 8, 1977, enjoining the FDA and the U. S. Customs from impeding or preventing the importation and subsequent interstate shipment of Laetrile, providing a practicing licensed physician submits an affidavit attesting the patient is a terminally ill cancer patient. That order of April 8, 1977, was modified on May 10 to specify the language of the affidavit and to limit the

quantity imported to six months' supply which would be 750-500 mg. tablets, and/or 1500 ml. of an injectable liquid. The Federal decree stated by Judge Bohanon makes no reference to the prescribing or manufacturing of Laetrile. Of course, in New Jersey one proposed bill makes the reference that I have just found especially troubling to manufacture, and the others do make reference to prescribing.

It is obvious that the bill sponsored by Assemblyman Gregorio would extend the federal court order to include manufacturing and introduction or delivery for intra-State commerce in New Jersey. And thus A-3295 particularly gives the Department of Health responsibilities it is not currently exercising and does not feel capable of exercising, and far exceeds the court order.

On the other hand, I said I would speak to what I called a Catch 22. I think that Senator Russo's bill certainly is more responsive to the inadequacies of policing manufacture in New Jersey because it does not mention it. And, yet, if you were to legalize the introduction into the State of Laetrile and not permit the manufacture, I submit that the monopolistic possibilities for those who manufacture elsewhere and the cost problems to the purchasers, because of the lack of competition, would be the other side of the problem. So, on the one hand, I do not believe we can police manufacture, and I do not want to see it in a bill, and other the other hand, if there is to be this substance used before the national testing in New Jersey, you would have the problem of no ability to manufacture. And I can't solve that one. That is one reason I would like to wait.

Since I have expressed the concerns of the Department of Health, and I hope have answered some of the questions on the list which the Committee submitted, I would like to address myself to some of the other questions which you raised and you were good enough to send to us and ask us to address. Your first question was, what is or is not permitted with regard to the use of or manufacture of Laetrile, in light of the FDA ban, court decisions, and the existing laws of the State? I have touched on the fact that the State of New Jersey now abides by FDA regulation because of our limited capability for testing new drugs and substances. However, I would point out that Judge Bohanon's ruling does provide some guideline for the limited distribution and use of Laetrile in New Jersey. As long as that court order is in effect, it would say that the substance can be brought into New Jersey. To that extent I would ask you, why would you need special and such relatively unlimited legislation in the State?

Your second question is, why has the FDA banned Laetrile as a drug when the substance is also referred to as a vitamin, and is, in fact, found in many foods? How does Laetrile as a drug differ from Laetrile as a vitamin? May not Laetrile be sold and consumed as a food under existing laws and regulations? Laetrile, although often referred to by its proponents as a vitamin, does not fit into that definition. According to Dorland's Medical Dictionary, a vitamin is an organic substance that occurs in food and is necessary for the metabolic functioning of the body. For example, the absence of vitamin C in the diet causes scurvy, and research has proven this. There is no indication and no scientific research to bear out the fact that Laetrile is essential for any metabolic functioning of the body; therefore, it does not fit the accepted medical definitions of a vitamin.

Conversely, Laetrile, because it is promoted as a pallative and often a cure for the treatment of cancer in humans, is and must be classified as a drug in accordance with our own statutes in this State. Both the Federal and State Administrations consider Laetrile a drug and subject, therefore, to the provisions of a new drug application.

You have also asked, do state laws to legalize Laetrile make any difference?

SENATOR SCARDINO: May I interrupt for a moment?

DR. FINLEY: Yes.

SENATOR SCARDINO: Do you state that both the State and Federal Administrations consider Laetrile a drug and subject to the provision of a new drug application?

DR. FINLEY: Yes.

SENATOR SCARDINO: On what basis do you make that statement? That seems to be what the question is all about. And you seem to make it very emphatic, or at least that is the implication that I get.

DR. FINLEY: Well, the definition of what I gave you as to what is classified as a drug under Title 24, New Jersey's own statute, would be any substance used for treatment or therapy.

SENATOR SCARDINO: Is this your opinion, or---

DR. FINLEY: No, I have had lawyers look at Title 24 and make that interpretation for me. In other words, Attorneys General who serve the Department have gone over that statute to find out what our responsibilities would be just strictly under New Jersey law. And they have given me the opinion---

SENATOR SCARDINO: So you are saying that if this were challenged in the court of law, you feel that there is enough in the statute, and it is worded in such a way that in your judgement the court would uphold this as a drug.

DR. FINLEY: That is the advice of attorneys to the Department. We could furnish you a memorandum to that effect, if you wish.

SENATOR SCARDINO: Doesn't that conflict with the ruling by the ffederal court judge? Isn't there a direct conflict between the two?

DR. FINLEY: No, I think Judge Bohanon's ruling really had to do with commerce, retraints of the trade, in that he has enjoined the FDA and Customs from preventing interstate shipment.

SENATOR SCARDINO: Except, as I read it, and you can correct me if I am wrong, is that it allows the terminally ill patient the right to obtain the substance provided he has written affidavit from his or her physician. Is that not correct?

DR. FINLEY: I think it insures his right to access.

SENATOR SCARDINO: Well, if it insures his right to access, then the question is, insures his right to access to what? And if it insures his access to the right to receive a substance, which this state under the interpretation of the laws as you cite it is a drug, and therefore it would be illegal for anyone in the State to obtain and to use this under the present law. Yet, that, in my judgement, puts it in direct conflict with what the Federal court has said.

What do you do to an individual, by the way? Suppose I decided I wanted to use Laetrile, and I use the Federal court judge's opinion as my basis for obtaining the drug, and I were your patient and I had received the affidavit, and you as a State authority now knew that I was doing this. What obligation do you have at that point?

DR. FINLEY: We do not go after them.

SENATOR SCARDINO: I know, but you are saying that I am doing something illegal. Now, I am a layman. I am not involved in the technicalities of the law, nor am I familiar with them, yet I have read Judge Bohanon's decision, and he said that it is okay for me to use this providing my physician gives me an affidavit. On the one hand it is legal, and on the other it is not. That is what we have to try to answer for the people of New Jersey at this point. That is what this Committee has to try to do.

DR. FINLEY: Well, you are describing, in a sense, an impossible dilemma, which Judge Bohanon's decree has raised. I have heard, and I believe you will have FDA people here testifying today, but I have heard it now said that although it is now recognized as a substance, it can be shipped in interstate commerce. You can have, if you desire, access to it. On the one hand, I have said, to those New Jerseyans who desire access, isn't Judge Bohanon's decree all that they need? On the other hand, I understand that the FDA still says, because of the interpretation of federal statutes which have similar language classifying something as a drug, as does New Jersey's Statutes, if something of this nature - court decree or no - is shipped in interstate commerce, they still have the right to test for safety and efficacy. Now, let the FDA people clear that up, but I have seen district and regional directors of FDA ask these questions when New York State was considering the same legislation. And they said they still felt that they had a federal responsibility under the statutes to set that up.

Yes, as far as I can tell, I would still have some--- In New Jersey we would still have, for a substance classified as a drug, some responsibility. The degree to which - without any staff - this would be done or exercised, I do not know. So I think you have both situations pertaining at this time. I think access to the substance is available. I would not presume that, since it is not at this time in narcotic traffic or the like, neither State nor FDA people would go after individuals any more than they would follow people back from Mexico who brought some substance back with them.

But as to what one would have to do or be responsible for doing under statutes with regard to manufacture, processing, distribution in interstate commerce, as far as the FDA within the State, as far as the State Health Department, this is a very confusing issue at this point. And on the other hand, I would not think that any Legislature would want to permit the unlimited introduction without any controls over an untested substance. You will hear a great deal about it being safe, but we also know that there are children who have ingested their parent's pills or substances who have died; so is it safe? Again, I can't give you simple answers.

SENATOR SCARDINO: Just to counter that, there is testimony the other way as well. There are children who have been di gnosed with some form of cancer---

DR. FINLEY: No, this is like children inadvertently getting into the uncapped aspirin bottle.

SENATOR SCARDINO: I am saying, there are those who have been diagnosed as having cancer who have been given the substance, and the family of these youngsters claims thatit was the Laetrile that ultimately helped the child. The way the testimony is written, there was a child who couldn't participate, couldn't even walk, and he is now running and playing, and all of this is as a result, according to the parents, of taking the Laetrile, so there are two sides to the subject and we are right back where we started.

DR. FINLEY: Well, I would have to really charge the legislature with thinking very hard, despite the claims, about the unlimited, uncontrolled introduction of a substance to our citizens that has also killed some people.

SENATOR SCARDINO: We also have to be certain through some form of documentation that people are absolutely harmed, or that this substance itself is harmful to the people who take it. Of all of the testimony that I have before me, both from the standpoint of the newspaper accounts, and written testimony of various experts on both sides of the field, I have yet to see any evidence one way or the other in that regard.

DR. FINLEY: There will be, and I hope you will have some physicians here this afternoon who can document this, but there was recently reported in the national disease reporting system, the death of a child in Buffalo, New York, a five-year old child, who had taken three or four of her father's substance. The father was the cancer patient. The father had the substance, and the child ingested the material.

SENATOR SCARDINO: I am familiar with that case.

DR. FINLEY: In the autopsy analysis of her tissues, it was the cyanide in the Laetrile that killed her. So there is at least one documented case of danger. And, again, I am not saying these things are uncontrollable. We have done a great deal nationally to put safety caps on adult medication and so forth, in order for children not to be able to get into aspirin, but you have to have the ability within your state to solidly police the manufacture, distribution, packaging, and all the other consumer protection devices, so that nothing harmful could occur within the State. You have to look at both sides of it. And that is what I mean by completely unlimited introduction without any controls or any checks.

SENATOR SCARDINO: Dr. Finley, if I may, can you somehow expedite your testimony, because I do want to give everyone here a chance to testify. I realize there are probably going to be more questions from the Committee before you are through, so if you could expedite your statement, I would appreciate it.

DR. FINLEY: Well, I would like to point out some other deficiencies in the proposed state legislation. I think you must be aware that nowhere do any of our bills state that the patient must be a cancer patient, therefore, there is this inconsistency with the court decree, and, frankly, I am a bit frightened by legalizing an untested substance that then might be used for anything.

You asked several questions, and I am trying to address some of them. You asked what has been the experience in other states, and I simply want to point out that while you mentioned the ten or twelve states where legislation has passed, in at least two or three of these states we know there is the intention by the Governor to veto it, which I would hope would happen in New Jersey, if you passed such legislation. I wonder if you also realize that there are eight or nine states in which legislative committees have killed the legislation. In other words, the states in which legislation has been proposed, - and the Committees having heard testimony - there are eight or nine states in which the legislation has never even been reported to the floor for a vote. The most recent, in order to give you some documentation, is the State of Massachusettes, where bills somewhat similar to New Jersey's died in committee, in a Senate Committee, incidentally, on the 27th of June.

Now, I would like to close by reading - because I have been asked to, and it is part of my responsibility - a letter, so it can be part of the record, which the Public Health Council of the State of New Jersey sent to the Governor

and seven of the eight Public Health Council members were present at the most recent meeting a week ago Monday, and voted unanimously to send this Resolution to the Governor. I might point out that the Public Health Council is made up of consumers, as well as professional people. It is not, by any means, totally a medically dominated group.

"Dear Governor Byrne, after careful consideration of the merits of Laetrile in the treatment of cancer, at a Public Health Council meeting on June 13, 1977, we recommend that you not sign any legislation which would make the use or manufacture of this drug legal in the State of New Jersey.

"The search for a cure for cancer has been a long and arduous one, and substantial progress has been made in many areas of scientific research. Unfortunately, Laetrile has not been demonstrated to be of any value in the treatment of tumors in animals or humans. After meticulous review, the FDA, the National Cancer Institute, the American Medical Association, the American Cancer Society and Memorial-Sloan-Kettering Cancer Center have not substantiated any claims which justify using this substance as an anti-cancer agent. To legalize its use, in the face of this overwhelming negative data, will endanger the lives of patients who are lured by non-scientific promises, refuse scientifically proven beneficial treatments and turn to this useless substance. False hope is a cruel panacea for cancer sufferers.

"We strongly feel that the maintenance of unimpeachable medical standards is a necessity and that Laetrile represents a serious compromise of these standards. We suggest that you join with your colleague, Governor Hugh Carey, in protecting citizens from this potentially harmful legislation."

Thank you. Are there any questions?

SENATOR SCARDINO: Thank you very much, Commissioner Finley. Senator Hagedorn?

SENATOR HAGEDORN: Do you have a written opinion from the Attorney General's Office with respect to our State legislation? We would like to have it.

DR. FINLEY: Particularly, as I understand it, why this would be construed to be a drug and therefore subject to the State legislation and State statutes, yes, I will certainly do that.

MR. BRUINOOGE: Commissioner Finley, as I read the statutes in New Jersey, the drug only needs to be declared safe in order to come under the Department's jurisdiction. Perhaps I read the statutes wrong, but it seems to me if someone came here with an application for the Department of Health to certify Laetrile as a drug, you would be under obligation to do so; is that right, because it has not been shown to be harmful thus far. You would have to show that it was harmful in order to reject that application.

DR. FINLEY: Well, we would first of all be under an obligation to review it, to, in effect, license or permit its manufacture or processing or distribution. That we all agree on. It would be under that obligation under the New Jersey Statutes.

Secondly, we would be under an obligation also to test for safety. We are under no obligation to test for efficacy, and that I regard as an anachronism or a failure in the law. This is a fairly old statute. And I have said that we could conceivably live with this legislation if we could add the responsibility for testing, but then we go full circle, because we don't have the budget or the staff to do this.

I don't know, Mike, are you under an obligation to declare something safe when it says you have to test it for safety and you don't have the capability

to do that basic type of testing? I would fear putting a stamp of approval, the State stamp of approval, on something on the basis of inadequate ability.

SENATOR SCARDINO: That is clearly understood from your professional posture, from your position as the Commissioner of Health and your responsibilities inherent with that position, but we are talking now about the health and the lives of the people. And I am going to just play the devil's advocate for just a moment and suggest to you that of all the testimony and statements I have read thus far, I have come to no firm conclusion that Laetrile is harmful. The only instance that has been cited is the case of a young girl who apparently swollowed several tablets that her father had for his use. And your reaction to that is, and it is a valid one, that if there were safety devices, and if we had manufactured it properly, whatever, it may not have happened. But at the same time, if that is the only argument that can be used in terms of its harmfulness, I really don't understand how that is sufficient.

Because in reaction to that you can say, a child can get a hold of a bottle of Liquid Plumr that you can go to any hardward store or any supermarket and pick up, and if a child swallows it because they don't know what is in it, you know what is going to happen. Yet, a person is allowed to go out and buy Liquid Plumr, because their pipes are stuffed up. Here we are talking about people who are on the verge of death.

DR. FINLEY: That is not explicit in this legislation.

SENATOR SCARDINO: We are talking in terms of the terminally ill patient---

DR. FINLEY: Not in New Jersey legislation.

SENATOR SCARDINO: Well, even if it is someone who is diagnosed as having cancer. God forbid, I think that if anyone were told that they were diagnosed as having cancer, they think of one thing. I know of people who unfortunately have reached that position, or that state in life, and it would seem to me that it is at that point that you begin to grasp for anything, anything whatsoever, in order to sustain life, in order for you to be cured. And if there is a substance, whatever it may be, that may give them some sense of comfort, whether it is psychological or whether it is physical, no one on the other hand can prove that it is going to do that person any harm. I don't understand why there is such a fuss about allowing an individual to use it.

DR. FINLEY: Well, I have two sets of answers. First of all, I mentioned that to the extent that there are three bills that you are considering, some are less troublesome to me than others, for reasons I have expressed. But none of them, unlike Judge Bohanon's court decree, make any reference to terminal illness, or make any reference to cancer. They are all simply Laetrile may come in, and if the patient signs what is not an inform and consent form, as far as I am concerned, and the prescription is obtained Laetrile can be used for anything, including - and I do have some of this in my testimony - a women who has just had a PAP smear, and comes back with the results of the cervical cancer screening program as having early stages of cancer. Now, we all know that if that is treated in the conventional traditional means it has a very high cure rate. So, how do you deal first of all with the fact that the bill makes no reference to the psychological state of the terminally ill patient for whom all else may have failed. It doesn't. It gives the women who may have some neighbor with an almost assured route to cure, the chance to eschew that cure. Therefore, as far as I am concerned, we

need next to go to what is the definition of harmful. I think for a person to be deterred from proven prevention of death is part of my definition of harmful. I do not consider a drug safe--- Because it is taken instead of something else will in my book statistically insure the death of a patient later on.

SENATOR SCARDINO: Dr. Finley, has anyone at any time come to you and asked for the definition of Laetrile officially?

DR. FINLEY: You mean as to an application to manufacture?

SENATOR SCARDINO: Yes.

DR. FINLEY: Well, the only application to manufacture which we have been presented with recently in New Jersey is Dr. De Marco's substance BVP. I am only bringing this up this difficult topic, because I would kind of like to show you what sorts of doors get opened when the notion is around that maybe what I regard as useless substances could now be manufactured within New Jersey. On that one we did contact the FDA to review.

SENATOR SCARDINO: I want to thank you very much, Dr. Finley, for testifying. I apologize for the heat here. (Prepared statement of Dr. Finley begins on page 9x in the appendix.)

Our next witness is Assemblyman Gregorio. Welcome, John.

J O H N T. G R E G O R I O: Thank you very much, Senator Scardino, Senator Hagedorn, staff, I really appreciate this opportunity to testify on behalf of my bill 3295. I don't have a prepared statement, and I think I can be very brief.

First, what I would like to do is explain the reason why I introduced the bill. Unfortunately, I have had a series of cancer victims in my own family. My mother died from cancer, and my father's two brother's died from cancer, and my father himself is a cancer victim. He had a laryngectomy in 1972. He had his larynx removed, which was malignant. In 1975 he had further trouble with swelling in the area of the groin. And he went to his physician, and he recommended that they operate and test the glands that were swollen. They did remove glands from his right leg, and found them to be malignant and of the type that stem from another malignancy. Upon further examination they found that he had a malignancy definitely tested and biopsied of the prostate gland. They also found that he had a lesion the size of a coin in his lung.

I personally know of case histories, and there was one whose husband is in the audience today, a women had cancer of the lymph glands and went through the whole series of conventional treatments, cobalt, chemotherapy, and the whole gamit of conventional treatments, and then was told that there was nothing more that anyone could do for her. They advised her husband to take her home, and to make her as comfortable as he could until she died. Well, that women decided to take Laetrile, and now, four years later, she is as healthy appearing at least, and working, and taking care of a fourteen room house, as she was before she had the lymphomatic cancer. Because of that story, I asked my father if he would be willing to try laetrile. He discussed it and talked about it with his own doctor. The doctor agreed to try it, but under supervision. They would examine him periodically to see how he was doing. He prescribed the Laetrile and gave it to him by injection. Now, two and a half, almost three years later, my father has been feeling very good. By the way, I would like to make it clear that the lesion in the lung was not biopsied. It was just expected to be malignant, but the prostate gland was definitely biopsied. The problem in the

prostate gland has not gotten any worse. He has no pain and no ill feeling, and is functioning as normal as a seventy-seven year old man can function.

I deliberately in this bill did not limit it to terminally ill cancer victims, because I have hbeen taking Laetrile for two and a half years too, because of the history of my family. I felt that I would like to try this as a preventative measure, and I think that anyone should be able to try it as a preventative. This basically comes from the pit of the apricot. You can get vitamin B17, as it is commonly known, or Laetrile, from many forms of food, apricot pits, peaches, apples, grapes, lentils, and I think if you are going to try to ban laetrile, I think you would have to try to ban apricots too. For about a year and a half I was taking five apricot pits a day. By the way, the FDA made it very difficult to obtain those. They were taking them off the shelves of the health food stores and warning people not to take them. Now, I have been taking them for at least two to two and a half years, and now I have decided to try the pill itself, because the price has come down substantially since I first heard about it.

My bill basically allows a patient upon written request of his doctor with the knowledge on the prescription that he has to be aware of the fact that it is not acknowledged by the FDA or any other agency as a cancer cure. And it also allows, different from the Senate version, the manufacture of it. I feel if we pass this without allowing the manufacture of it, you won't be able to get it anyway because there are so many difficulties. The FDA and these other agencies make it so difficult for you to get it, but I thinkt that New Jersey, being one of the largest states as far as the manufacture of drugs - there are more drug companies in New Jersey than any other state that I know of - that we ought to be allowed to manufacture it here, prescribe it here, and be allowed to take it here - anyone who wants to.

It seems to be rather hypocritical of the FDA to allow the sale of cigarettes, which they know causes cancer, and not allow a food substance to be sold. Believe me, Senator, I am still a skeptic. I am not positive that this does help. All I know is that it seems to have helped my father. It may be a spontaneous remission; it may be that his prayers are answered or my prayers are answered, but he has not had any more trouble since he has been taking Laetrile, and I know literally of about fifty or one hundred cases personally who feel that they have gotten benefit from Laetrile. It may be a figment of their imagination. You know, if you are going to ban this, maybe we should ban psychic healing and ban prayer too, because some people rely on those things. You know, Senator, you don't llook in the mirror in the morning and find out that you have cancer. You have to go to a doctor to find out that you have cancer. I think if you have faith in your doctor, and your doctor wants to try Laetrile - which no one has proven to be dangerous to anyone, except for that one case, the case of the young child in Buffalo who obtained and finished off her father's bottle of Laetrile and died, that may be so, but how many uhundreds of children have died from finishing a bottle of aspirin. I think that is a poor excuse - you should be able to.

No one has proven this to be harmful. I am a good example of why it is proven not to be harmful. I have been taking it for two and a half years, and I feel excellent. In a short synopsis, Senator, that is my story. I think that a cancer victim has to have some hope. In any case, if you don't have any hope, it just speeds up your death. If someone has some hope that there is a possibility of this helping them, I think they ought to have the right to try it.

SENATOR SCARDINO: John, thank you very much. My question at the outset would be, if you were to just summarize in a sentence or two what you honestly feel after all the information and experience that you have had, the sum and substance of your argument here would be what?

ASSEMBLYMAN GREGORIO: I would say it is a reluctance on behalf of the AMA and the FDA to realize that there is a possibility of this being good.

SENATOR SCARDINO: How about the question of drug or vitamin?

ASSEMBLYMAN GREGORIO: I am not a doctor. I don't know what the definition of a vitamin or a drug is. All I know is, this is a food substance. It is derived from a natural food. There is nothing added to it. I think if you can get it by eating apples and peaches and apricots---

SENATOR SCARDINO: I am trying to narrow it down, and maybe someone else may be able to answer the question more specifically as to whether it is a drug or a vitamin or a food substance. Now, is the food substance technically and logically speaking a viable third category?

ASSEMBLYMAN GREGORIO: Believe me, I have been really interested in this, and I have read all I could on this subject. I have a book here that gives you about ninety case histories that are verified of people who have been helped by Laetrile.

SENATOR SCARDINO: The definition that Commissioner Finley used in her statement, "Laetrile, although often referred to by its proponents as a vitamin, does not fit into that definition either. According to Dorland's Medical Dictionary, a vitamin is an organic substance that occurs in food."

ASSEMBLYMAN GREGORIO: Well, I think it fits that description.

SENATOR SCARDINO: I thought so too, when I read this, and then I said, if it occurs in apricot pits and almonds, or whatever else, it is occurring naturally.

ASSEMBLYMAN GREGORIO: It is also in peaches and apples, but in smaller degrees. I think they get the largest amount of it from the apricot. That is why they use it.

SENATOR SCARDINO: I am turned off on the exploitation of anything, and I know that you are too. You share that feeling with all of us in the legislature. And before I got involved in reading all of the testimony and before this became a really controversial subject, I happened to be talking to some people at pool side, just having a general conversation when this subject first came up, and the individual said to me, "You know, I have a friend who had been diagnosed as having cancer, and they found that after eating almonds continually that for some reason they got better." And they made the connection themselves with the almonds. Subsequently I was reading some testimony, and I found out that the substance itself is a derivitive of the almond. I am not saying that this is swaying an opinion of mine one way or the other, but the point is, it just seems to fall into place. People are claiming some relationship between these two things somewhere along the line. I think it is incumbent upon somebody - and hopefully it might be through the testing that is going to come about as a result of Senator Kennedy's hearings - to draw some positive conclusion here.

ASSEMBLYMAN GREGORIO: Well, I think if anything has been gotten from the proposal of mine and Senator Russo's, at least people are getting interested in it, and are willing to have tests on humans rather than on mice. By the way, on the mice there were two stories. One test by a Japanese doctor, I think is was, proved

to be beneficial. So, there are two sides to that story. But I want to make one thing very plain, Senator, I am not, and Assemblymen Deverin and Karcher are not, saying that this is a cure-all for cancer. We are not saying not to try cobalt and chemotherapy and surgery. We are just asking that this be allowed to be used along with the others if you like. By the way, I think that is the best idea, but you have to have faith in your doctor. If your doctor is willing to try this, I think you have a right to try it.

SENATOR SCARDINO: Would you entertain the possibility, as Dr. Finley suggested, of modification, in terms of making it clear that the substance will be used only in the case of cancer?

ASSEMBLYMAN GREGORIO: Absolutely not---

SENATOR SCARDINO: I am asking the question of the witness. Everyone who is asked to speak will have an opportunity to speak. Please be polite to the witness.

ASSEMBLYMAN GREGORIO: In my own case, Senator, that is the only thing in my whole life that I am afraid of because of my family's past history, and I would not stop taking apricot seeds or vitamin B-17 or Laetrile, whatever you want to call it, because I think that it is helping me.

SENATOR SCARDINO: How about if a person first received the permission or an affidavit from his physician?

ASSEMBLYMAN GREGORIO: Well, in my bill it states that you have to ask for it in writing and you have to be made aware of the fact that it is not acknowledged as a cancer cure. Taking a food substance, I don't see any harm in it.

SENATOR SCARDINO: That is in the bill?

ASSEMBLYMAN GREGORIO: Yes, sir.

SENATOR SCARDINO: Is that under Title 24, because otherwise, I don't see it in your bill.

ASSEMBLYMAN GREGORIO: On line four of my bill it says, "A patient who has made a written request for such substance on a form which shall contain the following statement, 'Amygdalin has not been approved as a treatment or cure of cancer by the United States Food or Drug Administration.'"

SENATOR HAGEDORN: That is only where a patient makes a request, right?

ASSEMBLYMAN GREGORIO: That is the only time that I am saying a person shall be allowed to use it. You get a prescription from your doctor, and before you can get it from your doctor, you have to ask for it in writing.

SENATOR HAGEDORN: It seems to me that the legislation is not very clear.

ASSEMBLYMAN GREGORIO: What is not very clear about it, Senator? I think it is very clear. You have to ask for it and you have to get a prescription from your doctor.

SENATOR HAGEDORN: Have you asked for it?

ASSEMBLYMAN GREGORIO: No, because there is no such law now. I am taking it illegally now, and I would like to make it legal.

SENATOR SCARDINO: I think it is clear from the Assemblyman's testimony that if it is not clear in the bill that it would be incumbent upon the Committee to clear it up.

ASSEMBLYMAN GREGORIO: If anyone can help to make it more clear, I would be very appreciative, Senator.

SENATOR SCARDINO: Fine. We now have the real chairman of the Senate Institutions, Health and Welfare Committee, Senator Alex Menza of Union County, here.

Thank you for coming. Alex, I am very happy to see you. Do you have any questions, Senator Menza?

SENATOR MENZA: No.

SENATOR SCARDINO: Are there any further questions of Assemblyman Gregorio? Michael Bruinooge.

MR. BRUINOOGE: Assemblyman, I think it is germaine to ask, your father is taking Laetrile now.

ASSEMBLYMAN GREGORIO: That is right.

MR. BRUINOOGE: Is he at the same time getting conventional therapy?

ASSEMBLYMAN GREGORIO: No, he is under a doctor's care, and he gets periodic check-ups, but he is not taking anything else but Laetrile.

MR. BRUINOOGE: No other chemotherapy.

ASSEMBLYMAN GREGORIO: He is not getting any other treatment, but he is under a doctor's care. He goes to the doctor every week.

SENATOR SCARDINO: Is that by his own choice, John, or has it been recommended?

ASSEMBLYMAN GREGORIO: No, I think that is by his own choice. He wants to be sure that if this Laetrile or vitamin B-17 is not working that the doctor will pick it up and then he can try something else, surgery, perhaps. What he is actually trying to do, Senator, is avoid further surgery. He can't speak. He doesn't have any voice now from surgery, and he doesn't want to have a lung removed and he doesn't want to have his prostate gland removed unless it is absolutely necessary. For the last two and a half years, Laetrile or God or some remission has stopped it from getting any worse.

SENATOR SCARDINO: Thank you very much. Do you have a question, Senator Menza?

The question that Senator Menza has asked me is whether or not your bill is clear - and this is on the point we discussed moments ago - as to whether or not the substance requires either a prescription or some form of affidavit from the attending physician? Will you kindly clear that up for us?

ASSEMBLYMAN GREGORIO: Well, the bill isn't that long. I would like to read the whole bill. It might clear it up.

SENATOR SCARDINO: No, I don't think you have to do that.

ASSEMBLYMAN GREGORIO: From my understanding, you have to give a written request to your doctor and then get a prescription from your doctor for the substance. It relieves the doctor from any penalty or disciplinary action.

SENATOR HAGEDORN: Assemblyman, as I understand it, your bill would not allow this use as a preventative, unless the doctor approved it, is that right?

ASSEMBLYMAN GREGORIO: You couldn't get it without the doctor's approval. But you don't have to be sick to go to the doctor. You can go to the doctor and say, "My family has a case history of cancer, and I would like to try Laetrile as a preventative. " And if he decided to do it, he could give you a prescription for it.

SENATOR HAGEDORN: Except there is one problem there, as I see it. That is the question of malpractice. It is conceivable that if you go to a doctor and the doctor approves it, and later on, the patient is dissatisfied, the doctor can get himself involved in a malpractice suit, if he dies.

ASSEMBLYMAN GREGORIO: Well, you have to sign a form which tells you on the form that it has not been approved for the cure of cancer. I think that

is a relief for the doctor in itself. Plus, it relieves the doctor of any penalty or disciplinary action by any state agency.

SENATOR SCARDINO: What it says is that the patient signs the affidavit, but it doesn't say that the doctor signs anything, and I think that is the question that is being asked.

ASSEMBLYMAN GREGORIO: Well, you lawyers have to get together and make it better. I will gladly accept your recommendation.

SENATOR SCARDINO: Senator Menza.

SENATOR MENZA: Yes. Assemblyman, there is nothing in this bill that I can see in reference to an affidavit. It says, "...has made a written request for such substance on a form which shall contain the following statement." What form? Is there a standard form that is being used by the State?

ASSEMBLYMAN GREGORIO: One will have to be made up. There is no form up to this time.

SENATOR MENZA: By whom, the Department of Health?

ASSEMBLYMAN GREGORIO: Senator---

SENATOR MENZA: We don't care how the bill is amended, Assemblyman, as long as it is permitted. Is that correct; is that true?

ASSEMBLYMAN GREGORIO: By the time the lawyers finish with this bill, I won't recognize this bill. But if you want to suggest who should make up the form, I would be glad to take your recommendation.

SENATOR MENZA: Lawyers are the backbone of our society, Assemblyman.

ASSEMBLYMAN GREGORIO: And all backbones have a little curve to them.

SENATOR SCARDINO: Thank you very much for bringing us your testimony today.

Undersheriff Pete Curcio. Pete, you said one minute or two. Will you identify yourself for the record.

P E T E R F. C U R C I O: I am Peter F. Curcio, 265 Livingston Avenue. About a year and a half ago, one of my sisters was told she had cancer, and from that point on, we kept reading and trying to find out what we could do to help my sister. One night I was watching the late news, and people were picketing the Waldorf Astoria where Betty Ford was the recipient of an award. One of the picketers was stopped and asked, "Why are you picketing here?" And the young lady said, "Why should Betty Ford be able to get Laetrile and go to Mexico and my sister is home dying?" And that has been on my mind since then, which is almost a year ago.

I appears to me that we have two standards. We are able to sell cigarettes in the corner drugstore that say "Harmful to your health," and here is a drug that may have no value at all, but the results of cancer being corrected or cured are practically nill. So, what does a person have to lose by going into the corner drugstore and being able to get Laetrile or anything else that - even in the imaginative mind - could really help them.

It really is disturbing that I see all this resistance. You hear people talk about the system. Well, that is the mob of government, to regulate the system. If you want to go to the racetrack - and everyone doesn't go to the racetrack - you can go. If I want to go use Laetrile over the counter, I can use it. If I want to buy a pack of cigarettes, I will be permitted to use them. I am definitely for this Laetrile.

SENATOR SCARDINO: Thank you, Peter. Are there any questions? If not, Dr. Evans, U.S. Food and Drug Administration.

D R. W I L L I A M E V A N S: Mr. Chairman, I am Dr. William Evans of the Food and Drug Administration. I thank you very much for your kind invitation to permit us to present our side of this very controversial subject. I have a prepared statement which is approximately twenty minutes long, which I will submit to the committee, and I would like to go into what are in our opinion the really serious problems about this, some of which I heard this morning.

SENATOR SCARDINO: Do you intend to read the statement?

DR. EVANS: No, I have submitted that statement because it is twenty minutes long. You requested ten minutes, and I prefer that anyway. (Prepared statement appears on page 21x in the Appendix.)

In the first place, it is a drug. Several federal courts have so found. Judge Bohanon created a temporary injunction allowing individual patients to receive this on the prescription of a physician. Now, the great question here is safety and efficacy, and that goes to the definition of a new drug. It has to generally be recognized as safe and effective. All the great pharmaceutical houses, of which your state has almost the majority, have to do this for any drug they wish to place upon the market in the form of an IND investigation of the drug or an NDA. This has not been denied to the sponsors of Laetrile. They have submitted IND's which are not thorough, and we would not accept them, and they sent in an NDA in the form of twelve to fourteen patients out of a population of approximately 1500 patients of Dr. Contraris - the so-called cancer expert - in Tijuana, Mexico. Now, this drug is not legal in Mexico either. It is subject to the same thing that Judge Bohanon created. There is a restraining order for a temporary time, and only one company is allowed to manufacture it in Mexico. They say it is legal in Israel - and I have a document coming right from their government that says it isn't. The man that is investigating it illegally in Israel is not a trained investigator. Now, I think you all are aware of the hearings before Senator Kennedy this past week.

Our Commissioner testified at the hearings of Senator Kennedy. You have the testimony there on the lack of safety of this product by Dr. Ross, Professor of Medicine, University of California. You have the death certificate of that child which was definitely due to brain anoxia, caused by poisoning with cyanide. The child took one to five tablets, and that has been gone over, so I won't go into it any further.

Now, we do know that under all tests, scientific tests and those done at several of the finest institutions in this country, this drug was found to be ineffective in animal tumor systems. These institutions have created approximately 50 drugs that we have found effective for cancer. Another thing that was brought out in Senator Kennedy's hearing - and you know there was a big hearing ordered by Judge Bohanon, an Administrative hearing that we held in Kansas City, Missouri, and during that hearing tons of information was sent in by the proponents. Every bit of that has been gone over by experts, and what it shows is that Laetrile is not one substance, it is many substances. It is not an isomer; it is supposed to be dextrorotatory or levorotatory. The effective one, they claim, is the levorotatory. And our examination has revealed that this is not one and the same substance. It is many substances. Amygdalin and Laetrile are not one and the same substance. It definitely is not a vitamin. This is from the scientific community, the greatest organizations in the nutritional field, and it is so stated, and the courts have so found on expert testimony. Now, there is another great problem in any drug, and

that is,good manufacturing practices. Apparently they are not following our chemical findings. All other drug manufacturers have to do this, observe good manufacturing practices.

Now, the other problem here, as I see it---This is the sixth state legislative body I have appeared before. Many of the top people, proponents of this drug,will appear and say more on this. I had the great honor of appearing in South Dakota in February, and I am appearing here in July. I have a change in temperature of about 125 degrees over a few omonths.

SENATOR SCARDINO: I have spent some time there, so I know exactly what you are talking about.

DR. EVANS: Now, the thing that I have seen, and what was testified to before the Senate Committee by their proponents, they want orthodox therapy to be done away with. Now, Senator Kennedy in his final closing statement told them, we will have this tested under good scientific tests. If it proves to be efficacious in any way, I will be its proponent on the floor of the United States Senate. But, he turned to the proponents, Dr. Richardson and a few others, and said, sirs, I expect you to also adhere to the results of a test of this type. They hedged. They said, "Nobody in orthodox medicine, orthodox cancer research,was capable of testing Laetrile, only those in their area of metabolic medicines, which none of us in orthodox medicine - and I taught for twenty-one years at Georgetown University - understands."

I had a doctor get up in South Dakota and say - a general practitioner, and I am all for general practitioners. I was not one, but I think they are the hard core of medicine. I'd hate to see them wiped out. - "I cannot use chemotherapy. I have no ability or training in surgery, nor in radiotherapy. I will use Laetrile on my patients." We were on statewide television. I told that man that he was not only guilty of malpractice - and I have said that to others in orthodox medicine - but he was probably guilty of manslaughter, because the great problem here is the divergence of patients from orthodox medicine at a point in the history of their cancer where they can be saved, and nobody knows when you pass that magic moment. There is no doubt that a great many people are being cured of cancer with surgery and/or chemotherapy or radiotherapy. They talk about mangling or burning, the proponents of Laetrile. My mother died of cancer. I know many friends who have died of cancer, and their families. That is not a reason. They died of pneumonia. When I was interning, 50% of the pneumonia patients died, and the very next year we had the sulphidamides and then penicillin, and the age of infection disappeared. It was no longer the greatest killer. At that time, nobody lived to get cancer. Childhood diseases, infective diseases, were the greatest killers by far, outside of war.

But you have to remember that people fear cancer, and I heard testimony that by the time the patients get home from their biopsy, the proponents are asking them to take Laetrile, and also telling them all the terrible things about surgery and chemotherapy. I don't like divergence. You have a person who is fearful. He is no longer sane when he is that way. The families are also fearful. I know how I felt when my mother's diagnosis was made.
They claim there has been no adequate diagnosis by biopsy,if it happens to be a blood cancer study. Now, I don't believe we can afford in this state or any other state to turn these patients away. I am sure medicine in some instances is guilty. We know about the rainbow pills that kill people. There are

doctors who have dollar signs in their eyes. Just because they are in the profession doesn't mean they are holier than thou. There are lawyers the same way, and also priests, ministers, or rabbis. And that goes for State Legislative and United States Legislative bodies also. We all know that. That is life.

But I urge you to look into this matter very deeply. You have some of the finest pharmaceutical institutions in the world right in your own state, and you might ask them. They would grab this because it would be a billion dollar bonanza, if they could get it as a new drug.

SENATOR SCARDINO: Is your major concern the exploitation of this product?

DR. EVANS: That is the biggest concern.

SENATOR SCARDINO: That is your biggest concern?

DR. EVANS: Yes. The diversion of patients from curative therapy, and exploitation from a monetary point of view---

SENATOR SCARDINO: Well, let me follow up on that, because I also share that fear with you, to be very candid, and I think you are right, it is something that we ought to be very careful about and look at very closely. However, in your professional capacity - and it is obvious from your brief description that you have had some considerable experience as a medical person - you have stated in your South Dakota testimony "Doctors who prescribe this substance are guilty of manslaughter."

DR. EVANS: I thought in his case, the statement he made, because he could not use chemotherapy - he wouldn't - he would not send them to some place like the Mayo Clinic which is close by----

SENATOR SCARDINO: In that case, I understand the connotation, and the statement that you made and why you made it, but let's now generalize a bit, if I may. Suppose I were your patient and I asked you to prescribe some therapy for me, and you suggested that I require chemotherapy. And I were to say to you, "Well, simultaneously, Doctor, would it do me any harm to ingest the Laetrile tablet daily?" What would your answer be? Will it do me any harm?

DR. EVANS: I will put it this way. It will do you harm in that it will at some point in time take you beyond the point where you may be cured by orthodox therapy. I will put it this way, my mother died just three or four years ago. She died of cancer very rapidly. I knew of Laetrile then. I am sure I could have gotten it. But I didn't even think of it, and I wouldn't do it today and I wouldn't do it for my wife---

SENATOR SCARDINO: I understand that, but my question was, as your patient, I am asking you, I am going to respond and cooperate and acquiesce to whatever treatment you feel is required for my cure, and I said to you at the same time, will it do me any harm to take a Laetrile tablet daily.

DR. EVANS: There is evidence which I presented Dr. Ross, that it does do harm, directly. It has cyanide in it. Enzymes in the stomach break that down. Even Dr. Crebbs, Sr., who started this thing way back in the 1920's stated it should never be taken orally, only by injection. We have evidence now through scientific methods that the Laetrile given by injection is excreted in its entirety as Laetrile.

SENATOR SCARDINO: If Laetrile has been a known substance all of this time, am I to understand that the FDA, or any one organization, association, or group, or individual has not in all of that time made some kind of a substantive study where it is documented factually whether or not it has done some harm? Because again, I have to say to you, as openly and as honestly as I can, that I have not received any documentation to that effect.

DR. EVANS: Dr. Ross' statement before the Kennedy Committee goes into the hazards of taking the cyanogenic compounds. I have given that to you.

SENATOR SCARDINO: Okay, we will have our staff review that, and hopefully we will be able to understand many of the technical aspects of that.

DR. EVANS: Judge Bohanon's order was a temporary injunction until we have an administrative hearing to make a legislative finding. The Commissioner has so done, and it is in my statement that this drug is not effective and not generally recognized as safe, and that is based mostly on the proponent's testimony and things they have submitted.

SENATOR SCARDINO: Are there any other questions?

SENATOR MENZA: I have a question. You have one piece of documentation relative to the toxicity of Laetrile. That reminds me, what are your qualifications, are you a physician?

DR. EVANS: Yes, I am a physician. I formerly taught at Georgetown as a clinical professor.

SENATOR MENZA: Pharmecology?

DR. EVANS: No, no, obstetrics and gynecology, but I had my share of cancer patients.

SENATOR MENZA: You mentioned in your testimony the fact of one child dying. Is that the only documentation you have relative to this subject?

DR. EVANS: Well, it is the only one we have with a death that is documented by a medical examiner, the Chief Medical Examiner of New York State.

SENATOR MENZA: In this report by Dr. Ross, is this based upon the studies that he did relative to --- Is Dr. Ross' study the only information available?

DR. EVANS: Well, there is other material in there too.

SENATOR MENZA: No, I mean detailed studies. HEW does studies constantly.

DR. EVANS: Well, I don't know what material--- What is there, I can't tell you. I have not been over it.

SENATOR MENZA: Well, are there other studies relative to the fact that the drug itself may be dangerous? Is it a dangerous drug? It seems to me to be a question of degree. If you are in too much water, you drown. If you make love too much, you might have a heart attack.

DR. EVANS: Well, let me put it this way, sir. Speaking of heart attacks, coronary thrombosis is one of the biggest killers, as compared to other cardiovascular diseases----

SENATOR MENZA: Doctor, I am not concerned with that.

DR. EVANS: Those patients shy away from seeing a physician when they have coronary---

SENATOR MENZA: Doctor, that is not my question. I am not concerned about that. I am concerned with the fact that you people have determined this drug to be dangerous to use. Forget the exploitation, because we get into philosophical discussions now, doesn't a person have a right to freedom of choice, as they say? Doesn't he have the right to commit suicide, for that matter? I am inclined to say yes to all of those questions.

DR. EVANS: You are?

SENATOR MENZA: Yes.

DR. EVANS: I will put it this way, Senator. I have had patients come into my office, and the first thing they will say is, "I want a shot of penicillin."

The easiest thing in the world for me to do is give them a shot of penicillin. Outside of killing with anaphylactic reactions, it has no side effects.

SENATOR MENZA: But assume that I come in and I say to you that I have cancer, and I decide that I want Laetrile. It is my decision, and I am a somewhat educated man, as a matter of fact. Now, you have spent a great deal of time telling me what a fraud and a hoax it is and what a profit somebody in Mexico is making and so forth and so on. Nevertheless, it is a decision of mine, knowing full well that it might be useless and it might be a hoax, and it might be a terrible thing that I am doing to myself and my family, neverthless, shouldn't I have the right to take it?

DR. EVANS: I wouldn't think so as a physician. You wouldn't have any more right to come in and ask for a quarter of a dram of morphine with a definite acute appendix if you didn't want an operation. I wouldn't give you a quarter of a dram of morphine under those circumstances which would get rid of your symptoms. I don't believe in that. I don't believe in giving an analgesic for a streptococcic throat, which might wind up with a rheumatic heart disease which will kill you.

SENATOR MENZA: I am interested, Doctor, in knowing very simply what reports exist on the subject as to whether Laetrile is dangerous. Forgetting the argument that it is dangerous because you will thereby prescribe other treatments and so forth, forgetting that, is the drug itself dangerous?

DR. EVANS: Well, the primary proponent of it is dead now, Dr. Krebs, Sr. He said it was hazardous and should never be given by mouth.

SENATOR MENZA: Everything is hazardous, Doctor. I would like to know what studies at the present time would demonstrate that this in fact is a hazardous drug?

DR. EVANS: The Food and Drug Administration hasn't the funds to do anything of this type in the first place, and I don't want to see Sloan-Kettering or any of the other great cancer institutions like M. D. Anderson spend and waste their time finding out whether this is toxic or not. They have spent too much time already in manpower and hours that they could have been doing something more useful.

SENATOR MENZA: To demonstrate that it is useless.

DR. EVANS: Yes.

SENATOR MENZA: Well, let's just put that aside, and assume for the sake of argument that it is useless, and it is a great hoax. The question I ask now is, is the drug itself dangerous? Does the drug make a reaction in the body that makes it dangerous?

DR. EVANS: Yes, enzymes in the gastro-intestinal tracts can release cyanide, a deadly gas.

SENATOR MENZA: Can you not say that about practically everything that has been prescribed?

DR. EVANS: No, sir. Let me give you another example. We now know that German measles in the first three months of pregnancy creates a high incidence of abnormal babies. Many of them abort, thank God. But we didn't always know that. Although this has been going on for thousands of years, it is only in the past fifteen years that we realized this. Just because we don't know something doesn't make it so.

SENATOR MENZA: I want to know with a reasonable degree of medical probability whether Laetrile itself is dangerous to human beings?

DR. EVANS: The Commissioner of Food and Drugs said it is not generally recognized as safe on the basis of all the information placed before the Food and

Drug Administration by the proponents.

SENATOR MENZA: Has there been a clinical report issued detailing the tests that were made and so forth?

DR. EVANS: Well, the tip of the iceberg is very difficult to find very frequently, and we don't know unless we are looking for something. Look at all the environmental hazards that are now being observed to cause cancer that we didn't know about.

No, cause and effect is a very difficult thing in medicine or any place else.

SENATOR MENZA: You see, the problem that I am having, Dr. Evans, is that the Assembly seems to focus on the fact that it is a useless drug, and then the comments on summary and evaluation reports, the council found no evidence of therapeutic value. Most of the information contained in Dr. Ross' report indicate that it is a useless drug. Now, I want to know, are there any studies around that would indicate that it is not only useless but dangerous?

DR. EVANS: Well, we have one report definitely now to prove it, the autopsy and examination of tissues. Now, on the basis of that---- Okay, show me one case of efficacy.

SENATOR MENZA: Yes, that is one child.

DR. EVANS: On the basis of relative safety and efficacy, and that is what all drugs have to be ruled on, aspirin causes bleeding in the stomach, and it is an over-the-counter drug---

SENATOR MENZA: Wait a minute, when I take two aspirins, and I don't have a headache anymore, that is a subjective finding. That is my testimonial.

DR. EVANS: Twenty-six percent of the effect of aspirin as an analgesic definitely is that, subjective. Pain is subjective. Let's take a cancer drug like methotrexate. It was first brought out at the National Cancer Institute that it killed 40% of the patients who took it. Now, on the face of it, you would say that was terrible, wouldn't you? But it was effective in 60% of the patients with metastisis to the lungs from corioepithelioma - a female cancer - which was 100% fatal within one year. Now, if you look at it that way, 60% of the patients have been alive now for over twenty years. We never say cured in orthodox medicine. We talk about how long persons survive. You cannot -- No doctor can say this patient is terminal. He is not God. He is a human being, and I don't believe anybody can say that. I have never known any physician whom I respected to say, "This is terminal cancer."

SENATOR MENZA: One last question. You have been testifying throughout the country, I understand. It is very interesting, the John Birch Society is in favor of this drug or the use of this drug. I presume that when you testified they also testified. Why has the John Birch Society taken any position on this, do you know?

DR. EVANS: I can't speak for the John Birch Society, sir.

SENATOR MENZA: Do we have anybody here to represent them?

DR. EVANS: I think it may be because of the freedom bit more than anything else. We haven't got total freedom in the United States, and God help us if we did. We could not be a society.

SENATOR MENZA: You are talking about a local communist, Doctor.

DR. EVANS: I just came here on the Jersey Turnpike, and then I got on the Garden State. It was fifty-five miles an hour, and I went forty-five

on the next one. Isn't that an infringement on our so-called freedom? Why can't I go down the Turnpike one hundred miles an hour? That is my freedom.

SENATOR MENZA: No. Let's not get philosophic, but it is because you may kill somebody else. If you want to kill yourself, do it, but not somebody else.

DR. EVANS: We are a society.

SENATOR SCARDINO: Yes, but you are talking about a situation that might hurt somebody else. Here we are talking about a situation where the decision is independent---

DR. EVANS: It has an effect on their families, their friends and everyone.

SENATOR SCARDINO: Every decision we make in life has an effect on our family and our friends.

DR. EVANS: Well, why can't I give out some of the hard narcotics as a physician?

SENATOR SCARDINO: I want to ask you a question from your professional standpoint, Doctor. Laetrile is a substance which contains cyanide, and one of the reasons, as I understand it, that the FDA prohibits its use is because of the cyanide content.

DR. EVANS: No, sir, it is not a drug that has been approved under the usual process that every other drug in the United States is approved under.

SENATOR SCARDINO: Are there other substances which contain cyanide and are being ingested?

DR. EVANS: That I can't tell you. There are 1200 products that have amygdalin in them. I am talking about food products, 1200 approximately.

SENATOR SCARDINO: Food products.

DR. EVANS: Right.

SENATOR SCARDINO: And they can be purchased at random at will?

DR. EVANS: Well, at your grocery store or food market. I don't know if all of them have it.

SENATOR SCARDINO: What makes them less harmful than Laetrile?

DR. EVANS: Sir, there is some evidence that some of these are poisonous. You are aware of bitter almonds and things like that. Now, I don't believe that apricot kernels are a food. I never saw them at any cocktail party or any restaurant I have ever been in. Apricot kernels are something that is thrown away, but somebody is making an awful lot of money and we have the evidence of that. Dr. Richardson was making about $10,000 a year before he went into this, but he has banked $1,200,000 in three years. That is a rip-off.

SENATOR SCARDINO: Forgive my facetiousness at this point, but I can't help but react by saying to you that the bubble gum manufacturers are making a lot of money too, and I constantly tell my kids not to chew it, because their teeth will rot. But I can't stop them because it is perfectly legal for them to manufacture bubble gum, okay.

DR. EVANS: That is the difference in the laws.

SENATOR SCARDINO: Well, the point that I am trying to make is, we are back to where we started from, and that is, I really am not satisfied that I have seen enough to show me that it is the right of an individual to make his or her own decision as to whether or not they want to use the substance.

DR. EVANS: Pardon me,sir, are we going to allow 2,000 other quack remedies we know about on the market too? Are we going to allow this in the treatment of infections and other metabolic diseases, et cetera? Where does it stop?

SENATOR SCARDINO: I am not suggesting that. All I am asking for, and I would welcome it, believe me, Doctor, is for concrete, easy to understand and read, documentation where Laetrile's substances have in fact been harmful to individuals who have taken it. I am in no position, and I am not qualified professionally, to make a judgment one way or the other. Maybe you are and you can arrive at that conclusion. I can only react to what is in front of me and to the testimony that I have heard both here today and less formally among friends, relatives, and anyone I have met within the last few weeks.

And, as rationally and as intelligently as I can, based on my own experiences, I can tell you quite honestly that I have not seen enough documentation to show me that it is adverse. I welcome - and I know the Committee shares this view with me - anything that would enlighten us in that respect.

DR. EVANS: Unfortunately, those who are using this product, the proponents of this product, are not about to give us this information. We get this information about hazards to health, side effects, everything else on every other drug.

SENATOR SCARDINO: But, Doctor, you told me that this has been a known substance since back in the twenties and before. If this were just put out a couple of weeks ago, then I might say to you, "Maybe there is a lot of quackery involved here." But this has been around a long time.

DR. EVANS: But not used for a long time.

SENATOR SCARDINO: It seems to me that somewhere along the line there should have been---

DR. EVANS: It has been a simple chemical without any use for years and years and years.

SENATOR SCARDINO: Again, I welcome the opportunity to receive whatever you can give us in the form of some concrete documentation---

DR. EVANS: There is one other thing I have to say to you as a Legislator in the State of New Jersey. The United States Food and Drug Administration made a seizure in Florida, which has passed the law, with criminal warrants in the courts. They did so also in Columbus, Ohio just this last Friday----

SENATOR SCARDINO: I am sorry, I didn't understand that last statement. They did what?

DR. EVANS: We also did the same thing with criminal warrants in Columbus, Ohio. The thing is this, it is almost impossible for any State to keep this product intrastate. The crossing of the border advertently or inadvertently after it is manufactured will put it under Federal law.

I don't know why certain States have done this. Every bill we see, and I have seen a lot of them now, has the same language. We know where it is coming from. We believe the states have their rights as individual units of the United States, but I don't know how this can stay within your state. And there has been lots of evidence of that nature already. The Attorney

General in Alaska told the Governor after he signed it that the bill was unconstitutional. In fact, there is no way they could use Laetrile in the State of Alaska because they can't grow apricots there or any other products there.

SENATOR MENZA: So what you are saying, Doctor, if this bill becomes law in the State of New Jersey, the State of New Jersey can be assured of criminal prosecution in intrastate and there may be a lawsuit brought by the Federal Government.

DR. EVANS: Only if we find that Federal law has been violated. If you keep it totally within your State, from beginning to end, there is no way the Federal law can touch it.

I am not giving threats. I grew up right next door to you in Manhattan. I was born in Manhattan and educated and trained in New York, and I will tell you this, I see what is going on. I feel sorry for the States. I understand that you legislators in these states are going--- It is an emotional thing now. You are no doubt representing the people in the state, and that is what you are doing.

SENATOR MENZA: Well, one more thing, Doctor. I don't know why people constantly and continuously underestimate what politicians are in fact. I don't know if it is a reflection on what the people want or whether it is politically expedient or not, and it may very well be quackery, and I am inclined to think that it is. But I am saying to myself, "So what." It is like the chiropractors and orthopedists. I go to a chiropractor, even though I have an orthopedist who is a good friend of mine. I don't know if the chiropractor has the training or the ability,but damn it, it works.

DR. EVANS: That is psychosomatic medicine.

SENATOR MENZA: Oh, come on.

DR. EVANS: That is a good part of all medicine, psychosomatic medicine. If you go to a dentist's office, you will find ---

SENATOR MENZA: Regardless, with all due respect to the American Medical Association, after all, they are members of our society. Do you know that? They are just people like us, and sometimes they are wrong.

DR. EVANS: I respect all politicians. As I said about doctors, there are good and bad.

SENATOR SCARDINO: Whenever I get the opportunity to speak, I have always likened the political profession to the medical and to the---

DR. EVANS: Yes, and the clergy too.

SENATOR SCARDINO: There is no question about it. As a matter of fact, Dwight Eisenhower said that quite some time ago.

DR. EVANS: I felt that way all my life. I almost went the other way too.

SENATOR SCARDINO: Thank you, Doctor. We appreciate your testimony. We would like to take a break now.

(Whereupon a luncheon recess was taken.)

AFTERNOON SESSION:

SENATOR SCARDINO: Thank you for coming back. This afternoon we are going to continue the Senate Institutions,Health and Welfare Committee hearings on the bills before us, Senate Bill 3289, 3354, 3295, all concerning the use of Laetrile.

Our witness at this time is Frank Beninato.

F R A N K B E N I N A T O: Thank you, Senator. First, I would like to open up by saying that the lady Assemblyman Gregorio was speaking of was my wife. My wife's name is Helen, and she has lympho-sarcoma. In fact, it was diagnosed by the pathologist in Trenton as lymphyo-tuberculosis-sarcoma. She was marked on her body on the chest near the diaphragm by the Wooster Cancer Clinic in Elizabeth. She was to receive thirty-six treatments of cobalt. At this time I knew nothing about Laetrile, so I went along with the cobalt simply because my doctor told me that was the thing to do.

After seeing my wife take three treatments of cobalt and not being able to sit up and eat, and not being able to go to the bathroom because she was so sick, I thought the rest of her life was going to be this slow death. It wasn't until she was almost completely done with the cobalt treatment that I heard about Laetrile. On the thirty-sixth treatment, Dr. Wooster came out, looked at me, and told me my wife had a very short time, that I should take her and show her a good time for the remaining days. I picked up a medical book, and in the book on cancer it said that lymphosarcoma, 92% do not survive much longer than a few months. It said 80% will survive about a year and a half. So, after three days of Laetrile, my wife got out of bed. Two weeks after Laetrile treatment she was doing her housework. We have a fourteen room home, four bathrooms, three grown children who drop their clothes where they take them off. She makes all the beds, does all the washing, all the cleaning, all the cooking, all the shopping, and even takes the garbage pails out.

Her treatment began in 1973, and to this day she is still doing the same things. If anyone thinks this is false hope, they can question me any time they want, and I don't care what capacity they are in.

Now, the wrong thing we are doing, Senator, we are making it very tough for a man who is a working man - the rich can support Laetrile at its present state. But a working man can't. It costs me $10 to $12 a day to keep my wife on Laetrile. Fortunately, I am in business, but if I was working for a living, and I came home with a $200 paycheck, you can see that I could not support my home, to keep my wife alive for three years.

The main thing that I would like to say is, we were able to put three men on the moon, and we spent a few bucks doing this. No one can make me believe that we don't have the medical brains to control the cancer problem we have in this country.

To get back to the rich, if the State of New Jersey doesn't pass this bill, then we who can't afford Laetrile, must leave the State of New Jersey and go to a state where this drug is legal. Again, the super-rich can take this, but the poor working men are people who can't ever face this problem. I have heard from Dr. Martin and other doctors on T. V. about the tremendous numbers of tests being done on rats and mice, and so on and so forth, but I have never heard one rat get up and say, "The pain is here, Hon. I can't sit up. I am nauceous.

I am sick. I hope God takes me." My wife did say all this, but after Laetrile, she did not repeat this.

I think it is a sad state of affairs when we have to just look at mice for our answers, and when the human being's opinion has no strength in the field of medicine. The FDA had 120 days to answer that charge in Kansas City, and I understood from the pamphlets I read that they never answered within that 120 days. It was after that time that they answered.

There is a Senator down in Trenton now, Senator Lynch of New Brunswick, and I would like you to call him some day and ask him how he feels now that he is on Laetrile. I am the man who introduced him to Laetrile, and I know how he feels. I myself take two thousand miligrams of Laetrile per day. I take it simply because I am being questioned many times by people as to what effect it has. I can tell you this, I have been taking it for two years, and I have taken it with every type of beverage known, scotch, rye, whiskey sours, anything imaginable, I took with Laetrile to prove there was no effect on me, no toxic effect.

You know, they say that there should be a good test on Laetrile, but we have to wait until we are terminal to have this test to judge how successful Laetrile is. I don't think that is a fair test. If they are going to make these tests,then they should be made equally. If they are going to have early clinical tests on cobalt, or chemotherapy, or surgery, if that is going to be prescribed for the cancer victims in the clinical tests, then Laetrile should also be given the same opportunity in early clinical tests - not when we are done with cobalt, chemotherapy, and we are terminal and we are ready for the funeral parlor. That is not a true test.

A man was up here just a little while ago talking about Mrs. Ford. That is true what he said, because I am the man who sent the material to Mrs. Ford, and I know she is taking it. In closing, I would like to say, give us laymen, the working class of people, an opportunity to live and not suffer with pain and hear the cries of our loved ones. Thank you.

SENATOR SCARDINO: Thank you very much. Where is your wife right now?

MR. BENINATO: Home, doing her housework.

SENATOR SCARDINO: Has she ever made any public testimony of her own?

MR. BENINATO: No, my wife will not go out of the house.

SENATOR SCARDINO: I am raising these questions because I am sure they are in the minds of others. You certainly have told us quite a story of quite an experience. Your wife is doing her housework?

MR. BENINATO: My wife is home doing her housework. I guarantee if you call her, she will answer the phone. You mentioned that our colleague, John Lynch, who is a well respected, well liked individual has been suffering with cancer now for some years, and you say he is now using Laetrile?

MR. BENINATO: Yes, Dr. Genato from New Brunswick is quite an enthusiast with advanced medicine and advanced equipment in the medical field, is taking care of him with Dr. Sokol. It was I who went to New Brunswick to introduce him to Laetrile.

SENATOR SCARDINO: What was the reaction of the attending physician, the one taking care of your wife? What was his reaction when he saw---

MR. BENINATO: He laughed at me.

SENATOR SCARDINO: Is he still attending your wife?

MR. BENINATO: Yes, every three months my wife goes to his office to be checked.

SENATOR SCARDINO: Does he say anything with respect to the substance?

MR. BENINATO: Delayed cobalt.

SENATOR SCARDINO: It is his judgement that it is delayed cobalt. And what does he say in terms of the delay lasting this long?

MR. BENINATO: He tells her to come back in three months. And I would like to make this clear at this point, my wife has not taken any orthodox medicine at all in three years other than the Laetrile.

SENATOR SCARDINO: Has she been to any other physicians?

MR. BENINATO: She has been to the Wooster Clinic in Elizabeth on Salem Avenue every three months for three years, and on her folder is written the word "Laetrile." And Dr. Wooster told her that if cancer comes back again any place other than the diaphragm, he will not treat her.

SENATOR SCARDINO: You are not saying that the Wooster Clinic prescribes Laetrile, are you?

MR. BENINATO: No.

SENATOR SCARDINO: What do you mean when you say that "Laetrile" is on the folder?

MR. BENINATO: On her folder at the Wooster Clinic is the word "Laetrile" because they know she went on Laetrile.

SENATOR MENZA: Did your wife get the cobalt treatments at the Wooster Clinic?

MR. BENINATO: Yes, thrity-six.

SENATOR SCARDINO: But she doesn't get them any longer?

MR. BENINATO: She has had no cobalt, no orthodox treatment,in three years.

SENATOR SCARDINO: Are there any other questions? Our next witness is Greg Kaye.

G R E G K A Y E: Senator, I brought with me several thousand signatures on a petition obtained in the last few weeks of New Jersey residents requesting immediate passage of S-3295. As the Chairman of the New Jersey Committee for Freedom of Choice, anyone who contacts our national office in New Jersey looking for a doctor or a supply of Laetrile, if they call our California office, they are referred to me. Since the publicity started back in April, the phone calls are coming in at a rate of ten to thirty a day. Of this number of people, only those who can escape the confines of New Jersey are able to find a doctor or find the supplies, which means many people can't.

Since S-3295 passed the Assembly by a vote of 62 to 5, if I recall, fifty people a day in New Jersey died of cancer. If only a small number of that group, such as Helen Beninato or Rose Larsen or Chris Herbert could have been helped during that time, I urge you to consider the bill this afternoon, 3295, as soon as possible.

I would like to read into the record some statements from international experts,some background ,on what Laetrile is. I tried to get them here today, but Dean Burke, unfortunately, is in Europe, and other people are on the road. The first thing I would like to quote from is the Nutrition Almanac published by Mc Graw-Hill. It is an extensive description of all vitamins, and this is their section on Laetrile. "Laetrile is an amygdalin, a simple chemical compound consisting of two molecules of sugar, one molecule of benzaldehyde, and one molecule of cyanide. Nitrilocides are known as Laetrile when used in medical dosage form. Laetrile is a natural substance made from apricot pits, and it is claimed by its developers to have a specific cancer preventive and controlling effect. Dr. Ernest Krebs, Sr., who was the first to use Laetrile therapeutically in this country considered Laetrile to be

an essential vitamin and called it B-17. However, Laetrile has not been accepted as a cancer treatment in the United States, because the Food and Drug Administration rejects its use in human cancer patients on the grounds that it may be poisonous to the cyanide and the chemistry of the body. This view is not held by Dr. Dean Burke, Chief Psychologist of the National Cancer Institute who has conducted extensive tests including the use of Laetrile, and states that, Laetrile is remarkably non-toxic compared to virtually all cancer chemotherapy agents currently studied. Other scientists claim that cyanide occurring naturally in food is not dangerous. In fact, it does exist in over 2,000 foods.

"Laetrile is manufactured and used legally in over 17 countries throughout the world, including Mexico, Canada, Germany, Italy, Belgium and the Phillipines. Natural cyanide is dropped in a sugar molecule; it is normally found in over 2,000 known unrefined foods and grasses. A concentration of about 2% to 3% of Laetrile is found in the whole kernels of most fruits, including apricots, apples, cherries, peaches, plums, et cetera. According to its advocates, the Laetrile is a highly selective substance that only attacks the cancerous cells. When Laetrile is eaten and absorbed by normal cells, an enzyme called rodenates detoxifies the cyanide which is then excreted through the urine. But because cancer cells are completely deficient in rodenates, and are instead surrounded by another enzyme which releases the bound cyanide from the Laetrile at the site of malignancy, Laetrile is believed to attack only the malignant areas. Under absorption and storage, they say that all doses of B-17 are not affected by the action of the acid in the stomach, but passed directly into the intestine, which substance is acted upon by bacterial enzymes. The bacterial enzymes in the intestines decompose---

SENATOR SCARDINO: I don t think you have to read all of that.

MR. KAYE: Well, the last thing I would like to read is the beneficial effects on ailments. They state that amygdalin may reduce the size of cancer tumors, ease accompanying pain, and inhibit the growth of cancer to other areas.

SENATOR SCARDINO: Okay, thank you.

MR. KAYE: If I can quote now from the Sloan-Kettering reports by two of the doctors there--- About three years ago they announced that all animal studies were ineffective and failed. About four months ago NCI and Sloan-Kettering said that they were going to use Laetrile on human patients, although they have never done animal studies, yet it was only about a month ago that Dr. Good announced that all tests had failed. Who are we to believe?

But in 1975, this report, which one of my Committee members handed to you, was smuggled out of Sloan-Kettering to the editor of our magazine, on Sloan-Kettering stationery. All these reports which are in your hands are in Dr. Segura's handwriting with the dates and the results. If I can call your attention, for example, to the first test of March 1, 1974, Dr. Segura ---

SENATOR SCARDINO: What page?

MR. KAYE: It is not numbered. It is on Sloan-Kettering stationery, dated March 1, 1974. He found that it reduced and inhibited 50% of th tumors, that it stopped lung metastises in 89% of the mice tested. Dr. Segura has conducted seven successful tests there, and his son-in-law Dr. Schmidt conducted an eighth. Clinical studies were also done in NCI by Dr. Dean Burke successfully. These reports were covered up, smuggled to our Committee, and we reprinted them with Dr. Segura's permission.

I would like to quote briefly from Congressman Larry Mc Donald of Georgia. This testimony from Dr. Mc Donald is in the magazine I gave you. He is a Congressman from Georgia. He says, "Approximately seven years ago, I first heard of the metabolic approach in the concept and the treatment of patients with cancer. The metabolic approach includes the use of dietary changes, trace elements, and vitamin supplements. The metabolic, therapeutic regimen includes the active use of amygdalin-Laetrile." According to Congressman Mc Donald, he states that amygdalin is a non-toxic food, and had been isolated as a separate compound over 100 years ago, long before the Food and Drug Administration was ever conceived. Of special interest, amygdalin has been used in patients with cancer in the 19th Century, long before the FDA.

He states that beginning in 1972, he started treating and advising patients with this metabolic regimen. The program includes the use of large amounts of amygdalin-Laetrile. At no time has anyone connected with this treatment ever promoted the concept that amygdalin-Laetrile is a cure for cancer, any more than proper diet and insulin are a cure for diabetes. Instead, we go back to initial concepts that this metabolic approach viewed as a control of the total disease state. In conclusion, Congressman Mc Donald said - and he is also an M. D., if I may remind you of that - "All of us members of the medical profession, as well as members of the lay public, should hasten to remember that virtually every major advance in medicine down through the ages was touted as quackery by the establishment ... at that time." We can quickly point to Jenner, Pasteur, Harvey, as examples. Unless some can honestly claim divine guidance, spokesmen for orthodox medical views should move with extreme caution in the area of judging from past records.

"Legally, the FDA is trying to control a food that was noted and isolated before the FDA was even founded. If this is reasonable, white sugar may be next on the list. It may be a good idea from a health standpoint, but it will continue with the same legal problem." This is from Congressman Larry Mc Donald.

SENATOR SCARDINO: Mr. Kaye, this testimony that you are giving now, do you have it written out in a statement.

MR. KAYE: It is on your desk. It is on page twenty-eight of the July copy of The Choice.

SENATOR SCARDINO: I am talking about the overall statement that you are making. Do you have it written?

MR KAYE: No, I don't, Senator.

SENATOR SCARDINO: Okay, how many times have you appeared before committees in the past?

MR. KAYE: I have not. I have done a great deal of speaking on behalf of the Committee in front of lay groups.

SENATOR SCARDINO: It may be helpful, if I can suggest this, if in the future you would put this in writing. It would be more beneficial to us, because a lot of the testimony that you are giving might require some additional research on our part.

MR. KAYE: Well, your aide should have suggested that to us before he invited us.

SENATOR SCARDINO: Well, it has always been a policy, because in cases like this it may be a while before we get the transcript. In any event, do you have anything else that you want to add?

MR. KAYE: Well, I have some remarks of more people.

SENATOR SCARDINO: Well, there are a few questions.

SENATOR MENZA: What is your background, Mr. Kaye?

MR. KAYE: Education-wise? I have a degree in political science, and my job is that of an insurance agent. My only background in this is that for over five years I was co-founder of the New Jersey Committee with Kris Larsen who will be speaking next. We saw it work therapeutically over five years ago.

SENATOR MENZA: How long has this magazine been in existence? It is quite an elaborate magazine. Is this all funded by proponents of Laetrile?

MR. KAYE: This is our magazine, the Committee for Freedom of Choice, a monthly magazine which the members receive.

SENATOR MENZA: Is there a parent organization?

MR. KAYE: No, it is an organization in itself. We have 1600 members here in New Jersey, and they receive this every month.

SENATOR MENZA: This is interesting, because I have read so many places about the John Birch Society being involved in this. Is this one of their publications?

MR. KAYE: No, sir, at no time---

SENATOR MENZA: Is Dr. Krebs involved in the manufacture and importation of Laetrile?

MR. KAYE: Dr. Krebs himself? Not that I know of. Dr. Krebs has patented the name of Laetrile. He patented a freeze-dried process which is now obsolete, but all manufacturing processes have been put in the public domain, and are available to anyone to manufacture.

SENATOR MENZA: What does Dr. Krebs do now? I notice he is an editor. Is he a practicing physician?

MR. KAYE: Dr. Krebs is a Biochemist. He is the science director of our committee. He is on a speaking tour continually. I had him here in New Jersey June 28, at Woodbridge High School, at which time I invited every member of the Legislature.

SENATOR MENZA: Still, didn't I read something about Dr. Krebs recently?

SENATOR SCARDINO: He appeared before the United States Senate Committee. That has been in the news.

SENATOR MENZA: Wasn't there an article in the New York Times recently about Dr. Krebs?

MR. KAYE: Oh, yes, there was an in-depth article.

SENATOR MENZA: Representative Mc Donald, is he still a---

MR. KAYE: He is a Congressman from Georgia.

SENATOR MENZA: Is he still a Congressman?

MR. KAYE: Oh, yes.

SENATOR MENZA: Then your statement, what you just recently read, was a statement that he made?

MR. KAYE: Yes, he did.

SENATOR MENZA: Who is Mike Colbert?

MR. KAYE: Mike Colbert is the editor or our magazine, The Choice. He is the author of two books, one by Arlington House, Vitamin B-17, The Forbidden Weapon Against Cancer, and another new book called Freedom From Cancer.

SENATOR MENZA: Is your organization non-profit.

MR. KAYE: It is non-profit, but not tax exempt.

SENATOR SCARDINO: How do you react to the statement to the effect that this is mere exploitation on the part of the proponents of Laetrile?

MR. KAYE: Well, Frank Beninato, whose wife is still alive, doesn't think it is exploitation.

SENATOR SCARDINO: I am talking about groups like yours specifically and Mr. Krebs' and the real hard core proponents, the ones who are supporting and pushing the use of Laetrile.

MR. KAYE: Senator, if that was the case, our committee would have the funds to fly Dr. Krebs in from San Francisco and Dean Burk back from Europe. We just don't have the funds the American Cancer Society has, which I think was $122 million last year. The New Jersey Freedom of Choice Committee for five years has been funded out of the pockets of Kris Larsen and myself. The literature that was made available to you was paid for by us, the film strips, et cetera. There has been no great money to be made. We have all gone in the hole. There may be idealogical reasons, or it may be because we have seen people helped with this, but the movement will not stop whether you legalize it or not. It will continue.

SENATOR SCARDINO: I raised this point and emphasized it, because the testimony that we heard this morning, those that question the effectiveness of Laetrile, made it clear in response to questions I asked that their greatest fear is the exploitation of the people, the money that can be made as a result of exploitation. And, of course, they tie that in with what they believe to be the ineffectiveness of the substance itself.

MR. KAYE: If I can make a comparison, Valium leaves Switzerland at $50 per kilo. By the time it is broken down for everyone's tranquilizers here, it is now $7500 per kilo, which, if my arithmetic is correct, is a 15,000% mark up. It is okay when the drug companies do it, when it costs $4 to manufacture a bottle of Laetrile and it is sold for $8 you are accused of a disasterous 100% mark-up. I think the abuses will be found among the drug companies. Our Committee has maintained all through this that this is a vitamin, and it cannot be patented. We have put the process in the public domain, available to anyone to manufacture, and a free market situation where the more people manufacturing it, the cheaper it will be.

SENATOR SCARDINO: As a vitamin, in your conception of a vitamin, and in this particular case, to what can you parallel this with, as an example? Can you do that for me?

MR. KAYE: Well, I parallel it with vitamin C. It took the orthodox medical establishment from the year 1710 until 1931 to admit that vitamin C was a preventative in the control for scurvy. I parallel it to vitamin B-1. This was the answer to the plague which scourged south of the United States for over a twenty-year period. I compare it to the beriberi epidemics and outbreaks in the Orient when those people were put on polished rice rather than unpolished brown rice, which contained the B vitamins, which was the control for that disease.

Dr. Krebs, in Kansas City, every time he speaks challenges the scientific establishment, and he states that every chronic metabolic disease in medical history that has been solved has been due either to a nutritional deficiency or to nutritional factors. And we believe that cancer is a nutritional deficiency and our therapy is not simply Laetrile. It is part of a much bigger regimen.

SENATOR MENZA: Mr. Kaye, let me get something straightened out here. You are saying that Dr. Krebs says this and that, and his investigation has done this and that. According to the New York Times, he is neither a Ph. D. nor an M. D. Maybe you can etell me, is he an M. D.?

MR. KAYE: No, aI never claimed he was; his father was an M. D. He has a

Ph. D. He was awarded an honorary Ph. D.

SENATOR MENZA: Is this Mr. Krebs, the editor of your magazine an M. D.?

MR. KAYE: No, Dr. Krebs, Sr., was an M. D.

SENATOR MENZA: Is this Dr. Krebs a Ph. D.?

MR. KAYE: Dr. Krebs, Jr., has an honorary Ph. D. awarded to him. If I can expound on that, I know Dr. Krebs rather well, and when he was interviewed here in New Jersey, he didn't come to his own defense, so maybe I can do it for him---

SENATOR MENZA: I am not judging him, by any means. I just want to put things in proper perspective. You know, if he is a scientist, fine. But he is apparently not a scientist- at least in our society.

MR. KAYE: He is internationally recognized as a biochemist. He has received the honorary degree, but the Krebs family has been harassed for many years, and when Krebs, Jr., was at the University of Southern California, they presented him with an affidavit that said, "Ernst, if you want to continue your education here, you must sign this affidavit that states you will never again advocate the use of Laetrile; you will do no clinical testing here with Laetrile; you will not speak about Laetrile." Ernst Krebs, Jr., could not bring himself to sign that affidavit, and hence had to leave the University of Southern California.

SENATOR MENZA: All right, he is a biochemist.

MR. KAYE: Yes.

SENATOR SCARDINO: Well, I would appreciate it now if you could kind of summarize your testimony and conclude, because we do have many witnesses. What I want to emphasize is we don't necessarily want you to cut anything out. We would just like you to cut it down and try not to be repetitive.

MR. KAYE: May I just quote some people whom I consider to be experts? Dr. Hans Neifer of the Silverston Hospital, Hanover, West Germany. Dr. Hans Neifer is one of the pioneers of radiology. In fact, at Sloan-Kettering they have a clinic named the Hans Neifer Memorial Clinic. Dr. Hans Neifer now practices cancer therapy with what he calls the Neifer regimen, which is, our metabolic therapy using the Laetrile, other vitamins and minerals and enzymes. If I can, I would like to quote him on what amygdalin is.

He states that it is totally a non-toxic systemically at commonly applied dosages. It has anti-cancer effects in both humans and animals as reported also in West Germany and East Germany, and published in a prestigious pharmacological journal, Drug Research. He states, "I have about 1,000 applicants from North America, and take on about one-fourth of them. They do not receive only amygdalin, but the entire program. As briefly indicated in this report, amygdalin is a non-toxic approach---

SENATOR SCARDINO: Excuse me, you are being repetitive now. We have heard a lot of this already, so, you know, you have made your point. What I am trying to say to you is, give us something that we haven't heard, and then let us have the opportunity to ask questions.

MR. KAYE: We have been accused many times this morning of not having any clinical testing or experts on our side, and the fact is there are. There are many who are international. Research has been done.

SENATOR SCARDINO: And you have this documentation to turn over to the Committee?

MR. KAYE: Yes, I do.

SENATOR SCARDINO: Has it been presented to any other committee before, in or around the State of New Jersey?

MR. KAYE: It was given to Mr. Deverin. These people did testify in other states. They were in Massachusettes testifying before they came here on the 28th.

SENATOR SCARDINO: Fine. I would appreciate it if you would leave that here.

SENATOR MENZA: I am not particularly asking this line of questioning with regard to the John Birch Society because I am prejudging anything by any means. I think it is very important. I see some names on this list that I recognize. Some of these people are very active in the John Birch Society, the American Opinion Magazine, and so forth and so on. Is this a publication of the John Birch Society? Is there any affiliation?

MR. KAYE: No, there is no affiliation as to publication of a totally autonomous group. The Committee for Freedom of Choice of Cancer Therapy, incorporated nationally in the State of California back in July of 1972. There is overlapping of membership. There may be Birchers involved, and I am well aware there are Communists involved. I don't think Andrew Mc Naulton can be called a Bircher. There are many liberals and many conservatives and many moderates. Most of the people involved with the Committee out of the 1600 here in New Jersey are people who came to this issue simply because they are looking for freedom of choice. Either they had a personal experience in their family, or they believe in the ideological issue. I am sure all the people who signed the petition--- I don't think there are this many Birchers in the country, never mind in New Jersey, affiliated with the Committee.

I would like to make two quick points. I heard a doctor this morning mention the toxicity of Laetrile. In Israel, Dr. David Rubin - which is also in that magazine I gave you - whose credentials are impeccable is using 70 grams of Laetrile a day to treat cancer patients. That starts on page one.

Also, you asked what the difference was among the bills. Our Committee is supporting Assembly Bill 3295 simply because it is more inclusive than the other bills. The other parts of Senator Russo's bill already dates back to---

SENATOR SCARDINO: May I interrupt you again? Is that because it permits the person to buy it as well as permitting individuals to manufacture it.

MR. KAYE: Because of the third paragraph which allows the introduction as well as the manufacture in New Jersey.

SENATOR SCARDINO: Are you aware of anyone at any time having made application to the Commissioner of Health for manufacturing Laetrile in the State of New Jersey?

MR. KAYE: In New Jersey, no, I am not.

SENATOR SCARDINO: Why not? Do you know why no one has made application to manufacture Laetrile in the State of New Jersey?

MR. KAYE: Because you have not yet acted on the bill. That is why the third paragraph is the most important part.

SENATOR SCARDINO: All right, I am going to ask for clarification on this.

MR. BRUINOOGE: We asked the Commissioner if under New Jersey State Law Laetrile would have to be recognized as a new drug, if it were shown to be safe, and she said yes. She said she may not have the resources to test it, but she would be obligated to test it in the State if someone came to her and said, "Here is the drug, can you certify it for us as a new drug." So I think it is a natural question to ask, why haven't you gone to the Commissioner and asked for Laetrile to be certified as a new drug.

MR. KAYE: Because Laetrile is not a drug. It is part of a total regimen, such as the Neifer regimen, the Richardson regimen, of a megavitamin therapy plus enzymes, minerals and diet. There are no drugs used, unless you consider vitamin C a drug or vitamin E a drug, or vitamin B-15 a drug. This has been grandfathered on the national level; it existed as a vitamin and was used therapeutically before the FDA existed - since 1830, in fact. It is not a drug. Why should we go through the process with the FDA of spending close to $20 million to test this, and wait ten years, where within the next year, 17,000 people are going to die in New Jersey and so many---

SENATOR SCARDINO: Let's stay with the specifics now. Does this same procedure apply to someone who wants to manufacture a vitamin in this State? Mike, is it your understanding that it could also be applied in that case?

MR. BRUINOOGE: No, it applies only to what may be determined to be a drug. Commissioner Finley feels that Laetrile would be considered a drug under State Statute.

SENATOR SCARDINO: All right, that is where the separation occurs, because it is obviously the feeling of this group that it is not a drug, it is a vitamin.

MR. BRUINOOGE: Well, at the same time they are asking the FDA in Washington to go ahead with their testing of Laetrile on a federal level.

MR. KAYE: No, excuse me, that is not what was asked.

SENATOR SCARDINO: Will you correct that, Mr. Kaye, go ahead.

MR. KAYE: At the hearings before Senator Kennedy the President of our Committee, Bob Bradford, agreed that we would help supervise the clinical testing, so only Laetrile by itself would not be used, but a total regimen would be used of the enzymes, minerals, and diet, as well as the other megavitamins. At no time did we admit it was a drug. At no time did we say we were going to apply for an IND permit. We feel as grandfather--- Our lawyers are now preparing a case that will be heard before Judge Bohanan to prove it is grandfathered. If we admit this is a drug, we feel metabolic therapy is the wave of the future. The Russians are using metabolic therapy in diabetes and heart disease with Vitamin B-15, also discovered by Dr. Krebs, which is interesting. They call him Doctor, and say he should have a Nobel Prize, but here they arrest him.

It would defeat our whole purpose to call this a drug. It is not a drug, and we are not going to admit it is. I have been taking it for five years in the form of a food, an apricot kernel, and to me that is not a drug. If that is a drug, then so are oranges and lettuce, and where do we draw the line?

SENATOR SCARDINO: Are there any other questions?

MR. BRUINOOGE: You have not agreed with Senator Kennedy's Subcommittee that Laetrile should be tested as a drug by the National Cancer Institute? You do not really go along with that process. You are fighting that process.

MR. KAYE: No, our agreement was, as far as I know, we didn't agree to have this tested as a drug. We agreed to clinical testing, which we did, on the condition that our Doctors, such as Paul Wedel, and our Committee would be there to see that the total correct regimen was used, which is the best treatment available today. We consider this a control. There can be break-throughs in the future, but we think this is the best modality available today.

If I can finish on why we are supporting A3295, the first two paragraphs of both bills are a mute question here in New Jersey. It is perfectly legal for a Doctor today to administer Laetrile. It is perfectly legal for a pharmacist to

fill a prescription. The only supposed illegality - and there is no statute anywhere in the country except the State of California - is to bring it into the country. And the Bohanan case has overcome that. So my point is, the only part of the bill which hasn't been met is that third paragraph in 3295, which is excluded in the other bill.

SENATOR SCARDINO: Mike, in response to the question surrounding Senator Kennedy's Committee and their deliberation on the bill, when they came to the agreement on testing, I notice, in the article that is very carefully written, no where do I see it mentioned as a drug. It is just being tested as a substance to determine its effectiveness or its harm, if any. That is just for clarification.

Now, if anyone has indications otherwise with respect to the testing only, I would like to know.

MR. KAYE: The opponents in Washington continually use the word drug, and the proponents continually use the word vitamin, and they use the word substance, as does the bill.

MR. FRAKT: There is one further point on this, existing State law says that anyone can apply to the Commissioner of Health for the introduction of a new drug, under Title 24. The third paragraph of the bill that you are referring to also says that it can be manufactured in accordance with Title 24, so the bill has an internal reference to our drug statutes. You are saying that it is not a drug, but you are supporting a bill which says its manufacture must be in accordance with the application for a new drug that we presently have on our books.

MR. KAYE: Mike already clarified that that does not cover the manufacture of vitamins.

SENATOR SCARDINO: You are missing the point. The last sentence of section two says, "provided that such manufacture, introduction or delivery is conducted pursuant to Chapter 6A and 6B of the New Jersey Statutes." And they cover the introduction of new drugs within the State.

SENATOR MENZA: Title 24 covers the Drug Act, and the schedules that are contained in Title 24 come from the Federal Government. So you are in a vicious circle. You have three schedules in Title 24.

MR. FRAKT: That particular section pertains to the use of interstate for a drug manufactured within the State. You can now apply to the Commissioner of Health for its approval as safe. The Commissioner earlier testified that there would be a problem with resources to do that. This bill also contains that same language---

SENATOR MENZA: Yes, but in any event, there is a defect here that I just can't get a handle on. This paragraph would not have any relationship to a truck coming in with the stuff from Pennsylvania, for example.

MR. KAYE: No, except the postal officials are imposing an interstate ban that no one knows about. They have never been instructed to confiscate. The only ban was bringing it into the country. The customs officials were told to confiscate it. Judge Bohanon took care of that. He enjoined the FDA and now those people who bring it into the country are paying a tax on it.

SENATOR MENZA: You mean it is not banned interstate now?

MR. KAYE: Supposedly it is, but they are not doing anything to stop the flow. If you wanted it tomorrow, I could have it for you.

SENATOR MENZA: We will if this bill becomes law. You can be assured that the State Police will pick it up when you leave Pennsylvania. One other question, is it being manufactured anywhere in New Jersey?

MR. KAYE: No, not that I know of. The patients here in New Jersey are using what comes from Mexico.

SENATOR MENZA: So most of the source of Laetrile comes from Mexico that is being run by one individual, basically.

MR. KAYE: No, that is not correct. It is a corporation, and the Chairman of our Committee Bob Bradford sits on the Board simply to test the purity and to make sure it is the highest quality available in the world. It is not one person handling this. It is also being manufactured in Germany, and in many other countries, and manufacturing was being done in the United States in some states.

SENATOR HAGEDORN: My problem with the testimony is your support for 3295, where the inference in the bill, as I understand it, is being recognized as a drug, because you have to apply for it on written request. Now, your testimony has been that it is considered a vitamin. I don't see how you can support 3295.

MR. KAYE: The authors of the bill don't refer to it as a drug; they refer to it as a substance. That hasn't been settled yet.

SENATOR HAGEDORN: I don't know about the statute. They are required to make a request for a vitamin.

MR. KAYE: This is a bill to decriminalize what is already de facto, simply to make it more clear for the people involved. This is patterned after the Nevada bill which passed both houses by a tremendous margin. As far as I know, there have been no problems in Nevada or Arizona. Both bills were similar.

What I am concerned with in the third paragraph is that it decriminalizes anyone who introduces it into the State of New Jersey, which can be a doctor or pharmacist or drug wholesaler.

SENATOR HAGEDORN: Wouldn't it be much easier procedurally and much simpler procedurally to make application to have it approved as a vitamin rather than a drug?

MR. KAYE: You don't have to have vitamins approved, as far as I know.

SENATOR SCARDINO: Thank you very much. Mr. Larson.

C H R I S L A R S O N: Thank you, Senator. I am Chris Larson. I am a member of the Committee for the Freedom of Choice in Cancer Therapy. Five years ago, I became involved in Laetrile when they rushed my mother to the hospital for an asthma attack. She had been suffering from asthma and emphysema and diabetes and congestive heart failure for some time. And they discovered that she had cancer of the breast. After tests, the doctor said her choice of therapy would be a radical mastectomy, the removal of the breast. But considering all her other conditions, they felt that it would not be advisable. The chances were less than 50% that she would survive the operation. So we took my mother home, and they didn't give her any other types of therapy or recommend any kind of medication. She started to lose weight quite rapidly and she was suffering from severe pain in the breast.

Shortly thereafter I went to a rally, and I saw a filmstrip called, "World Without Cancer." And it described the beneficial effects of Laetrile. I looked into it, and the only source of Laetrile I could get at the time was the apricot kernels. Shortly thereafter I was able to get the tablets. Since then, I started my mother on the kernels immediately, and eventually got her on to the tablets, and she was 75 years old with all those other conditions at the time, and she just celebrated her eightieth birthday. She is without pain, and she stopped losing weight. As far as I am concerned that is what worked, the Laetrile.

I have had occasion since then through my activity with the Committee to work and study with Dr. Paul Wedel from Salem, Oregon, who is the most renowned physician in this country using Laetrile at the time. He himself suffers from cancer, and he suffered for the past twelve years, and he brought his cancer under control with Laetrile.

One of the gentlemen this morning said that Laetrile taken orally was dangerous. Dr. Wedel controlled his cancer for the past twelve years with oral doses of Laetrile, and he administers up to fifteen grams or more a day to patients in critical situations. Dr. Wedel has treated over 3500 terminally ill patients. Like the doctor said this morning, he doesn't know of any doctor who would term anyone "terminal." Evidently he speaks to doctors in different circles than I do, because they all use that term when they feel the patient is about to expire. Dr. Wedel, like I said, has used Laetrile on over 3500 terminally ill patients in the past ten years, and half of those patients are still alive. And those patients are patients who came to him after orthodox treatment had been administered and been given up by their physician. They have turned to Laetrile through Dr. Wedel.

I have a very limited knowledge of medical records, but I don't know myself of any other doctor who has that type of record, where they could say that half of 3500 patients are still alive that were supposed to die within weeks or months because of cancer. They have conducted some tests in Europe where they have found that a lot of cancer patients live longer and with less discomfort if they are not treated at all for cancer. When you are talking about orthodox chemotherapy and radiation therapy, they are conducting all kinds of tests all over the country, which have been read into the record, and about seventeen countries are able to use Laetrile. It is now over twenty-six countries, and Israel is the latest one that is doing extensive research on it, and having tremendous results with their tests.

Another thing that was brought up here was the controversy about how long the drug has been around. The drug has been around for over 100 years as an analgesic, pain killer. There was also a question as to the length of time other drugs have been given for approval of the FDA. Dr. Savon of the Savon Oral Vaccine, introduced his vaccine in the United States ten years earlier than it had been accepted. He had to go to Russia and use it on fifty million people before our society aceepted it. In that ten-year period, how many people suffered from polio. Every major break-through in medicine has been met with tremendous resistance by the medical societies, and it is for that reason that I think they are opposing this break-through. I have my own opinions, but I won't go into them right now.

SENATOR SCARDINO: Thank you very much. I appreciate your testimony. Dr. Koeck.

D R. G E O R G E K O E C K: Members of the Committee, I am Dr. George Koeck. I have been associated with the National Cancer Society for thirty years. For thrity years I have treated cancer patients. I have seen their symptoms, their sufferings, their emotions. I have seen many of them die, and I have seen many of them who were saved and are living today without cancer. I am here primarily to plead for the cancer patients. Anything that we can do for the cancer patient is the only important thing that we are here for.

Now, cancer can be cured, and cancer is being cured. In 1920 very few cancer patients were cured at all. By 1950, 25% of cancer patients were being cured.

Today, in 1977 anywhere from 33% to 50% are being cured, and a greater number can be cured. The key, the important ---

SENATOR SCARDINO: Excuse me, do you mind if we interrupt you? Are you talking about cures or remissions?

DR. KOECK: I am talking about cures, not remissions.

SENATOR MENZA: What is your background, very quickly?

DR. KOECK: I have been working with cancer patients for thirty years. I have worked at the New York Memorial Hospital for two years just on cancer therapy.

SENATOR MENZA: In what capacity, as a physician?

DR. KOECK: As a physician, surely, in radiation therapy and oncology. Then at the Mount Sinai Hospital in New York and the Veteran's Hospital in Philadelphia and New Jersey I have also been associated. I have been on the Medical Staff of the New Jersey Medical School, in the radiation therapy department, and at the present time I am a consultant to many oncology offices in the State.

SENATOR MENZA: You are appearing here for the American Cancer Society?

DR. KOECK: Yes.

SENATOR MENZA: In what capacity?

DR. KOECK: I am a national delegate director, and I also am on the national committee for unproven methods of cancer management.

SENATOR MENZA: Do you speak for the society?

DR. KOECK: I am speaking for the society today, yes.

SENATOR MENZA: Thank you.

DR. KOECK: As I was saying, the important key to cancer therapy today is early diagnosis and early treatment. That is the most important aspect of cancer for survival. In the United States, in this coming year, there is going to be close to 700,000 cancer patients. Of that number about 125,000 will be early cases, and if we divide that roughly into the number of states, New Jersey is going to have between 2,000 and 2500 new cancer patients. Now, if these new cancer patients are treated early, regardless of what the tissue involved is, the chances for survival are at least 85% to 90%. If there is a lag of three months, six months, or nine months in delay in treating cancer, with proven scientific methods, then that 85% to90% goes down to 15% to 20%. The most important thing is early treatment. You only get one shot at treating cancer, and that first one better be right. If that first one isn't right, and it isn't done at the time that you get the disease, then it is going to be disseminated; it is going to be very difficult to treat.

Now, you have been interested mostly in whether or not the substance Laetrile is harmful. I will skip, therefore, the scientific investigations and all the other information that has been obtained from the testing of animals and so on to show that no scientific methods so far has shown it to be effective, either in the prevention or in the treatment of cancer.

Now, we in the cancer society feel that it is harmful, that it is very harmful. First of all, you have heard, which is sort of a sore point at this time, about the baby that took cyanide, but definitely it is on the record. There is definite proof at the Sloan-Kettering Hospital in New York by Dr. Stork, who performed an awful lot of investigations on animals with Laetrile to show its ineffectiveness. He has come up with the definite fact that the higher dose that they were giving these animals caused death, cyanide death, in these animals. So, this can be definitely gotten from the Sloan-Kettering people in New York - that a higher dose of Laetrile caused death in these animals.

Now, there is another evidence of chronic cyanide poisoning in Africa, in Malaya, and in Jamaica. There is a grass called the cassia grass, which is one of the grasses that we talked about having these substances in it. And this cassia grass has a chemical in it very closely aligned to amygdalin. The study of these people who have been chewing this cassia grass for years shows that they have chronic cyanide poisoning, and on top of that, a fellow by the name of Mc Naughton who is researching the Laetrile problem has a note of warning on the oral preparation of Laetrile saying that it can be dangerous if it is taken by mouth.

In New Jersey we have been known in the last few years as being a cancer alley state, meaning that the statistics we have of cancer survival in New Jersey are not as great as those in other states. Now, whether this is true or not, I don't know, but certainly some harm can be done now by legalizing, and the harm you are asking about, I talk about as late delay. As I said, the key is early treatment, early diagnosis. Say New Jersey legalizes Laetrile for terminally ill patients. This sort of gives the doctor and the patient the feeling of, "Well, they have okayed it; there must be something in it that is good." If it is good for the late patients, why isn't it good for early patients? So what happens, the greatest harm in this business would be someone taking Laetrile three months, six months, nine months or a year, at which time cancer would be devebping, and then they would have lost their chance--- As I say, you only get one chance.

There have been reports to substantiate this, coming in from the large oncology centers, the M. D. Anderson Hospital in Texas, the Sloan-Kettering Hospital and the National Cancer Institute, and a lot of these other people will state that there are people coming in every day that are terminally ill cancer patients that have been on Laetrile. Now, I would like to mention, when Assemblyman Gregorio talked about his father who was still living today and refused to have any surgery done and so on, I would like to tell you, with carcinoma of the prostate, you can live fifteen or twenty years without any treatment. This is the way that disease goes. So it doesn't make any difference. And the other patient that was treated by Dr. Wooster ought to get down on his knees and thank Dr. Wooster that he treated this patient with cobalt therapy and not Laetrile.

As a final plea, I would suggest that before anything is done, wait until all the information is in. I would suggest that if a double blind study is done to show whether or not Laetrile has any effect on humans, let's find out and see if this is true or it isn't true, rather than going ahead and making it legal at this time. Because if you make it legal, there are going to be probably hundreds of people who are going to die every year in New Jersey because they are taking Laetrile and they are not taking a substance which can give them a chance for life. That is all I have to say.

SENATOR SCARDINO: Your testimony is very forceful, and I want to thank you again for taking the time to come here. I just want to react to the point that you made concerning testimony given by Mr. Beninato and his wife. I think that is the one you made reference to. You said that he should thank the Doctor who prescribed the cobalt treatments - and I think she had some thirty-six treatments, if I am not mistaken. How would you react, if you were sitting here, to this man's testimony when he said that he was told by the attending physician that there was no more that could be done for his wife, and that he said, according to Mr. Beninato's testimony, that the doctor told him that his wife had but a short time to live, and

that he went to a journal and looked it up and he found out that she only had a few months, according to the expert testimony, and in any event, it was at that point, out of sheer desperation, grasping for whatever he could, that he latched on to Laetrile and gave it to his wife. How do you react to that?

DR. KOECK: Well, in various ways. First of all, this is the opinion of one doctor, and this is something which he probably felt would be a routine, seeing others, but it is not an infallible answer. We have seen many patients who were considered terminal - and this is another problem, how are you going to consider terminality? You can't because there are many patients who are considered terminal today, and a week from today or a month from today they are changed. I would suggest that if this were done, that he should go to another doctor, to another clinic, get another opinion. We have seen patients ourselves whom we felt were not going to live for a month, but you follow them, and proceed with your type therapy and you keep going. An awful lot of these people come around again. They may not be cured, but they may live for years or months. Now, in this case, this may be a survival. I don't know. It is quite a while now since---

SENATOR SCARDINO: Let me ask you that question another way. Let's use this one case as a specific example, and there are many, many more. Suppose it was the will of the State, through the legislature, to prohibit the use of Laetrile entirely and we denied this woman who has been using it now for five years the right to continue, and theoretically, months and weeks later she expires, and it is anyone's guess as to why or what happened. How do we cope with something like that?

DR. KOECK: Well, you can easily cope with that because you have nothing to stand on. You don't have any ground to show that this patient was refused an effective method of cancer treatment. She wasn't refused any effective method, because this has never been proven to be an effective method of cancer treatment.

SENATOR SCARDINO: But in her case, she believes it to be an effective method of treatment, and it is not doing her any physical harm.

DR. KOECK: Well, I would say that the chances of it doing her harm and not helping here were great, and I wouldn't go along with that.

SENATOR MENZA: Well, the question in my mind is whether there is an effective method of treatment. I have had many of my relatives go to the Wooster Clinic, which is a very respected clinic, as you know, and it is right around the corner from me, as a matter of fact, and they have many doctors with good reputations. All of my relatives who had cobalt treatment all died. Our family is very strong and have good hearts, but they died of cancer.

You see, I don't know, Doctor. You have made a good presentation, and it can be a very cruel hoax, and yet you can't really summarily dismiss these testimonials. They can't all be wrong. If you get ten thousand people who say they have seen little green men coming out of a spaceship from Mars, one is right. You just can't summarily dismiss this kind of thing. The problem I have is the medical profession does have, unfortunately, somewhat of a habit or a history of doing just that.

DR. KOECK: Senator Menza, let me say this, when I first started my practice, there was a Mr. Evans who came from England, and Mr. Evans had a book that thick with the testimonials that the Laetrile people have and the pictures, and everything else like that, and he claimed that his family for generations before him were able to extract some roots of certain types of herbs from South America and Australia, that was going to cure cancer. They tried it. After that, if you

remember, there was the Hocksy Hoax in this country about how Hocksy was going to cure cancer, and then lately the cribiacin thing. The crubiacin thing was something similar to this, the same sort of thing. They all died a natural death because they failed to prove that they were effective. And Laetrile is going to die that same sort of death, but how many people are we going to have die before that is proven. That is the thing that bothers me, the cancer patients who are going to die taking Laetrile instead of having proven scientific methods of treatment.

SENATOR SCARDINO: Thank you very much. Mr. Leone.

A L D O L E O N E: My name is Aldo Leone, and I am here representing Option, Inc. Option, Inc. is an organization formed recently to endorse any kind of legislation that would legalize in this particular case Laetrile, but that more particularly hopes to be active in preserving what we believe to be the privacy rights of individuals, and specifically the privacy rights of individuals with respect to health care. I am a layman. I have no expertise in the medical field or in the legal field. I am active in finance.

We have collected several thousand signatures, Option, Inc., from people who share this kind of sentiment. The sentiment basically is that we believe bureaucracy has developed into something too large and massive, almost a monarchy in which it is too far removed from the people, and we believe there is a serious risk and danger in relying solely upon, for example, the FDA, for the final judgement to be made in the medical field.

There are, of coures, going to be exceptions. We believe in certain regulations, but if the FDA, which is really a few individuals, is given final authority to make all of the decisions in this country with regard to medicine, we believe that will create a condition that is potentially corrupt. We have seen government be corrupt or officials be corrupt in government, and we are quite certain that history will repeat itself if too much power is granted to too few people.

That is basically the aim of Option, Inc., to see to it that people have choices, that they can be informed by the federal government if a particular substance is dangerous or if that substance has no value, and still they should have the choice to use it. I became involved with this particular issue when my mother died about two years ago of cancer, and I would like to relate why I believe Laetrile has value and why I am active in trying to preserve the privacy rights. Mother died June 3, 1975. She received orthodox treatments. She received chemotherapy and surgery and in particular she received fluorouracil, a very commonly used chemotherapeutic agent. She passed away approximately within a year of the operation. Incidentally, phyororacill is owned - the patent rights are owned, fifty percent, by the American Cancer Society and I do not believe that that ownership of those patent rights is commensurate with perhaps an unbiased opinion.

The results were, as I say, that mother died. We administered Laetrile to mother during the last forty-five days of her life. The results were that all her vital signs improved. The blood count improved; her renal activities improved, and she generally improved for approximately three days, then unfortunately through an accident the hospital administered the wrong medication to mother. It was medication designated for Mr. Nelson. I noticed it and pointed it out to the nurse, and she scurried out and they changed it. I am not saying that the wrong medication killed mother, but it may have accelerated her death. We don't know. That is a speculation,

but it certainly couldn't have helped. We performed an autopsy on mother, and the pathologist - which I didn't bring with me, but I can tell you what it says, and I can submit it to the Committee if they would like a copy - and I discussed the autopsy for about two and one half hours. The autopsy did reveal a microscopic examination of the lung tissue and the liver that a marked necrosis of the adenal carcinoma had occurred, and I will take a little liberty to translate that. It simply means that there was a significant damage or death or destruction to the cancerous tissues. I asked the pathologist how he interpreted this result. We examined four possibilities. One was that the normal dying process would cause the high death rate in cancer cells. He indicated that that was not a possibility. Normal death does not cause cancer cells to die any more quickly than normal cells. The other possibility was that the tetracycline administered to mother inadvertently, which was the medication designated for Mr. Nelson, could have caused it, and he said, no, because that was strictly an antibiotic. The third possibility was a spontaneous necrosis of the cancer, and he said he had never seen in his experience a spontaneous necrosis of the cancer cells in the liver or the lungs, but only in the testes and ovaries. And then the fourth possibility is that some external agents would have caused this marked necrosis, and he indicated that he didn't believe it, but it was a probability or a possibility. Therefore, I was led to believe that the Laetrile which we administered had this effect, and would be useful for other people, and therefore I became active in making that information known.

SENATOR SCARDINO: How old was your mother when she passed away?

MR. LEONE: Sixty-six, a very young sixty-six. It has been stated before, but I would like to reiterate this in a different context, that Dr. Kinamatsis Segura, who is a biochemist with the Sloan-Kettering Institute has never disavowed his earlier findings from the six experiments he did, in which he found that Laetrile was useful and had affirmative action with metastisis. He has subsequently participated in other experiments with other biochemists in which they have not found the same findings, however, he has not disavowed, or in any way rescinded, his earlier statements, and I think that is to be recognized.

Also, Dr. Dean Burk, for thirty-five years Chief of the Toxicology Department with the National Cancer Institute, has publicly in writing, on television, and by phone, and I have spoken to him, endorsed Laetrile as useful. He has said it is valuable in the treatment of cancer. He has also made some very discreet insinuations and actual statements, I guess, that the National Cancer Institute, he believes, has suppressed information. Now, that sounds a little venal and a little strange, but he has made those statements, and I think they should be made part of the record. I personally do not believe that the medical profession is conspiring in any way to withhold Laetrile or withhold any cancer cure. I believe they are dedicated men who believe as they state they believe. However, I do believe there is an inertia of dogma that kind of blinds them, perhaps, and keeps their minds close to the experimentation, clinical testing of Laetrile. I believe they are sincere and honest, but I think they are taking their expertise and imposing it upon us, and I don't believe they have the right to do that.

I think that their expertise should be offered to us. We should have the choice to decide if we want to accept their expertise or not. It should not be imposed through the government upon us without choice. And that, basically, is the position of Option, Inc., and as spokesman, I have indicated.

SENATOR SCARDINO: Are there any questions?

SENATOR HAGEDORN: How is Option, Inc., financed?

MR. LEONE: Option, Inc. is being financed through donations that we are soliciting.

SENATOR MENZA: I would just like to make a general statement. It is like the Committee dealing with mental health, you realize it is a very difficult problem without simplistic solutions, and the more testimony I hear, the more I am getting somewhat confused. I remember when I was a kid, and I was in a laboratory and we knew the chemical qualities of something. We knew exactly what would happen if we put another compound in. We knew it would change colors or one of many, many other things. It would seem to me, however, that in order to cure something, you must know what causes something. And it appears to me - it may be very bad logic - that if you don't know the cause of cancer, how can you say thereby that this is or is not a cure. Are we not looking for traditional approaches in our cancer cures? Or perhaps if we knew the cause of cancer now - and I pose this question just as an academic question - wouldn't it very well be the case of Laetrile being the exact vitamin or drug or whatever it may be that addresses itself to what causes cancer? I am not trying to be philosophical, but we live in a society of rules and structures and chemistry and medicine that is exact, or should be, and it would seem to me that in order to determine whether something is a cure or not for cancer, perhaps we better know what the cause of cancer is. If you don't know what the cause of cancer is--- I don't know, I could go around and around. There are conceptual problems here.

I wish some of the physicians would perhaps address themselves to that concept, perhaps. And I would also ask whether they continue traditional methods at the Wooster Clinic? Is it always the traditional method? Is it always taking the tumor away or is it always cobalt? Is there any experimentation happening with the average physician in dealing with the cancer patient? Are there any other drugs being used? Do we use the same type of therapy all the time? I am sure that these questions that I am posing are somewhat silly to most people out there, but I have a very structured mind, and it seems to me that in order to find certain answers, you have to pose certain questions.

SENATOR SCARDINO: Thank you, Senator Menza. Mr. and Mrs. Alperin.

I R V I N G A L P E R I N: My name is Irving Alperin. I am a layman. I am an old Jersey boy. I have been living in Georgia for about thirty-three years, but I was raised in Long Branch. My mother-in-law has developed cancer. Since April second she has had three operations, and the last one was two weeks ago today. The surgeon worked on her for about three, three and a half hours trying to open up her small intestine and open a passage way so that her food and nutriment could go through there the way it should normally. She had a colostomy in the first operation. Ostensibly he was going to hook her back up, but when he got in, the cancer had spread. It was all over the small intestine and all over the peritoneal wall. He used the word "seeded." It has just spread. He has never seen anything spread so fast.

He was very concerned and very upset, and we were very upset. The only hope he could offer was if she healed - and he wasn't sure if she would - the only treatment he could use possibly was the chemotherapy. That was if she healed. Now, he had cut on and sewn on her intestine, and he was concerned that it might not even heal,

that it wouldn't even grow together, that it might leak, and if it leaked, that would be the end, because then she would have peritonitis. Anyhow, we started looking into Laetrile. My wife and I were going to go to Mexico. We tried to get it in this country first of all, and the FDA had impounded a shipment, and there just didn't seem to be any available anywhere in the country. She could not take anything by mouth, so we had to get the liquid. We decided to go to Mexico. We wanted to go on a Saturday morning, hopefully, and be able to see the doctors down there, and get our Laetrile and be back by Monday. As it was, they couldn't see us Saturday. In the meantime, my mother-in-law's condition became very serious. My doctor/brother was there with us on Saturday night, a week ago Saturday and said, "She looks like she is dying, you better not go." I mean, she was that far gone.

I decided to go by myself, so on Sunday afternoon I went. I had an appointment with the doctors Monday morning---

SENATOR SCARDINO: You went to Mexico.

MR. ALPERIN: I went myself to Mexico with affidavits from the doctor that she was terminally ill. According to Judge Bohanon's ruling, with the affidavit and a doctor's signature duly notorized, et cetera, we could treat her with Laetrile. I got back to Kennedy at six-thirty on Tuesday morning after riding all night. Dr. Gable did not consider it worthwhile. He did it because there was nothing else to do. He said he would treat her with Laetrile. He is a doctor, and just to please us he would try it. The surgeon was also not very optimistic about it. He said he didn't care really. It was beyond him. If we wanted to do it, it was okay with him. He would allow the Laetrile to be used.

Dr. Gable said, all right, as long as you went to Mexico and got it, we will use it. So on Tuesday she had an injection; on Wednesday she had an injection; on Thursday she was having her injection, and the doctor said, "We have a technical problem. I want a conference with you two when we get done." The technical problem was that the hospital told him to quit. He is not to use Laetrile. This was after the conference. He said, what you might do is go down and talk to the Administrator of the hospital and see if you can change his mind. He is a nice guy. Go ahead and talk to him. We went down to see the Administrator, and the Administrator could not see us. The Assistant Administrator saw us along with the Chairman of the Medical Board, Dr. Kirby. They took us in this conference room, and the first thing they started with was, "you know, this is an illegal drug. You can be prosecuted for having it in your possession. It is illegal for the doctor to administer it." He practically accused us of smuggling. We got the stuff in Mexico with a doctor's affidavit. We came through customs and paid duty at the border for the Laetrile, and he is accusing us of smuggling.

Anyhow, Dr. Gable said, "Well, this doesn't really mean anything." And again Dr. Kirby called our doctor and said, "No, no, you can't use it. " But he is a nice guy and he said, "I will give her one more shot." So on Friday he gave her another shot. And Saturday morning at eight o'clock he calls us and says, "I have been suspended by the hospital. I cannot see Mrs. Woronoff. I cannot bring any more new patients into the hospital. I can see my old patients, but that is all. I can't even look in her room."

This is what has happened in our case. We are looking for an answer. We have a note here from the doctor as of last Thursday, the last day he saw her, and

a statement by the nurse as of yesterday that she has had no pain the last couple of days. She has been going to the bathroom by herself. She took a walk yesterday, and as far as we know she is free from pain. The nurse states in this note that she has not had a shot of demerol for twenty-four hours. This was yesterday, so today is another twenty-four hours. She is doing great. She has asked her daughter here to bring her glasses, and she has a new career since she retired from her dress business. She is taking singing lessons, and she is taking piano lessons. She is going on television, so she wanted her to bring her - she is eighty years old, by the way - lyrics, so she can study her lyrics now. She is that far along since last Saturday when she was dying.

We attribute this all to Laetrile. As far as we can see, this is the only thing they have done to her that they hadn't done before.

MRS. ALPERIN: May I say something? All I told Dr. Gable when I knew my mother was terminally ill was that I just wanted her to die with dignity. I don't want her to have the pain that I understand goes with the morphine shots. I had seen her Saturday night in horrible, horrible pain. And this is my mother. This is difficult to watch. I hope none of you ever have this problem. I said I couldn't go, because it didn't look like she would make it. His brother/doctor was visiting with his wife, and he said, "Don't go, Mimi." So I stayed and Irving went. This past Saturday brother Martin and his wife came to visit again, and I looked at him, because he thinks it is nonsense. I said, "Martin, how does she look?" He said, "Much better." I have been questioning mother daily. She thinks she is getting some food. She doesn't really know what is going on. She is not aware that she has cancer. She is aware that she is very, very ill.

I question her as to her pain, and if you would like to read it, we have a signed statement from Dr. Gable the last time he was allowed to check her that she was free of pain on Friday. I then questioned the nurse, and as of yesterday she said she had not had demerol for twenty-four hours and she has had no pain. I called at intermission and I asked how she was doing, because really I am here for some help. She is fine today. In fact, she is getting very bored, and she is getting very bitchy. That is a quote from my mother. That is a good sign. I mean, I am not believing what I am seeing. All I wanted was for her to be free of pain. She is eighty years old. I am not saying I want her cured. She has had a very traumatic experience. She has had three major surgeries. Her husband passed away after fifty-seven years of marriage, and this is too much for one person. I just want her to die without that kind of pain.

Now, the hospital has absolutely refused to allow Dr. Gable to give her the injections. I don't know what kind of recourse we have. I appreciate the fact that there are bills pending, but in the meantime my mother is dying, and I don't have time. This means I either have to do something illegally, which I don't care to do - because obviously we have done everything officially and properly---

SENATOR MENZA: Let me ask you a question. This all happened within the last week, and your mother is getting better, you say?

MRS. ALPERIN: Since the actual noticeable improvement, the first time was Thursday. Unfortunately, Wednesday they gave her some barium to check on her surgery.

SENATOR MENZA: Who guided you on this affidavit? How did you know about the affidavit, and how did you go about it?

MRS. ALPERIN: Okay, when we talked about Laetrile, my husband came flying

in for her operation with a book in his hand by Dr. Richardson, and he must have been reading it on the plane, because he was all fired up, and he is not a very enthusiastic individual usually. And he was all fired up about this, and he started reading about this. And I said, fecetiously if this cancer doesn't kill my mother, the phone bill will, because I called Oklahoma City to verify the judge's document. I called California. I called my Congressman. We are from Atlanta, Georgia, and he was not available. In the back of my mind the bell rang about Larry Mc Donald. He is not from our district, but I remember Laetrile and Larry Mc Donald.

SENATOR SCARDINO: Can I interrupt and see if we can just stay with the specifics.

SENATOR MENZA: You said you got an affidavit based on Judge Bohanon's decision. And then you went to an attorney and he drew one up and then you signed it.

MRS. ALPERIN: No, there is a very special form.

MR. ALPERIN: We got one form from the FDA, because the judge's order said that they had to disseminate this form, and we got one form from the FDA, we got one form from Mr. Leone---

MRS. ALPERIN: There was a pharmacy in Maryland that distributes Laetrile.

SENATOR MENZA: Let's have the staff, Mr. Chairman, get a hold of that form for us.

MR. ALPERIN: I have a copy of it, if you would like to have it.

SENATOR MENZA: Great. I would also like you to brief this decision.

MRS. ALPERIN: I really need help from somebody here. That is what I am here for.

SENATOR MENZA: So you then called down to Mexico and made an appointment with a doctor, and the doctor--- What kind of doctor? Tell me about that.

MR. ALPERIN: He is an M. D. It was Dr. Raoul Morales at the Citadel Clinic in Tijuana.

SENATOR MENZA: Is Laetrile--- So you went to Mexico, I take it?

MR ALPERIN: Yes.

SENATOR MENZA: Then you went through customs?

MR. ALPERIN: They said, do you have anything to declare, did you buy anything in Mexico. I said, "Yes, I bought Laetrile." And they said, "Where are your bills." And I showed him the bill I got. And he said, "Didn't you get any pills?" I said, "No, I just got the liquid." I pulled out the form with the cost of it on, and he charged me 5% duty. And I paid the duty. I have the paid bills and the receipt from the duty and everything. So it came in legally.

SENATOR MENZA: How did you get the name of the doctor down in Mexico.

MRS. ALPERIN: It may have been from California. I made so many calls. There were just a few places that --- I believe the Cyto Pharmacy in Mexico, and this clinic is right next door, and this doctor is supposedly very renowned.

There is a pharmacy that distributes this in Maryland. It is the Bob Henderson Pharmacy.

SENATOR HAGEDORN: Why did you go to Mexico?

MRS. ALPERIN: Because there was none to be had in the United States, because the FDA had impounded a shipment at the border, supposedly illegally, because they had papers.

MR. ALPERIN: They had all the affidavits. They were importing it for patients. And there was a tremendous shipment that was impounded.

SENATOR MENZA: In Maryland there is a drugstore, or a pharmacist?

MRS. ALPERIN: Henderson Pharmacy legally distributes Laetrile.

SENATOR MENZA: Legally?

MRS. ALPERIN: Well, that is a matter of question. They have affidavits. They get it with doctor's affidavits.

SENATOR MENZA: We are now hearing that there is a pharmacy in Maryland that distributes Laetrile. Why didn't you go there?

MR. ALPERIN: His shipment was impounded.

MRS. ALPERIN: My mother is terminally ill. I have a pressing problem. It isn't that I can wait until the legislation passed.

SENATOR SCARDINO: You have made that clear, Mrs. Alperin. At what hospital is your mother.

MR. ALPERIN: Monmouth Medical Center in Long Branch.

SENATOR SCARDINO: And her name?

MR. ALPERIN: Sydell Woronoff.

MRS. ALPERIN: I am also very concerned with Dr. Gable being subjected to any harrassment, or whatever they can do to him. I consider him a hero.

SENATOR SCARDINO: I am sure that Dr. Gable has some due process that he can go through.

MR. ALPERIN: We called the hospital and pleaded with them. We said we had these legal papers from Judge Bohanon. It is a class action suit on behalf of all terminally ill cancer patients, and he has said it is legal; it is okay. Their counsel tells them that it is an illegal drug, and therefore they are not going to administer it, and they have recourse to the courts. We consulted a lawyer, and the lawyer said, "Yes, for $1,000 I will be glad to try to get you an injunction." I don't know how long it will take, but this was yesterday. We are not millionaires. We can't afford this kind of stuff.

MRS. ALPERIN: And besides there is not the time with mother. She becomes freer and freer of pain, and for whatever reason--- I don't know the reason.

SENATOR SCARDINO: Is she now off of the Laetrile?

MR. ALPERIN: Yes, she has been off since last Friday.

SENATOR SCARDINO: Have you seen any reversal?

MRS. ALPERIN: Well, what worried me a little bit yesterday afternoon was that she had just a few little pains. But if she were to be capable, I would take her out of the hospital, which would solve a lot of problems. But I can't because she is wired up.

SENATOR SCARDINO: Maybe some of the people here may know the answer to the question we are wrestling with. The question is whether or not the hospital administration has the right through policy to deny the use of Laetrile on its premises. What we have heard all day in testimony is an attending physician's right to sign the affidavit which will allow the patient to go wherever he or she has to go to obtain the substance. In this case here we are dealing with a different situation in that we are talking about the administration aspect of operation, and whether or not it is within their rights - the hospital's rights - to deny the use of the substance and to deny anyone who is employed or practicing on the premises to use the substance.

We are in a quandary about just how we can approach that situation. Do we have a response to that?

MR. LEE: I spoke to the emergency administrator of the hospital on behalf of Mrs. Alperin, and he asserted the right. He stated that they could assert

the right, and would deny the use of Laetrile regardless of the affidavit which Judge Bohanon has so signed.

DR. WYNN: I am Dr. Wynn, and I am on the staff at the St. Barnabas and Overbrook, at least at both those institutions there is a pharmacy committee who judges whether a drug may be used in the hospital. A physician can apply to that Committee, and wanting to use the drug for research, would have to go to the research committee. In two states now, Florida and Indiana, there are specific provisions within the law which give the hospital the right to use Laetrile without any sanctions.

SENATOR MENZA: Are you now stuck with the court's decision in April of '77, the class action?

DR. WYNN: I was going to discuss that with my attorney. There is a lot of trouble with that class action.

SENATOR SCARDINO: You have to stick with the question specifically, because it is very important. We are trying to--- Let's take the assumption that this individual is taking the substance before they went into the hospital, and felt it was doing them some good. Can that be carried over into the hospital, and can the person continue taking it, or would it be against the rule of the hospital if they decided that it was not allowed. Obviously, it would be against the rule of the hospital.

DR. RUBIN: I am Dr. Rubin from the College of Medicine and Dentistry. Most hospitals have a set of by-laws which established the Medical Board, which is a Committee of physicians elected by the medical staff and sanctioned by the administration Board of Trustees. It is the Medical Board that makes policies and rules for medical treatment of all patients. They can refuse to use aspirin if they choose to do so for their own reasons. And they can make it against the rules to use it in the hospital, and any doctor who enrolls on the staff of the hospital must agree to abide by the rules of the Medical Board, or else he is not allowed to practice in the hospital. This has nothing to do with any legal matter whatsoever---

SENATOR SCARDINO: Even in light of a District Court ruling with respect to the one we are dealing with here today?

DR. RUBIN: The District Court ruling only says that it is not illegal and you can't be prosecuted. If the Medical Board says we don't want this form of treatment, we don't think that appendectomies should be done this way, they should be done that way. If that is what they decide, then that's what the rules of the hospital are.

SENATOR SCARDINO: What relief does the physician have?

DR. RUBEN: Well, he can appeal to the medical board. He can appeal to the medical society, but ultimately the medical board in the hospital makes the rules.

SENATOR SCARDINO: Can those rules be overturned by any other agency outside the hospital administration?

DR. RUBEN: Well, I imagine that you as lawyers would know better than I do if any unfair administrative decision is effective in this State.

SENATOR MENZA: We will ask Dr. Albano just what the policy is. The question is, we have a District Court ruling. I don't know if it is present or not in the State of New Jersey, but let's assume for the sake of argument

that it is. The Laetrile people are in a quandary because it is not illegal to dispense it, but if you dispense it, you are going to lose your privileges at the hospital. For all intents and purposes it really cannot be used, and you are thereby subordinated to the courts.

DR. RUBEN: I think that would have to be left to the courts and the legislators to say whether this is an unfair and capricious administrative decision. This is what I would do if a hospital medical board passed a rule against me.

SENATOR MENZA: The situation I think as it exists now - and we will double-check with Dr. Albano as to what he would do with a physician - is that you can't be prosecuted, because it is not a crime. Assume for the sake of argument that it is now the law of the land, and the hospitals say you can't be prosecuted but we can dismiss your privileges. Dr. Albano may even go further to say they can take your license away, although it is not a crime, because ethically you messed up.

Now, what you do is inviting a lawsuit. Say that Albano has taken away the license, and you guys kick him off the staff as arbitrary and capricious, and they win, if this case holds.

DR. RUBEN: Yes, but you would have to say this is the same thing as abortion to the Catholic hospital who will not perform abortions.

SENATOR MENZA: They lost, didn't they?

DR. RUBEN: There are Catholic hospitals that refuse to perform abortions.

SENATOR SCARDINO: All right, I really appreciate your offering testimony at this time. Mr. and Mrs. Alperin, we are going to pose this question to Dr. Albano. Mr. Bruinooge of our staff just went out to give him the highlights, and emphasize what we have discussed here today, and we will see what our Medical Director has to say in response.

But I think you understand, from the dialogue, the problem as it exists probably a litte differently than when you sat down. I do appreciate, under the circumstances that you are living under right now, your coming today and spending some time and sharing your experience with us.

MR. ALPERIN: I came up from Georgia this morning specifically to be here.

SENATOR SCARDINO: Well, thank you very much.

MR. ALPERIN: Thank you for your attention.

SENATOR SCARDINO: Dr. Koven.

B E R N A R D K O V E N: I am Dr. Koven. I am appearing as President of the Oncology Society of New Jersey. Your hearing group may already have our position read into the record, but I have it here, and I will read it again as the official statement, because it is short.

"Based on considerations made by our membership at its special meeting, the following resolution was adopted by unanimous vote. It reads, the Oncology Society of New Jersey is a professional organization representing recognized cancer specialists in New Jersey. We are not committed to any one approach to cancer treatment. Our only purpose is to try to provide the best available treatment for all cancer patients, whatever they may be. We deplore the current efforts to make Laetrile available to cancer patients in our state. Laetrile is a chemical substance of no proven value for the treatment or prevention of cancer or any other human disease. We believe that the administration of Laetrile or other worthless substances to sick patients may be harmful when it results in dealy. or avoidance of potentially effective methods of treatment. We feel it is essential that the

public understand that Laetrile is of no proven value and its use in place of standard treatment may be dangerous."

Perhaps as a background to this I might take a few moments to tell you of my own interest in working in the cancer field. I was trained in cancer chemotherapy at the Memorial Sloan-Kettering Cancer Center twenty years ago, and have been practicing cancer medicine since that time. I have been a member of the attending staff since that time. In addition, in this county, Bergen County, I have been Chairman of the Cancer Committee of the Medical Society since the early 1960's. We badly need additional treatments to improve our results with cancer. Surgery has been developed to a fine art. Radiation therapy has improved and continues to improve. Our chemotherapy consists now of twenty-six available drugs, and in answer to a question raised earlier, indeed, there are new drugs. I have some in my office, which, as a recognized investigator, I am allowed to use through the Food and Drug Administration. These are drugs which may be generally available next month or possibly next year.

I have tried to keep an open mind on all the agents that are proposed as cancer remedies. I went through the trouble of going to Tijuana, Mexico, and interviewing Dr. Ernesto Contreras at the Clinic Del Mar to see about his work with Laetrile. I was impressed that he was a gentleman who sincerely believes he is helping his cancer patients. He told me, and this is not generally known, that in addition to Laetrile he gives standard chemotherapy consisting of the drug fluorouracil- mentioned previously - and another drug called cytoxan. He told me also that he does not use those drugs, which, if they infiltrate into the tissue can cause irritation and necrosis of tissue, because that might unduly delay the time, particularly, out of country visitors spend in Tijuana.

Unfortunately, many patients who came back may have temporary benefits from the known effects of drugs such as the floriyoracil or cytoxan, but continue only on the Laetrile. In general, they are unaware that they have had other medications, and they believe any improvement, when seen, is due to the Laetrile. When their supply of Laetrile runs out, they have to come back and be recycled, so to speak, or they have to have Laetrile smuggled in. This is not a new problem. The drug has been around in California, Canada, and in many other countries for more than twenty years. And in those drugs which have found a value, it has not taken too long. A case in point is a drug like adriamycin that developed in Italy several years ago, and in the past decade it is now extensively used in this country. However, our problem with Laetrile is that we have paperback books such as this, called "Laetrile, The Anti-Cancer Drug Control For Cancer." In this book, among other cases cited, is a young person with advanced Hodgkin's Disease who received Laetrile and allegedly was cured.

The siren song of the easy cure, the easy treatment, is unfortunately leading people with early cancer to depend on promotions such as Laetrile to cause a cure, hoping that they will avoid the necessity of painful and sometimes risky diagnostic procedures and uncomfortable therapeutic procedures. A young person today with Hodgkin's Disease may have tests which are difficult to pronounce, but they involve accurate staging of the disease, x-ray studies up to and including an exploratory operation with removal of the spleen and open biopsy of the liver. Obviously no one would like to have this if he thought treatment with a simple remedy such as Laetrile would make it all unnecessary.

Earlier Dr. Koeck spoke of results of early treatment. Women coming to diagnostic centers for early detection of breast cancer who have a lump diagnosed at a screening center have an 85% chance of cure with proper treatment. If, on the other hand, such a young women hopes not to lose her breast or a substantial part of it, but may take a remedy instead such as Laetrile, an early cancer becomes late cancer, and there is much less that we can do. The pure aid for late cancer, once the lesion is greater than about an inch in diameter when glands under the arm are involved, and certainly when there is distance spread, becomes very, very low, indeed.

I think the main hazard in allowing Laetrile to be accepted as cancer preventative, cancer cure, is that people who have curable cancer will go over that gray area into incurable cancer, and having lost that one chance, there will be no retrieving them.

In the interest of brevity, I think I will terminate my remarks, but I will be happy to answer any questions that the Committee may have.

SENATOR SCARDINO: Are there any questions of the Committee?

SENATOR MENZA: Doctor, one fast question, you don't know the cause of cancer, so how do you know the Laetrile wasn't the cure.

DR. KOVEN: If we don't know the cause of cancer, we do not know the cause of most cancer. We know most causes of lung cancer - heavy cigarette smoking. We don't know the cause of breast cancer, but it can be cured when it is early in 85% of the cases.

If you wanted me to say that because I don't know the cause of it, why shouldn't I use Laetrile, this is a sort of Russian roulette I will not accept for any patient of mine.

SENATOR MENZA: Yes, but I am not trying to put you on the spot. Is that a decent reasoning process? If you don't know the cause of most cancer, how then do you know that the Laetrile does not cure it?

DR. KOVEN: I am sorry, I fail to see the logic the way the question is posed. We know it has been tested in animals, and the data have been reviewed exhaustively. If a test is done by the National Cancer Institute or the Memorial Sloan-Kettering, where I am affiliated, I would see that a group of known effective agents could be used, plus a plecebo, plus another agent, plus Laetrile. I have an open mind. I would be delighted to see an agent which is generally well tolerated by patients to have a beneficial effect.

I mention that I went down to Tijuana, Mexico, to see for myself if it had merit. I came away unconvinced.

SENATOR MENZA: Do you have reports from your facility? Do you have clinical reports from your facility which can be furnished to the Committee?

DR. KOVEN: From the Memorial Sloan-Kettering, yes, it will appear in the annals of surgical oncology; the members of the staff have already had reprints. This involves the latest report on animals in which Dr. Segura, whose name has been mentioned, is one of the senior authors where all attempts to repeat his initial works which were quoted were unsuccessful. This will be shortly in print, as soon as the medical publication appears.

SENATOR MENZA: Since we are considering the bill now, there may be some urgency in our decision one way or the other, is it possible for you to

furnish us with a copy of that as soon as possible?

DR. KOVEN: I will attempt to get you a draft of that, yes.

SENATOR SCARDINO: Dr. Koven, in respect to the substance itself and its testing, has it been proven, from your standpoint, to be harmful to the animals that it is administered to?

DR. KOVEN: In the cases of toxicity with the cyanide containing agent, apricot pits and so on have been quite well documented. The case of the infant, as we mentioned, a man who in California---

SENATOR SCARDINO: I am talking specifically in terms of the tests that you allude to, only. Has it been determined professionally from your judgement and your standpoint to be harmful? Is the substance itself harmful?

DR. KOVEN: The tests that we spoke of at Sloan-Kettering are in mice with tumors.

SENATOR SCARDINO: Let me ask you the question another way. I think it was either Assemblyman Gregorio or Mr. Beninato, but someone talked about using "X" number of grams, 2000 milligrams a day. If I was to take 2000 milligrams a day, in your judgement, of Laetrile, starting today, would it have an ill effect upon me?

DR. KOVEN: It would make a difference if you took it by vein or by mouth.

SENATOR SCARDINO: I am taking it in tablet form.

DR. KOVEN: In tablet form, ten capsules of aprikernel can cause cyanide poisoning in an adult. Taking Laetrile by vein, it is not effective any way. It passes out in the urine unchanged, so you probably would be safe if you had Laetrile injected into your veins. If you were to open the ampul or take the equivalent tablets, you would be careful how much you drink or swollow, because then you might have cyanide toxicity. It has to be processed. Krebs, Sr. mentioned this. It breaks down the agent and cyanide is released in the body.

SENATOR MENZA: So there is no cyanide toxicity in taking it through the veins; is that correct?

DR. KOVEN: From what I have heard, the preparation made in Mexico, given by vein, is not toxic, to my knowledge. The cyanide is not released in the body, despite the theoretical approach of enzymes present in cancer cells.

SENATOR SCARDINO: In your professional judgement, then, Mr. Beninato is doing harm to himself if he is taking 2000 miligrams in tablet form?

DR. KOVEN: Was he taking it in tablet form?

SENATOR SCARDINO: I don't know whether he said tablet or not.

DR. KOVEN: Well, then, in the old days people built up small levels and developed some immunities, so that their food wouldn't be poisonous. I personally would not like to ingest cyanide.

SENATOR MENZA: If we amended the bill, then, Doctor, to say that it could only be done by injection, your opposition would be based on the fact that it is worthless. Is that what your objection would be?

DR. KOVEN: No, I think my main objection is that valuable time might be lost with the siren song of the easy cure for early cancer, and these patients then may be irretrievable for cure when that cancer has been advanced to the inoperable level.

SENATOR SCARDINO: Thank you very much. We are going to pause for a few moments to allow our stenographer to rest her hands.

(Whereupon a short recess was taken.)

AFTER RECESS:

SENATOR SCARDINO: Ladies and gentlemen, if I may have your attention, please. I want to explain why we extended the break. We had promised Mr. and Mrs. Alperin in their testimony that we would try to research more closely the question surrounding the action of the Monmouth Medical Center as described by Mr. and Mrs. Alperin, and whether or not they had any recourse in this matter. It is not the intention of this Committee to intervene in the hospital's administrative policy or decision. I want to make that fact very clear, and a matter of record.

However, it is also clear that Mr. and Mrs. Alperin have a serious situation on their hands, one that is being met with great anxiety on their part, and from that standpoint, we attempted to find out whether or not there is some course they can take. I want to caution you that what we are going to offer to you now is merely an opinion, and you can take it for what it is worth and proceed accordingly.

It is as follows: Under Judge Bohanon's decision an affidavit signed by a physician certifying that a patient is terminally ill is all that is required to get a supply of Laetrile. We knew that already. And this is, by the way, from a discussion of one of our staff members, Mike Bruinooge, with the Attorney General's Office. However, in a case where the validity of the affidavit is opposed by a professional organization, as appears to be the case at the Monmouth Medical Center, and affidavit certified in court will take precedence over professional action. This is the opinion given the Committee today by the Office of the Attorney General.

In our opinion, that is, the Committee's opinion, therefore, Mr. and Mrs. Alperin, your recourse is through the courts, if you so desire to take that, and you could do that immediately if you want to. Again, I express to you the fact that this was gotten moments ago and it is an opinion, and no more, and it is up to the courts to decide.

MRS. ALPERIN: Now, when you say court, which court? Is this federal or what?

SENATOR SCARDINO: You will have to check with an attorney on that. I think we as a Committee had hoped that at the end of today's hearings we could somehow define for the citizens of the State of New Jersey exactly where they stood legally on the subject concerning this question of Laetrile,- obtaining the substance, how they can go about obtaining it legally, et cetera. That, of course, will not be possible in our judgement at this very moment. That is, today. However, the staff and the Commitee will take all of the testimony that was given to us, and that which will be given to us, up to the conclusion of this hearing, over the next few days and analyze it and scrutinize it, and come up with an opinion on the part of the Committee and an explanation to the citizens of the State of New Jersey as to just exactly what their position is, and what their recourse might be in respect to this Laetrile question. That is obviously what is paramount in the minds of many people, as to whether or not they can legally obtain the substance at this time, and we hope that we will be able to clear the air in the next couple of days.

MRS. ALPERIN: Thank you for your time.

SENATOR SCARDINO: Is there anything that the Committee wants to add to my comments? Thank you for your patience. We will proceed and continue with the hearing. We will now hear from Mr. Daniel Herbert.

D A N I E L H E R B E R T: My name is Dan Herbert, and with me is my daughter Christine. She was diagnosed at Sloan-Kettering in January of 1974 as having leukemia, and she was put on a program at that time of chemotherapy. She got in a remission approximately about one month later, and they continued on with the chemotherapy with rather strong doses. The pharmacy down at the hospital questioned the dosages several times when I went down to pick up the prescriptions when she was an outpatient. We picked up certain drugs at the hospital and we were allowed to take them home and give them to her.

A local doctor then administered the chemotherapy after she began to be treated as an outpatient. He was formerly from Sloan-Kettering. However, after several months of watching the effects of these very toxic drugs - and I have a list of them here with me along with the side effects - we became very concerned. She became very ill. She was losing her equilibrium. She lost her hair completely at one point, and she was very sick at the stomach and spent most of her time in bed. She tripped over her own feet when she did try to move around. We were told at Sloan that their recommendation was to continue this program for three years. When we realized that the dosage was going to remain the same for that period of time, we b came very concerned and started to look elsewhere to see what other treatments were available, in order to see what we could do.

We did read about Laetrile. And after getting some idea about it, we took a trip to California. We consulted two physicians in California. We also went into Mexico and consulted with two physicians there. One was Dr. Contreras. We found that they all pretty much agreed with what the recommendation should be in regard to the treatment with Laetrile.

At this point I would like to point out that Laetrile, in my opinion, is not the whole answer. In addition to the Laetrile, there is a very strict program including vitamins and minerals and enzymes. There is also a rather strict diet. A patient has to want to be cured and has to have willpower. When they have this--- You can see my daughter. I brought her along. They say a picture is worth a thousand words. I think this is proof enough of what can happen if you treat the body right. Of course, before they prescribe this, they find out what is lacking in the body, as far as body chemistry is concerned.

I might add that the second doctor in Mexico, before he made any recommendation, asked us to check into a hospital outside San Diego and a doctor on the staff made a complete examination and consulted with the doctor from Mexico before he made any recommendations. But, anyhow, after nine months of the chemotherapy treatment, we had gathered enough information and decided to try the Laetrile. We were very conservative at the beginning and decided to try it along with the chemotherapy. Immediately we saw results. She looked better; she felt better. Her weekly blood count, which she has had taken every week from the day she became sick and still does, improved steadily.

So, after three months of this we decided it was having its effect and doing a good job. At that point we decided to stop the chemotherapy and go on the complete Laetrile program and that was two and a half years ago. She has been on it ever since. We still go

back to Sloan-Kettering on approximately a quarterly basis. She was there, the last time, a week ago Friday, and she had a bone marrow test, blood test, and she was diagnosed to be in good health. Everything we have done we have made them aware of. I have even encouraged them to correspond with our doctor in California, Dr. Richardson. We finally chose him because there was not a language barrier, and he was able to see to it that we got the supplies we needed.

That is pretty much our story. I am trying to go as quickly as I can. I know it is hot. If you would like to ask me or Chris a question, feel free to do so.

SENATOR SCARDINO: Thank you very much. I welcome both of you here today. Thank you for coming. I have a question that I would like to ask, but before I do, I think Senator Menza would like to ask a question.

SENATOR MENZA: How often do you go back to the clinic?

MR. HERBERT: Sloan?

SENATOR MENZA: Yes.

MR. HERBERT: Originally we were going once a month, and then we spaced it to two months, and then three months. I mentioned this before, our last visit was a week ago Friday, and the prior visit, I have the bill here, was February 11th.

SENATOR MENZA: What do they do for her?

MR. HERBERT: No treatment whatsoever. It is strictly to monitor her condition, and the whole idea originally was to watch her closely, and if we felt that she was going in reverse, we would shift gears in a hurry. She continued to improve.

SENATOR MENZA: What did they say the last time you were there?

MR. HERBERT: Excellent health.

SENATOR MENZA: Has the young lady been cured?

MR. HERBERT:On the visit in February, Dr. Rosen her doctor over there got me aside and said, "It looks like we have the thing cured."

SENATOR MENZA: Where do you get the Laetrile?

MR. HERBERT: Originally, the first shipment we had sent from Mexico. That was stopped. We now have a source in California, and I would rather not discuss it any further.

SENATOR MENZA: It comes in the mail.

MR. HERBERT: I would prefer not to discuss it.

SENATOR MENZA: Is it taken orally?

MR. HERBERT: Both. She takes it, 1000 milligrams a day six days a week by mouth, and she takes an injection once a week.

SENATOR MENZA: What are the attitudes of the physicians at Sloan?

MR. HERBERT: Their attitude was that heavy doses of chemotherapy cured her, and I am not saying it didn't. However, they wanted to keep her on chemotherapy for three years, and sometimes, I think the treatment may be worse than the disease.

SENATOR MENZA: They say the chemotherapy was the cure, not the Laetrile.

MR. HERBERT: That is correct.

SENATOR MENZA: When did the chemotherapy end?

MR. HERBERT: It ended in February of 1975, exactly one year after we started it.

SENATOR MENZA: And at the time that it ended, did you end it voluntarily, or was it suggested by them?

MR. HERBERT: Oh, no, they objected strongly. In fact, when her doctor was objecting so strongly, I had asked him to let us see and talk to a few patients that had used chemotherapy for three years, and his comment was, "That is highly irregular. And it will not be proper to do that."

SENATOR MENZA: Did they mention a cure in, say, the spring of '75?

MR. HERBERT: No, no. His theory was,or argument was,that the longer we stayed on the chemotherapy, the better the chance was for total recovery. However, we were looking for the long pull and wanted to keep her healthy and active, and to us the toxic effect of the drugs was taking its toll, and I couldn't see her surviving through it all and becoming healthy. Her white count was kept very low,to the critical point, so we were fearful of her coming into contact with any disease. That could mean the end.

SENATOR MENZA: When was the last time your daughter had echemotherapy?

MR. HERBERT: February of 1975.

SENATOR MENZA: So it has been over two years, and she had reactions from chemotherapy which ended how long after the chemotherapy ceased?

MR. HERBERT: Depending on which drug they gave her - some were worse than others - it is a series of drugs.

SENATOR MENZA: She hasn't had those symptoms since then?

MR. HERBERT: Absolutely not. In fact, when we went to California for the initial treatment, she took the first treatment in the morning, and this was after she had been taking Laetrile for three months by mouth, and we then decided to go with the full program of Dr. Richardson which is injections everyday for twenty days.

SENATOR MENZA: Let me just say this: They are of the opinion that chemotherapy was the thing that worked.

MR. HERBERT: That is correct.

SENATOR MENZA: You, based upon your early observations of your daughter, are convinced that it was Laetrile that did it.

MR. HERBERT: I am convinced that she wouldn't be sitting here in her condition today if we completely followed what they suggested. I am not saying that the chemotherapy might not help, but I am saying they abuse and use it too long. Their treatment is awful potent.

SENATOR MENZA: In your opinion, was it the Laetrile that helped?

MR. HERBERT: I certainly do feel it would help,and if I have to, I will move out of the State to get it. That is how I feel about it.

SENATOR SCARDINO: It was by your own decision to cease chemotherapy?

MR. HERBERT: That was the hardest decision I had to make in my life, yes.

SENATOR SCARDINO: But it was the opinion of the doctor that you continue it, correct?

MR. HERBERT: At Sloan they said we should continue with the chemotherapy, but I will say this, after we made our decision they were very cooperative, and we wanted it that way. We wanted them to know and learn everything---

SENATOR SCARDINO: Have they offered you any theory or opinion as to just what happened since your daughter ceased chemotherapy? Do they explain it at all?

MR. HERBERT: Well, initially he had said - and this was perhaps a year ago - that it looked like the strong doses of chemotherapy did its job. In effect he was saying that the chemotherapy did it, and I can't say whether it did or didn't; I don't know. But I do know that we have weekly blood tests taken at a local laboratory, and we can go back to the week that she started, and it will show that her condition improved. The blood count improved as well. When we stopped the chemotherapy and went on with the full regimen of Laetrile, it really improved, and she is now active. She plays competitive sports. She plays tennis in high school. She was out of school almost a year, but she has gone back and she is a straight "A" student and participates in all sorts of sports and leads a normal active life.

SENATOR SCARDINO: Christine, is there anything that you would like to say?

C H R I S T I N E H E R B E R T: No, my father has said it all.

SENATOR SCARDINO: Senator Hagedorn.

SENATOR HAGEDORN: I just want to emphasize, if I hear the testimony correctly, that is, there was a marked improvement at the time you decided to discontinue the chemotherapy treatment and started with Laetrile.

MR. HERBERT: That is correct. That could be two-fold. The Laetrile certainly, I think,helped but the fact that the discontinuance of the toxic drugs, which, really in effect are designed to kill the cells in the blood stream, were stopped, that had its effect also. Stopping that had its effect also. It was going on too long.

SENATOR SCARDINO: Thank you. The heart and soul of the Institutions, Health and Welfare Committee is now leaving, Senator Menza. Alex, thank you very much for taking time out to come here today.

I am now going to call as our next speaker Dr. Arnold Rubin.

D R. A R N O L D R U B I N: Senators, if I might begin, I wanted to make sure that this young lady was not in the room for ethical reasons before I started my comments, and they will become obvious in just a minute.

I had prepared a few comments. I am going to go around some of these and start to make a few comments appropos to what was just said. Because I am frankly appalled.

By way of introduction, my name is Dr. Arnold Rubin. I am an M. D. I am Director of Oncology at the College of Medicine and Dentistry of New Jersey, and I have been involved in cancer research, particularly leukemia research, for almost twenty years. I am a former Leukemia Society Scholar. I am a member of the American Society of Clinical Investigation. And I am the holder of several government grants for cancer research as well as leukemia research, and presently in my position at the State Medical School, I am directing a program for cancer education both at the undergraduate and post-graduate level.

The previous case that was just discussed is almost a perfect example of the dangers that we are getting into right now. This young lady was apparently diagnosed as having acute leukemia, and from her age one would assume that she had the acute leukemia of childhood. This is a disease which used to be uniformly fatal. Before chemotherapy, modern chemotherapy, and during the age in which Laetrile was still available,

according to the proponents, this disease was uniformly fatal. With the new discoveries of chemotherapy, and radiation therapy, over the past fifteen years we are able to induce remissions on virtually 100%. In other words, make these people perfectly well, so that nobody, including the most sophisticated physician or hematologist, could detect the presence of disease.

However, up to the past few years when we have been using more sophisticated methods, the disease always came back. Now, using the methods that have been developed at the St. Jude's Hospital in Memphis, Tennessee, we can safely predict that roughly 40% to 50% of all children with this type of leukemia will live normal lives without any further therapy necessary after three years. Now, the three years is a very important number. It may be that one could start treatment after nine months or even after two months, but taken as a whole on a statistical basis, the best chance that the child has of surviving for an indefinite period is to take the chemotherapy for three years. It is known that this chemotherapy is toxic and the method that Sloan-Kettering uses is a little bit more powerful, one might say, than the one that we would use or the one that many other institutions around the country use, and does have more side effects. It is not necessary to have that many side effects. One can adjust the dosage and obtain the same results. However, if one stops the drug short of three years, the statistical chance of this leukemia returning at any time in the future is very great.

We have had a similar or related problem in a youngster whose mother happened to have some sort of odd religious belief. She felt that chemotherapy was harmful to this child, although this child never had any undue side effects other than transient hair loss. The child was put into remission with this disease and given chemotherapy for less than a year and then took the drugs irregularly and then apparently stopped. This was now three years later. We just had to admit the child back to the hospital in a full relapse. This child will die. I am most concerned with this young lady. I don't think this was a wise decision, and based on these facts - and I think we can call them facts because they have been proven by several large studies, including nationwide studies, running into hundreds of patients - that one would expect, on the basis of the chemotherapy that this child has had to see the results that we see now without any addition or an alternative form of medication, but one wonders what is going to happen in a few years.

Now, what I really wanted to emphasize, listening to the conversation this morning, it seems that the thing that troubles this Committee most is the danger in legalizing the taking of this drug. And I think I just outlined the major danger right now. The danger runs larger than that. It runs into sanctioning a drug which has not been proven to be effective or safe, because this drug in humans has never been proven to be safe. I must beg to differ with some of the statements that were made this morning. Just because a drug has not been proven to have toxic side effects does not mean the drug does not have those side effects. And one can call into play many examples of this. One good one was thalidomide, which the FDA managed through their wisdom to keep off the market, and we can say the horrible tragedies that happened to children in other countries did not happen here, except for those people who smuggled it in from the outside.

Another example is the drug phenacetin, which was used for many years as an analgesic as part of the Anacin or APC combination that used to

be used - and maybe many of you might have been in the service when they gave APC's almost like droplets of water. It was many years before we realized that the drug phenacetin, which was a major component of the anacin or APC drug, was causing kidney damage. It was only in retrospect that we realized this, and it was only through investigation of all the possibilities that this came to light. Therefore, one cannot accept that a drug is safe until it is proven safe. And this, I think, is a major responsibility for any agency, whether it be the FDA or a State agency, to prove before it releases this to the public.

We have the crux of an issue here, what is Laetrile. And we have heard all sorts of claims, and I am afraid it has never been defined even in this hearing. If Laetrile is a foodstuff, then there is no need for me being here, and there is no need for many of the professional people to be here, because we are not going to comment on foodstuffs. Frankly, I was brought up in another age, when we didn't feel well, we took chicken soup. And I will defend to my last drop of blood my right to take chicken soup when I don't feel well. But I don't call it a drug and neither does any other physician that I know of.

A drug is a drug whether it is called a substance or not. If it is used as a drug, then it is a drug and it should be tested as a drug and it should be evaluated as a drug. Now, we have a system for doing that. We have a very reliable system. I am sorry Senator Menza is not here, because the answer to this question is, one does not have to know the cause of a disease in order to know whether or not you are curing it or even benefitting it. The logic does not follow. The cure for small pox or the prevention for small pox was discovered long before we even knew what a virus was. But through the work of Jenner and through the work of Pasteur - who, I am afraid never heard the words virus - this disease was prevented through proper innoculation. So, it isn't necessary to know the product. But we do have a method for testing drugs, and a rather rigorous method. And what absolutely appalls me is that we would talk about administering drugs to patients without this rigorous method of evaluation, because of the inherent dangers, both psychological and the dangers to the patient from taking the drug, and the dangers to the population as a whole of sanctioning this drug, because the public doesn't know how to evaluate it, and I am afraid to say, neither would this Committee admittedly know how to evaluate it without proper testing.

The system - and I don't have to go into any great detail - involves a series of phases where the drug is first tested on animals and on tissue culture. If it is a drug that is supposed to destroy cancer cells, it must meet these criteria. In fact, we know what causes the cancer in many animals. It is a virus. So, we can even answer that question. But all of the studies that have been done to date do not justify even human trials of this agent.

It would not even get to the early phase, the study of the pharmacology and toxicity of the drug, were it to be compared with many of the agents that are actually better than Laetrile that have already been thrown out because of their marginal usefulness, and they are being thrown out almost every day. A whole group of them have been thrown out by the National Cancer Institute because of their marginal usefulness, and they are being thrown out almost every day. They are drugs that we have used that have shown effects, beneficial effects, on some patients, but the drugs are of such marginal use that we don't want to go through the expense and trouble of bookkeeping because other agents are better.

Now, when a drug is found to be relatively safe, through rigorous testing, we are able to use it in large numbers of patients, and there are systems set up, through national cooperative groups, of which the Medical School of New Jersey, since I have arrived, has joined one of these groups, and we have access to a national testing program, computerized. So, if we are trying a new drug, we have a system we can go through to have the drug approved by the appropriate committee of this national cooperative group, and they are very liberal about this sort of thing, because any drug that has any chance of being of benefit is used and is brought through the system. If it is approved, we are able to use it, but we keep numerous records, meticulous records. When something is happening, we know it is happening, because we keep these records, and we can present them to you in detail, and break them down to answer almost any question you could think of. I defy the proponents of Laetrile to do this, because they don't keep the records. As a matter of fact, how many hundreds of cases were boiled down to twelve or fourteen, whatever the figure was, all of which were questionable. So the diagnosis has to be verified by more than one person. The staging has to be verified. Our measurements for efficacy are done quantitatively. We use a Cronofski scheme from zero to one hundred percent to describe the performance of the patient. We don't go on subjective improvement. We would not accept the previous case that was reported of this lady who had surgery, and obviously recovering from the surgery feels a lot better, also getting Laetrile. This is not any way to judge how a treatment works. One waits until they are stabilized, and then you try the treatment to see if it improves them any further.

All of these systems have been spelled out in great detail, and I think perhaps the Committee ought to see some of the protocol on how one does evaluate cancer drugs in a proper fashion, and if you were to hold up the Laetrile regime in comparison, it would be almost ludicrous to even consider it.

On cannot even talk about vitamins because this drug does not meet the definition of a vitamin, and that was defined earlier by Dr. Finley, and I don't think she was quoted correctly in a subsequent comment. It is not a vitamin. Vitamin B-12 is the last of the B complex that we have seen.

Furthermore, one might make a few other comments that I hope would enlighten a little bit with respect to the reasoning behind this method of treatment. We have heard that it is a new method of treatment that involves metabolic manipulations. This isn't new. Metabolic manipulations are old. Intermediary metabolism was taught to us in medical school. Many of us have studied it in great detail. As far as we know, in terms of what we consider metabolic diseases, such as hyperthyroidism or diabetes, cancer is not that sort of a disease. We know that much about cancer.

Furthermore, when we approach the cancer patient, we approach him or her in a comprehensive fashion. One has to think not only of the patient's tumor or the size of the tumor, but of everything else involved which includes that patient's psychological well-being, the problems of the family and of the environment and also what the patient eats or doesn't eat. These are all taken into account in the treatment. The most dramatic aspects of it happen to be radiotherapy or chemotherapy or surgery, and this is what one focuses on, but it is not the only.

There have been a number of diseases that were thought to be cancer, and one best example of that is the disease of pernicious anemia. That, for many years, was thought to be leukemia, and was a universally fatal disease, until some bright people at the Harvard Medical School, Boston City Hospital complex, discovered that there was a factor missing from the stomach, and in fact this was due to a deficiency of Vitamin B-12. We now know that we can cure the disease by Vitamin B-12. As far as we know, cancer is not a deficiency disease, and the drugs that work or the agents that work against cancer do not work to replace a deficiency, the same as one cannot say that pneumonia is due to a deficiency in penicillin. It is a drug that is used to treat the disease. So, the argument proposed by the proponents of Laetrile is again too ludicrous to discuss, and I think should be passed over.

With respect to the comments regarding the so-called medical establishment, I think it should be emphasized here that when it comes to cancer, there is no such thing as an establishment, because we are all running very hard. We are all running very hard to cure this disease. If you think that the politicians would do each other in for one vote, just for getting first authorship on a paper, we would do each other in. We have been involved in this for a number of years, and one visit to a cancer research meeting would, I think, satisfy you that there is nobody that is supressing any form of treatment which has even the vaguest chances of being beneficial. We would climb over one another to have a little bit of that research so that we would be given a little bit of the credit for contributing to the cure of cancer research.

Frankly, I have been in depressions a couple of times in the past six or seven years when I thought someone had come up with some really important breakthrough, and it turned out that it wasn't as important as it originally was thought. But I went into a depression because, here I had been working all these years, and someone else found it. Here is my chance. All I have to do is get those apricot pits and go to work, and I am going to win the Nobel Prize. Now, why wouldn't I be doing that? I can do it because I have the license to do it; I have approval because I belong to a national cooperative group, and I have grants to do cancer research from the government; I have every ability to do this, and I recently had the opportunity involving another vitamin - which involved another unfortunate leukemia patient that we knew was not going to do well, and the patient was involved with another vitamin, the name of which escapes me at the present time -which was smuggled from Ireland, and it was being dispensed by some sort of an Eastern European veterinarian illegally in a garage somewhere in Long Island. I contacted this man indirectly and I told him if he would come to me in my laboratory with this drug I would guarantee him in writing that we could arrange a joint research project in which he could be the senior author, to give him full credit, and that if this worked, I would get on top of the Empire State Building and people would listen. Well, he refused. He would not engage in this sort of cooperative study. He preferred to administer this drug in his own fashion in this garage in Long Island.

So, you can see the problems that we have. We would like it thrown out into the open, any comments made impuning the cancer researchers, and I won't say the medical establishment, because I don't think I am part of any establishment. But as an independent cancer researcher, I am absolutely

insulted. And I think that it is even beyond contempt to comment upon this, because there are many of us who have dedicated our lives to this, and we could do a lot better financially and a lot better maybe in ego satisfaction - which may be even more important - doing other things. But we have chosen to do this for one reason or another, and we are stuck with it. I don't like anyone telling me that I am supressing any form of treatment, because I, speaking as an independent researcher for other independent researchers, really resent such an implication.

Finally, I would like to issue sort of a challenge to the State of New Jersey. Although I have lived here for over ten years, I have worked full time here for the past two and a half years, and it is true that we have been accused of being the cancer capital of the country, but I think we ought to take heed of that and begin to think about it, because not only are we the "cancer capital of the country" - whether that is true or not - but we are also the State population-wise that contributes least to cancer research in this country. For the size of this State and the number of urban centers in this State, it is absolutely appalling how little research goes on in cancer in this State. Therefore, I would challenge the Senate and the Assembly of this State to do something about this. We have been trying for the past two years, as some of you may be aware, from our previous efforts. But I think if our time, effort and money could go toward trying to find the real cause of cancer, what the problems are in New Jersey, why there seems to be so much of it and what we might do about it, I think we would all be better off.

SENATOR SCARDINO: Thank you very much, Doctor. At the outset let me ask you, are you for the complete banning of the use of Laetrile?

DR. RUBIN: I am for making it illegal as any drug would be considered illegal until a proper IND form was filled and approved by the FDA. I am not against the use of the drug if it works, but I think it should be treated as any other form of treatment and go through the proper channels.

SENATOR SCARDINO: You have undoubtedly concluded in your own mind, and from your own professional standpoint,that it is a drug. As you know, that is the question we have.

DR. RUBIN: I know. This is really the important issue at this hearing. I don't know what it is. That is the problem. You said used as a drug.

SENATOR SCARDINO: I understand that. I am not trying to box you in, believe me. I am trying to clear the air. But throughout your testimony, and I have listened to you as intently as I possibly could, I heard you continually use the word drug. And you used the term therapy- as a therapeutic aid in the cure of cancer.

DR. RUBIN: Yes, sir.

SENATOR SCARDINO: Yet, it has been noted, even prior to the testimony today, that the proponents tried to avoid the use of the word "cure" or the use of the word "drug" in relationship to Laetrile. My point is this, if I can establish it as solidly as I can, if it is your contention that this is a drug and that there is no room to perceive otherwise, from whatever source it comes from, that it is not a drug, then of course your opinion is fixed, and I understand then from where you are coming. But if there is any room or any opening that it may be something other than a drug and it can be used as a form of a vitamin or as a food substance, then I think we are just about where we started from this morning.

DR. RUBIN: I am afraid that is where we are, Senator. I have no objection to using apricot pits as a food substance, just as any other food substance. But what I think is wrong is to approve it for use as a treatment. Now, if the proponents of this drug do not want it to be used as a treatment, then we are wasting our time here, because we shouldn't be involving sworn affidavits or case histories - just put it on the market. If they claim that it does something, then let the Federal Trade Commission argue with them.

SENATOR SCARDINO: In your practice, Doctor, have you at any time ever used some form of treatment or medication that a colleague of yours would object to or would never use over his or her dead body.

DR. RUBIN: All those have to be in relative terms. I would say the answer to that was a guarded no. I have never used such a drug that would be considered---

SENATOR SCARDINO: Well, let's put it another way. Suppose that he was professionally opposed, diametrically opposed, to the form of treatment or the medication that you prescribed. Could this situation exist, where you could have a patient and the patient comes to you, and you might prescribe "x" but the patient can go to another doctor and he will prescribe "a" and "a" and "x" just have no relativity whatsoever. Is that possible?

DR. RUBIN: That exists, yes.

SENATOR SCARDINO: Okay. Then it would be up to the patient to determine which physician in this case he or she is contented with, or which application is in fact doing him or her the best good; is it not?

DR. RUBIN: That is correct, only inasmuch as one accepts that both forms of treatment have validity in terms of testing and efficacy. The problems are really in establishing what the disease is and how best to manage the disease. It is not a question of whether this drug works or that drug doesn't work. That is not the question.

We might have alternative forms of approaching a solution to a given problem, but both forms would have merit.

SENATOR SCARDINO: The bill, as I read it, alludes to Laetrile as being a drug or sanctioning its use as a cure for cancer. What it does is just releases the attendant physician of any immunity if it is his or her determination or opinion that they want to use this---

DR. RUBIN: I think we are quibbling with words, because a physician who is prescribing a substance for the treatment of a disease - I will call it a drug. I don't know what anyone else wants to call it, but that is what I will call it, and if it is being used as a drug, then it is a drug. If he is prescribing chicken soup, we all know what that is, but it is not construed as a drug. If this is legalized, according to the wording in the bill, as I recall it, the implication is that this has merit as a treatment, while admittedly there are a number of contrivances to try to get around the question of whether it really works or not. Legalizing it gives it some degree of sanctity, and I think that would be wrong.

SENATOR SCARDINO: Dr. Rubin, thank you very much. We are being told by the landlord that we can't stay very much longer, so if those of you who remain can quickly add to the discussion that we have had today, I would appreciate it. Dr. Ralph Winn.

D R. R A L P H W I N N: Thank you, Senator. I am Dr. Winn, and I am here to speak under two hats; one, I am a practicing Oncologist. I treat cancer patients, and I won't go into my background, but it included partially running the Drug Ward at the Sloan-Kettering. I am now practicing in New Jersey. My other hat is as a member of the Public Health Council, and as such have a function to serve in this State to protect the health of the people. As such, I come to urge you to ban Laetrile in this State.

I have had a glimpse into your life today, and now I would like to give you a brief glimpse into mine, what it is like to be a cancer doctor and be faced with this drug. It is a drug. When a patient comes to me, he comes to me because he wants to be helped. He wants, one, to know that I have looked into all available treatments, but even more than that, he wants to know that I have used the knowledge that I have to see whether that treatment is reasonable. I have to bring the knowledge that I have to bear.

Let me give you an analogy. If you went to your physician for high blood pressure, and he said, "I know of a drug that is being touted for high blood pressure. I have testimonials that the people who take this drug feel better, but no where can I find evidence that the blood pressures are lower, they didn't take the blood pressures," what would you think if your physician said, "That is the drug I am going to use for you." That is what I am up against when I see Laetrile.

When I evaluate a drug - and I have been a part of many drug experiments - we use a ruler, that is our instrument. We place it on the tumor, whether it is the liver or the lung --- And, incidentally, I treated Mrs. Leone, Albert Leone's mother. We went through this with Laetrile. He will tell you, every time she came to my office and we tried some new drugs, I measured her liver. The liver didn't get smaller. It didn't work. The drug failed. I have gone through the Laetrile literature. There is none of that objective evidence. A man sat here today and said, "3500 cases of terminal cancer - 1300 cured." Where is it? I can't see it. You can't tell me that the liver shrank 50%, which is what I would consider a good response. How can I in good conscience do this to any patient?

So, the problem, as I see it, is, how can a physician in this State do this to any patient of his? The other aspect, and the one, Senator Scardino, that you have been bringing up time and time again, I think, is the valid one. What harm can you do? I submit to you that you will do great harm if you legalize this substance. I think that you will do harm on several levels. One, just to go into the toxicity - and I won't go through it again, you know about the Buffalo girl. Let me give your staff a couple of other references. In the New England Journal in 1964 there are some case reports of girls in Turkey who took apricot pits and got cyanide poisoning. Here is the substance causing disease.

I don't have the references, but there are references that I can get for you on children dying from bitter almonds - in case you have any friends taking almonds. They are not harmless substances; they contain cyanide. I guess it was Dr. Evans who went through this. There is a disease in Africa called tropical nutritional ataxia. This is a disease to the natives from eating too much cyanide continuously during their lives. Over long periods they become paralyzed. This is not a harmless drug. Secondly, and I think

I will end here and make it short, but I can't tell you how sick I am. Do you know what you saw here? You saw a father with a twelve year old girl at the time who had leukemia, which is a curable disease, and on the basis of vicious, fowl, cruel propaganda he stopped the treatment that was saving her life. Fortunately, she sat here and she was all right, but she could be dead today, and that is the harm that you are going to do if you legalize this substance. Thank you.

SENATOR SCARDINO: I appreciate your coming here. Thank you very much for staying with us as long as you did.

Our last witness is Mr. Gervasi.

P A S Q U A L E G E R V A S I: My name is Pasquale Gervasi, and I am a retired pharmacist. First I wish to thank this Committee for the opportunity to express my opposition to Laetrile. Through extensive copy recently mailed to you, you have been pretty well informed exactly how I feel on this matter. Therefore, rather than attempt to recount one by one deaths and injuries arising from the use of Laetrile, I shall speak instead of the havoc that the irresponsible promotion of this drug is creating upon the practice, and the art of prevention, of the distress that it is sowing against those agencies and establishments whose sole function is to protect us against injurious contaminated foods and faulty dangerous drugs, and if the doubts that are cast upon the integrity of practitioners and medical research scientists who have dedicated their lives to humanity. It is deplorable to witness these devoted individuals cast in the role of the bad guys by the very people they are striving to help.

It was almost 350 years ago when Thomas Adams wrote in his works that prevention is so much better than healing. He was proclaiming so long ago what today is the aim of every participant in the health field and the goal of every specialist in the art of prevention. The bills we are considering today, however, if legalized, would shun it instead. We would be repeating a life of legislative foresight that resulted in the solving enactment of a drinking law five years ago, a law that lowered the age limit from twenty-one to eighteen years of age.

When Assembly Bill 3295 was released, the Committee had conceded that Laetrile had no value in the treatment of cancer, but had sought approval for it anyway on arguments that were based on hearsay and emotionally ridden testimonials, by ignoring a politically important factor, preventive factor, time; it had neglected to give final consideration to the fact that getting treatment at the earliest time possible often spelled the difference between life and death. Emotionalism rather than solid logic was the ruling force here. What else could have prompted the statement that was reportedly made by the Committee Chairman, with the release of the bill? The Committee had released it, he said, because "We maintain it is not a drug, but is a nutrient vitamin."

In the face of two court decisions, plus the fact that Laetrile has never been scientifically validated a vitamin, this opinion is pure, unadulterated hogwash. And 62 out of 67 in the Assembly swallowed it down - along with the Laetrile.

A company had tried to distribute Laetrile in a milkshake mix, as a food. In May, 1975, the United States District Court Judge Malcolm Lucas

barred further distribution of the product after ruling it was an unapproved and misbranded drug.

Less than a year later, right in our very own State of New Jersey, Judge Vincent P. Biunno of the United States District Court enjoined two other companies from marketing amygdalin labeled as "Bitter Food Tablets." Judge Biunno found that calling amygdalin a bitter flavor was a "patently absurd and transparent attempt to avoid the drug provisions of the Federal Food, Drug and Cosmetic Act,"and said,"its sale for any food or drug use constituted a fraud on the public. "

I hastily add here that I don't believe that those who voted for the bill intended to encourage fraud. And I don't believe either that they would actually think that thousands of research scientists could be so financially motivated that they would falsify their findings in order to block the sale of Laetrile and/or impede the finding of a cure. This would be sheer lunacy. One, possibly two, might be morally rotten - but all of them?

As recently as nine days ago, following a study in which "nude" mice were used as the experimental animals, Laetrile was again reported worthless by researchers at the Battelle Memorial Institute in Columbus, Ohio. Another article immediately following this one reported that a Waltham, Massachusettes women who had gotten a court judgement last month to use Laetrile had died in the hospital after more than three weeks treatment with it. But from the rising demands that are now urging tests with human sugjects, it is obvious that these studies and reports, along with many others like them, simply fail to deliver the warnings one normally expects they should. They are being drowned by the intensive, unrelenting propaganda that extolls the wondrous virtues of this worthless substance.

This phenomenon no longer distrubs me; it frightens me. To submit to proposals that would enlist humans to prove that a drug that has previously failed with animals is indeed a failure, is to endanger the lives of innocents who have misplaced their faith in a fraudulent nostrum, innocents who have been swayed with hawking calls of "Freedom of Choice, Freedom of Choice."

Anything that encourages the blind to leave a road that leads to help, in order to follow instead a path that ends at the edge of a cliff is not "Freedom of Choice." It is suicide.

Joining those who are trying to restrain and wipe out a drug that threatens the life and well-being of each and every one of us, I respectfully urge every member of this Committee to vote against the release of these bills. Thank you again for your courtesy.

SENATOR SCARDINO: Thank you very much, Mr. Gervasi, not only for your statement, but for staying with us as you did all day long.

MR. GERVASI: There is a question that I would like to ask. From the fact that the material I forwarded to you pretty well covered exactly what I wanted to say, I personally believe there was enough material in there to ask questions of me. You have been informed of it, but I guess in your own good judgement you saw fit not to ask any questions. I thought the material that I submitted to this Committee would be adequate enough for you to ask me questions today.

SENATOR SCARDINO: As far as I am concerned, and I know the Committee shares this feeling, we have stayed far into the night. We are limited as to

the time we are allowed to stay here today. I appreciate your testimony, and I can assure you that it will be covered adequately, and if there are any questions, we will get back to you directly.

MR. GERVASI: In my letter to Chairman Menza, I told him originally that most of us who are against the use of the Laetrile feel that we are spitting into the wind. I must honestly say that is just what I felt today, I have been spitting into the wind.

SENATOR SCARDINO: Thank you for your testimony, Mr. Gervasi. That concludes the hearing today. I want to thank all of the members of the staff of Legislative Services, Steve Frakt, Irene Salayi, Mike Bruinooge, one of our newer members Thalia Cosmos, and our intern who spent the day with us, Dave Moralis. I also want to thank my aide, Joan Scurbo, for her presence today, and I also want to thank our stenographer Virginia and our recorder Terry who have done an outstanding job today, and I appreciate it. I thank all of you for your endurance and your patience.

* * * *

within 30 days of the entry hereof (F.R. App.Proc. Rule 4(a)).

SO ORDERED.

Glen L. RUTHERFORD, Individually and on behalf of a class composed of terminally ill cancer patients, Plaintiffs,

v.

UNITED STATES of America et al., Defendants.

No. CIV-75-0218-B.

United States District Court, W. D. Oklahoma.

April 8, 1977.

Action was brought against United States for injunctive relief to prohibit government from interfering with importation and use of laetrile. The District Court, Bohanon, J., held that action could be maintained as a class action on behalf of all terminally ill cancer patients who by affidavit are declared by a practicing physician to be terminally ill, and that such persons were entitled to injunctive relief to permit importation and use of laetrile pending Food and Drug Administration compilation of an administrative record to supports its claim that laetrile was a new drug requiring approval.

Injunction issued.

See also, D.C., 424 F.Supp. 105; D.C., 399 F.Supp. 1203; 10 Cir., 542 F.2d 1137.

1. Federal Civil Procedure ⇐161

As function of equity, class action must be invoked and applied only in accordance with basic principles of fairness and reason. Fed.Rules Civ.Proc. rule 23, 28 U.S.C.A.

2. Federal Civil Procedure ⇐161

Class action possesses as its basic objective the efficient resolution of claims of many individuals in a single action, elimination of repetitious litigation and possibly inconsistent adjudications involving requests for similar relief, and establishment of an effective procedure for those whose economic position is such that it is unrealistic to expect them to seek to vindicate their rights in separate law suits. Fed.Rules Civ. Proc. rule 23, 28 U.S.C.A.

3. Federal Civil Procedure ⇐181

Review of facts and circumstances of suit against United States to permit importation and use of laetrile and the requirements of rule showed that it was appropriate to administer suit as a class action on behalf of all terminally ill cancer patients meaning anyone who, in affidavit is declared by practicing physician to be terminally ill, rather than, as requested by plaintiff, a class including all victims of cancer and their spouses who are responsible for cost of treatment. Fed.Rules Civ.Proc. rule 23, 28 U.S.C.A.

4. Federal Civil Procedure ⇐161

Although not specifically mentioned in class action rule, essential prerequisite of class action thereunder is that there must be a class, and whether class exists is a fact question to be resolved in each case. Fed. Rules Civ.Proc. rule 23, 28 U.S.C.A.

5. Federal Civil Procedure ⇐161

Class action rule is to be construed liberally and a class does not have to be readily ascertainable that every potential member can be identified at outset; only general outlines of membership of class must be determinable initially.

6. Federal Civil Procedure ⇐161

Requirement that there be a class will be deemed satisfied if class identification is sufficiently definite so that it is administratively feasible for court to determine whether particular person is a member. Fed.Rules Civ.Proc. rule 23, 28 U.S.C.A.

7. Federal Civil Proce

Question of whet proceed as class action determination of trial plies the correct criteri decision should be con his discretion. Fed.Ru 28 U.S.C.A.

8. Federal Civil Proce

Where ultimate ef al remedy may depend applicability of class a cial discretion should allowing class action. rule 23, 28 U.S.C.A.

9. Federal Civil Proce

It is not fatal to action that some mer prefer not to have vio remedied. Fed.Rules U.S.C.A.

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12. Drugs and Narc

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13. Drugs and Narc

Food and Drug not have unbridled d pleases in determinin a new drug, and its rudiments of fair pl

7. Federal Civil Procedure ⇐162

Question of whether to allow suit to proceed as class action is one primarily for determination of trial judge, and if he applies the correct criteria to facts of case his decision should be considered to be within his discretion. Fed.Rules Civ.Proc. rule 23, 28 U.S.C.A.

8. Federal Civil Procedure ⇐162

Where ultimate effectiveness of federal remedy may depend in large measure on applicability of class action device, all judicial discretion should be directed toward allowing class action. Fed.Rules Civ.Proc. rule 23, 28 U.S.C.A.

9. Federal Civil Procedure ⇐161

It is not fatal to maintenance of class action that some members of class might prefer not to have violations of their rights remedied. Fed.Rules Civ.Proc. rule 23, 28 U.S.C.A.

10. Federal Civil Procedure ⇐181

Merely because many cancer patients may have no interest in use of laetrile did not preclude maintenance of class action on behalf of all terminally ill cancer patients to allow them to import laetrile for their use if they so desired. Fed.Rules Civ.Proc. rule 23, 28 U.S.C.A.

11. Federal Civil Procedure ⇐161

Court always has authority to change class designation should developments so require. Fed.Rules Civ.Proc. rule 23, 28 U.S.C.A.

12. Drugs and Narcotics ⇐9, 10

Food and Drug Administration has power to determine whether particular drug requires a new drug application in order to be sold to public; its decision that a product is a new drug is reviewable. 5 U.S.C.A. § 701 et seq.

13. Drugs and Narcotics ⇐9

Food and Drug Administration does not have unbridled discretion to do what it pleases in determining whether a product is a new drug, and its procedures must satisfy rudiments of fair play.

14. Drugs and Narcotics ⇐10

Where Food and Drug Administration declares a new drug where no new drug application is in effect and no manufacturer is submitting such application, such declaration is reviewable by district court. Federal Food, Drug and Cosmetic Act, § 1 et seq., 21 U.S.C.A. § 301 et seq.; 5 U.S.C.A. § 701 et seq.

15. Drugs and Narcotics ⇐1

Congress has authority to proscribe all drugs it considers dangerous to public.

16. Drugs and Narcotics ⇐3

Food and Drug Administration could not ban use of laetrile under grandfather clause if in fact laetrile had been used prior to the cutoff date in treatment of cancer and without ill effect, it was not necessary that the drug be shown to have been effective in treatment of cancer.

17. Injunction ⇐136(3), 137(2, 4)

Generally, if questions presented in suit for injunctive relief are grave and difficult and injury to moving party will be irreparable if relief is denied while inconvenience and loss to opposing party will be inconsiderable if relief is obtained, preliminary injunction should be granted.

18. Injunction ⇐136(3), 137(2, 4)

Since plaintiff class, all terminally ill cancer patients, was in danger of suffering irreparable injury if relief in form of allowing such patients who wished to import laetrile for use was postponed or denied and the potential loss to the Food and Drug Administration from granting of relief was slight and record disclosed indications that laetrile was exempt from new drug classification under grandfather clause, court would grant temporary injunction to permit class to import and use laetrile while the Food and Drug Administration developed proper administrative record to support its claim that laetrile was a new drug.

Burton J. Johnson and Kenneth R. Coe, of Watts, Looney, Nichols, Johnson & Hayes, Oklahoma City, Okl., for plaintiff class.

S. Paul Ragan, Associate Chief Counsel, Enforcement, Food and Drug Administration, Rockville, Md., and William S. Price, Asst. U. S. Atty., Oklahoma City, Okl., for defendants.

MEMORANDUM OPINION

BOHANON, District Judge.

This cause came before the Court Friday, March 18, 1977, upon plaintiffs' "Application to Clarify Plaintiff Class" in the above-captioned class action. Plaintiffs requested that the Court enter Orders certifying the plaintiff class as including "all victims of cancer and their spouses who are responsible for the cost of treatment," and declaring as members of the plaintiff class all persons certified by a physician as having cancer. Defendants argued that plaintiff does not represent a class within the meaning of Rule 23 of the Federal Rules of Civil Procedure, that certification, in any event, should be limited to terminal cancer patients, that the FDA was within the scope of its authority in banning the importation and interstate transportation of laetrile, and that consequently the FDA should not be enjoined from preventing the use of laetrile.

Three basic issues emerge from the March 18, hearing and the evidence, arguments and submitted briefs.

The Class Action Issue

Plaintiffs seek class certification in terms detailed above. Defendants oppose certification, asserting "that the class plaintiffs purport to represent is 'too ill-defined and ephemeral in makeup' to render its members 'capable of definite identification,'" and arguing that, at most, certification should encompass only terminal cancer patients.

[1] The class action was an invention of equity, mothered by the practical necessity of providing a procedural device so that mere numbers would not disable large groups of individuals, united in interest, from enforcing their equitable rights. *Montgomery Ward & Co. v. Langer*, 168 F.2d 182, 187 (8th Cir. 1948). As a function of equity, it must be invoked and applied only in accordance with basic principles of fairness and reason. Under federal law, precepts of class action theory are delineated in Rule 23 of the Federal Rules of Civil Procedure.

[2] Rule 23 possesses as its basic objectives the efficient resolution of the claims of many individuals in a single action, the elimination of repetitious litigation and possibly inconsistent adjudications involving requests for similar relief, and the establishment of an effective procedure for those whose economic position is such that it is unrealistic to expect them to seek to vindicate their rights in separate lawsuits. *Federal Practice and Procedure* § 1754, Wright and Miller.

[3] Having carefully reviewed the facts and circumstances of this case, the applicable case law, and the requirements of Rule 23, the Court is persuaded it is appropriate to administer this matter as a class action.

In so deciding the Court has necessarily determined that plaintiff class is so numerous as to render joinder impracticable, that there are questions of law and fact common to the members of the class, that the claims of the representative plaintiffs are typical of the claims of the entire class, and that the representative plaintiffs will fairly and adequately protect the interests of the class. Additionally, the Court has concluded that defendants have acted on grounds generally applicable to the class in a way that renders injunctive relief proper. Rule 23, Federal Rules of Civil Procedure.

[4-6] Although not specifically mentioned in Rule 23, an essential prerequisite of an action thereunder is that there must be a "class." *Weisman v. MCA, Inc.*, 45 F.R.D. 258 (D.Del.1968). Whether a class exists is a fact question to be resolved in each case. *Clark v. Thompson*, 206 F.Supp. 539 (D.Miss.1962). Rule 23 is to be construed liberally, and the class does not have to be so readily ascertainable that every potential member can be identified at the outset. *Carpenter v. Davis*, 424 F.2d 257

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(5th Cir. 1970). Only the general outlines of the membership of the class must be determinable initially. *Berman v. Narragansett Racing Assn., Inc.*, 414 F.2d 311 (1st Cir. 1969). The requirement that there be a class will be deemed satisfied if class identification is sufficiently definite so that it is administratively feasible for the Court to determine whether a particular person is a member. *See Federal Practice and Procedure*, § 1760, Wright and Miller and cites therein.

Based on the evidence and arguments introduced since this case's inception, and to expedite administration of the Court's Order of January 4, 1977, plaintiff class is hereby certified as encompassing all "terminally ill cancer patients." The phrase "terminally ill cancer patient" refers to anyone who, in affidavit form as hereafter described, is declared by a practicing physician (M.D.) to be terminally ill.

Such affidavit shall include the following:

1. that there is histologic evidence of a rapidly progressive malignancy in the patient possessive of a high and predictable mortality rate; and
2. (a) that further orthodox treatment would not reasonably be expected to benefit the patient; or
   (b) that laetrile will be administered only in conjunction with established and recognized forms of cancer treatment; or
   (c) that the patient has made a knowing and intelligent election to take laetrile after being fully apprised of the full range of recognized treatments available and of the fact that laetrile is considered by most cancer experts to be of no value in combatting the disease.

Defendants assert that early diagnosis and prompt treatment are critical in the management of cancer and that needless and untimely deaths will occur if laetrile is used in preference to established methods of cancer treatment. Such arguments have little applicability to that fraction of cancer patients whose lives orthodox medical science professes no capacity to preserve. To speak of laetrile as being "unsafe" for these people is bizarre. Additionally, it is connotative of a paternalism incompatible with this nation's philosophy as to the proper relationship between the government and the citizenry.

Rule 23 is designed to avoid a multiplicity of lawsuits while protecting the substantive rights of plaintiffs and defendants. *In Re Four Seasons Securities Laws Litigation*, 63 F.R.D. 422 (W.D.Okl.1974). The salient issues in this case are such that defendants' position is in no way prejudiced by class action treatment; instead, defendants are saved the time and expense of defending a multitude of suits. At the same time, such treatment affords immeasurable benefits to the plaintiff class. Requiring litigation of protracted and expensive individual lawsuits would effectively serve to deny many terminal cancer patients the opportunity to have their claims adjudicated. Their disease has often left them with limited funds, and made time an even more precious commodity. It appears to the Court that ignoring the advantages of class action disposition of this case would evidence an indifference to judicial economy and the general spirit of the class action concept.

[7] The question of whether to allow a suit to proceed as a class action is one primarily for the determination of the trial judge, and if he applies the correct criteria to the facts of the case, the decision should be considered to be within his discretion. *Gold Strike Stamp Company v. Christensen*, 436 F.2d 791 (10th Cir. 1970).

[8] In cases such as this, where the ultimate effectiveness of a federal remedy may depend in large measure on the applicability of the class action device, all judicial discretion should be directed toward allowing the class action. *Esplin v. Hirschi*, 402 F.2d 94 (10th Cir. 1968).

[9, 10] Defendants urge that many cancer patients have no interest in the use of laetrile. The issue before this Court is not the wisdom of using laetrile, but rather the right of cancer patients to do so if they choose. It is not fatal to the maintenance

of a class action that some members of the class might prefer not to have violations of their rights remedied. *Leisner v. New York Telephone Company*, 358 F.Supp. 359, 372 (S.D.N.Y.1973); *Norwalk Core v. Norwalk Redevelopment Agency*, 395 F.2d 920, 927 (2nd Cir. 1968). The rights of patients unimpressed by laetrile's alleged therapeutic qualities are in no way prejudiced by this decision. Such persons must be as free to disregard laetrile as are their fellows to invoke it.

[11] Further consideration of the appropriate bounds of the certified class is possible since the Court always has the authority to change class designations should developments so require. *Guarantee Ins. Agcy. Co. v. Mid-Continental Rlty. Corp.*, 57 F.R.D. 555 (N.D.Ill.1972); *Esplin v. Hirschi*, *supra* at 99.

The Issue of Laetrile as a New Drug

This Court makes no determination on the limited evidence before it as to laetrile's ability to combat the ravages of cancer. Defendants have introduced evidence tending to establish the general opposition of medical authority in this country to the use of laetrile. Contrarily, the Court is aware of instances of patients and physicians in various parts of the country emphasizing personal experiences with laetrile's ability to counter aspects of the disease's manifestations and discomforts. Regardless, such issue is not before the Court, and the Court is cognizant that it possesses "neither the facilities nor the expertise" to independently determine the drug's therapeutic value. *Tutoki v. Celebrezze*, 375 F.2d 105, 107 (7th Cir. 1967).

It is unlawful to introduce any "new drug" into interstate commerce previous to the FDA's approval of a "new drug application" (NDA) establishing such drug as "safe" and "effective" for its intended use. The FDA has banned the importation and interstate shipment of laetrile on grounds that an NDA on its behalf has neither been filed nor approved.

In support of its position that plaintiffs are entitled to no substantive relief, defendants urge, *inter alia*, that the initial determination of the safety and efficacy of a "new drug" is the responsibility of the FDA, that FDA has no duty to approve a "new drug" in the absence of an NDA, and that the administrative procedures applicable to new drugs and outlined in the Federal Food, Drug and Cosmetic Act must be exhausted before a court has jurisdiction. These arguments are only relevant if the premise is accepted that laetrile is, in fact, a "new drug."

[12–14] It is clearly established that FDA has power to determine whether a particular drug requires an approved NDA in order to be sold to the public. *Weinberger v. Hynson, Westcott & Dunning*, 412 U.S. 609, 624, 93 S.Ct. 2469, 37 L.Ed.2d 207 (1973). Its determination that a product is a "new drug" is, of course, reviewable. *Weinberger v. Hynson, supra*, at 627, 93 S.Ct. 2469. FDA does not have unbridled discretion to do what it pleases. Its procedures must satisfy the rudiments of fair play. *Weinberger v. Hynson, supra*. Where FDA declares a "new drug" where no NDA is in effect and no manufacturer is submitting an NDA, such declaration is reviewable by the district court under the Administrative Procedure Act, 5 U.S.C. § 701 et seq.; *Weinberger v. Hynson, supra*.

In an opinion in this same case, *Rutherford v. United States*, 542 F.2d 1137, 1143 (10th Cir. 1976), the Circuit Court held that FDA could not escape the obligation of producing an administrative record to support its determination that laetrile is a new drug, noting that "it is not a new drug merely because they [FDA] say it is." The Court further observed that based on the record in the case it appeared doubtful that FDA had in fact developed such an administrative record, and added that "to support its determination, FDA in the case at bar . . . would have to present *substantial evidence* to support the proposition that laetrile is not generally recognized among qualified experts as 'safe and effective' and that laetrile is not grandfathered by either of the exemptions discussed above." (emphasis supplied)

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As to the "grandfather clauses" the Circuit Court specifically found that if laetrile were either marketed as a cancer drug between 1938 and 1962 and recognized as safe, or if used as a cancer drug between 1906 and 1938 under the same conditions as presently used, it is exempt from being classified as a "new drug" by virtue of definitions contained in the Federal Food, Drug and Cosmetic Act. *Rutherford v. United States* (10th Cir.) *supra* at 1141.

Defendants recognize in their submitted brief that: "With respect to the grandfather clause of the 1962 amendments, the test generally is whether Laetrile was 'marketed before 1962 for exactly the same uses for which it is presently being sold and was generally recognized as safe for those uses.' *Tyler Pharmacal Distributors, Inc. v. United States Department of Health, Education and Welfare*, 408 F.2d 95, 99 (7th Cir. 1969)"

Nonetheless, FDA contends that if laetrile were marketed prior to 1962 it must still be shown to have been "effective" as well as "safe" if employed in the treatment of "a life-threatening disease."[1] *Durovic v. Richardson*, 479 F.2d 212 (7th Cir. 1973). The Supreme Court in *Weinberger v. Hynson, supra*, stated that "the 1962 amendments [of the Food, Drug and Cosmetic Act] for the first time gave FDA power to scrutinize and evaluate drugs for effectiveness as well as safety." 412 U.S. at 630, 93 S.Ct. at 2483. In any event, the case relied upon by FDA is clearly distinguishable from the case at bar. In *Durovic v. Richardson, supra*, the Court held that "(a)ny delay in the institution of effective therapy (e. g., radiation, surgery, effective chemotherapy) caused by the use of an ineffective drug allows the disease to progress beyond control. Delay means almost certain death." Significantly, in the present case plaintiff class is comprised of persons already determined to be terminally ill. Adopting FDA's rationale would mean that an individual suffering from a life-threatening disease for which there exists no known effective treatment would not lawfully be entitled to any treatment at all since no drug could be deemed "generally recognized as effective" in such a situation.

[15, 16] Congress undoubtedly possesses the authority to proscribe drugs it considers dangerous to the public welfare. *Weinberger v. Hynson, supra* at 622, 93 S.Ct. 2469. The record in this case does not necessarily disclose any such Congressional intent as to laetrile. The FDA is not empowered to enforce its convictions concerning laetrile on the basis of its congressional mandate to monitor the introduction of "new drugs" into our society, if in fact laetrile has been used for decades in the treatment of cancer, and without ill effect. As implicitly recognized in *Rutherford v. United States*, (10th Cir. 1976) *supra*, the issue of the efficacy of laetrile is, at most, of secondary importance in this case. The legality of FDA's ban on laetrile is under attack on the theory that FDA arbitrarily and without sufficient basis in fact characterized laetrile as a "new drug;" so far FDA has presented little, if any, evidence to combat that allegation.

The Issue of Injunctive Relief

On August 14, 1975, this Court enjoined defendants from preventing the use of laetrile by the then named plaintiff in this action. Such injunction was subsequently upheld on appeal, the Circuit Court determining that the issues raised by FDA's classification of laetrile as a "new drug" were sufficiently "substantial, difficult and doubtful so as to support the granting of a preliminary injunction," and the case was remanded for further proceedings. *Rutherford v. United States*, (10th Cir. 1976), *supra*, at 1142. Thus the issue of this Court's jurisdiction to enter such an injunction has already been disposed of on appeal.

On January 4, 1977, this Court entered an Order remanding the case to FDA for de-

1. "The FDA argues that a drug offered for use in a life-threatening disease that is not 'effective' is thereby not 'safe' either. Thus even under the pre-1962 law Laetrile would have to satisfy effectiveness criteria. This argument may lose its force in the case of a terminally-ill patient or in the case of a patient suffering from a disease for which there are in fact no 'effective' remedies." *Rutherford v. United States* (10th Cir. 1976) *supra*, note 5 at 1142.

velopment of a proper administrative record, and directing that "until such time as the FDA proffers to the Court an administrative record containing substantial evidence in support of its determination that laetrile is a 'new drug' under the terms of the relevant statute, such determination is held to be without force or effect as to the plaintiff class in this case, and defendant FDA is hereby enjoined and restrained from preventing plaintiffs' importation or interstate transportation of laetrile for purposes of their own consumption under the terms of the Food and Drug Act, including § 505(a) of the Act, 21 U.S.C. § 355(a)."

[17] Generally, if the questions presented in a suit for injunction are grave and difficult, and the injury to the moving party will be irreparable if the relief is denied, while the inconvenience and loss to the opposing party will be inconsiderable if the relief is obtained, the injunction should be granted. *Morton Salt Co. v. City of South Hutchinson*, 159 F.2d 897, 899 (10th Cir. 1947).

[18] Plaintiff class is in danger of suffering irreparable injury if relief is postponed or denied. Any legal right they might possess to use laetrile may be of academic value if secured only at some undetermined future time. For the terminally ill the phrase "justice delayed is justice denied" contains special significance. Defendants' potential loss from the granting of injunctive relief is slight at most. Certainly defendants are charged with an important responsibility in safe-guarding the public from dangerous drugs, and they are to be commended for pursuing the task diligently. Nonetheless, the danger in the use of nontoxic but unproven cancer treatments by the public "is in their delaying or foregoing diagnosis and treatment which is generally recognized by the medical profession as beneficial and effective." *United States v. General Research Laboratories*, 397 F.Supp. 197, 199 (C.D.Calif.1975). "Where a person is terminally ill with cancer and unresponsive to other treatments, the public harm is considerably reduced." *Carnohan v. United States*, Civ. No. 77-0010-GT (S.D.Calif.1977).

In most instances in which relief in the form of a preliminary injunction is sought, the burden is upon the movant to establish by clear proof that he will probably prevail when the merits are tried, and that irreparable injury will be suffered unless injunctive relief is granted. *Penn v. San Juan Hospital, Inc.*, 528 F.2d 1181, 1185 (10th Cir. 1975); *Crowther v. Seaberg*, 415 F.2d 437 (10th Cir. 1969); *Automated Marketing Systems, Inc. v. Martin*, 467 F.2d 1181 (10th Cir. 1972). Even under this more stringent standard, injunctive relief would still lie. The record in this case discloses many indications that laetrile may well be established to have been marketed for the last twenty years or more as a cancer treatment, to have been generally regarded by most experts as "safe," even if not "effective," and thus to be exempt from "new drug" classification by virtue of the previously discussed "grandfather clause" provision. Defendants' brief contains references to the report of the Cancer Commission of the California Medical Association published in 1953, which report on its face establishes the longevity of laetrile's recognized use. While concluding that laetrile was ineffectual as a "cure" for cancer, the report generally regarded it as safe and perhaps even palliative to some degree. Interestingly, the 1976 edition of the FDA Code Regulations (21 C.F.R. 121.101(c)(2)), as well as multiple earlier editions, places amygdalin [2] on the "Generally Recognized as Safe List."

Conclusion

Defendants adamantly urge that the use of laetrile is expensive, ineffectual and unjustifiable. Such contentions are serious and cannot be lightly regarded.

Of some significance, however, is the fact that laetrile's high cost is undoubtedly a

2. "The Court finds from the record that Laetrile, Amygdalin and Vitamin B-17 are all one in the same, and the term Laetrile will be used to represent all three." *Rutherford v. United States*, 424 F.Supp. 105 (W.D.Okla.1977).

direct consequence of its illegality in the United States; ironically, this requires traveling all the way to Mexico to enjoy its use lawfully.

This case raises questions of fundamental political and philosophical consequence. Freedom of choice necessarily includes freedom to make a wrong choice, and there is much force to the argument that matters of the type herein under discussion should be left ultimately to the discretion of the persons whose lives are directly involved.

The point can be couched in simple terms. Many intelligent and mentally competent citizens in this nation have made a deliberate decision that they would like to employ an unproven and largely unrespected treatment in an effort to comfort, if not save, lives that orthodoxy tells them have already been lost. They do so with an acute awareness of professional medicine's assessment of their choice. Their decision should be respected.

An appropriate Order will be entered herein.

ORDER AND DECREE

Based upon the Memorandum Opinion filed herein this day,

IT IS HEREBY ORDERED that plaintiff class in the above-captioned case is certified as encompassing all "terminally ill cancer patients." The phrase "terminally ill cancer patient" refers to anyone who, in affidavit form as hereafter described, is declared by a practicing physician (M.D.) to be terminally ill.

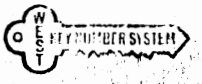
Such affidavit shall include the following:

1. that there is histologic evidence of a rapidly progressive malignancy in the patient possessive of a high and predictable mortality rate; and
2. (a) that further orthodox treatment would not reasonably be expected to benefit the patient; or
   (b) that laetrile will be administered only in conjunction with established and recognized forms of cancer treatment; or
   (c) that the patient has made a knowing and intelligent election to take laetrile after being fully apprised of the full range of recognized treatments available and of the fact that laetrile is considered by most cancer experts to be of no value in combatting the disease.

IT IS ALSO HEREBY ORDERED that the defendants in this action, the United States of America, its agents, agencies and instrumentalities, including, in their official capacities, Joseph A. Califano, Secretary of Health, Education and Welfare, Donald Kennedy, Commissioner of the Food and Drug Administration, and Vernon D. Acree, Commissioner of U.S. Customs Service, and their successors and agents are enjoined from impeding or preventing the importation and interstate transportation of laetrile by any members of the plaintiff class or their duly designated agents.

IT IS FURTHER ORDERED that such laetrile can be imported and utilized solely for the personal use and benefit of the plaintiff class members.

The Clerk shall send, by registered mail, a certified copy of this Order and Decree to each department administrator referred to herein.



Manuel VAZQUEZ, Plaintiff,

v.

WERNER CONTINENTAL, INC., Defendant.

No. 76 C 2927.

United States District Court, N. D. Illinois, E. D.

April 8, 1977.

Former employee filed suit against his former employer alleging discriminatory ac-

JOANNE E. FINLEY, M.D., M.P.H.
TESTIMONY BEFORE SENATE INSTITUTIONS, HEALTH AND WELFARE COMMITTEE

July 19, 1977

I would like to thank you, Mr. Chairman, and this Committee for providing an opportunity for the airing of the three bills relating to the substance known as Laetrile that are under consideration today. Any hasty legislative action without thorough review of all aspects and all issues would be unwise. You are to be commended for inviting members of the professional community and the lay public to share information about Laetrile with this committee.

I come before you today to urge that this committee exercise restraint and that you not take impulsive favorable action on the three pieces of legislation regulating the manufacture and distribution of Laetrile.

It is my firm belief that favorable action on these bills at this time is premature. In my statement I will try to outline for you the very real limitations that exist on the State level for adequate review of a new drug application and some of the movement on the federal level to undertake appropriate research as a preliminary to widespread distribution in the United States of Laetrile.

A-3295, the bill sponsored by Assemblyman John T. Gregorio in Section 3, 1.5 and 6 relieves manufacturers of liability for producing Laetrile but provides that manufactue, introduction and delivery must be conducted pursuant to Chapters 6A and 6B of Title 24 of the New Jersey Statutes.

If we examine that statute we find the State's responsibility over the manufacture and distribution of drugs intended only for intra-State commerce, is confined to the single concern of safety. Is the drug safe to take? Is the drug safe if ingested by unsuspecting children? Is it being manufactured in a clean environment, absent from contaminants? No where in the New Jersey statute does it call for testing for the efficacy of the drug. What is efficacy? Defined by Webster it is the power to produce a result. The result intended here is an improvement in or even cure of cancer.

New Jersey does not now review new drug applications. By statute, we have this responsibility only for drugs sold exclusively in intra-State commerce. On the rare occasions when we are called upon to investigate and determine whether a drug can be introduced in New Jersey for "intra-State" commerce, we have contracted with the federal Food and Drug Administration to provide the necessary protective review.

We do not presently have the staff trained to test substances for human medical or therapeutic use. The budget for the cosmetic and drug unit in the Department is only $251,759. It pays for a staff of 12 involved in the inspection of, the manufacturing, processing and distribution of cosmetics and devices, as well as drugs. Two staff members presently are on loan to the Attorney General's office. In actuality, we are talking about the need for a considerably larger appropriation if we are to take on the additional responsibility of testing new drugs even solely for safety.

Further questions must be raised about testing limited to safety as provided in New Jersey's rather archaic law. If we are to assume testing responsibility for a drug we could not in good conscience exclude testing for efficacy, "The power to produce a result." Human health and peace of mind make this a necessity. Perhaps we could live with a Laetrile law, if N.J.S.A. 26-6A & 6B were amended to include a responsibility for reviewing both safety and efficacy and if the program was funded properly to hire the expertise to do this.

Currently the Senate Subcommittee on Health and Scientific Research chaired by Senator Edward Kennedy is seeking an accommodation with the proponents of Laetrile. Under Senator Kennedy's leadership the committee has evolved a position in which Senator Kennedy will assure proper support for immediate, well organized national research on the effectiveness of Laetrile. He appears to have persuaded Laetrile proponents to wait for this and if Laetrile is not proven effective to withdraw their pressure for legalization. Who better than Senator Kennedy can know first hand how vulnerable people are when searching for a cure to save the life of a loved one--how willing they are to grasp at any straw--or to try any approach.

I submit to you that it makes sense to allow this matter to be researched thoroughly on the federal level where the capacity exists for the appropriate kind of investigation and later for the FDA to regulate if there is proved safety and efficacy. Therefore, in answering one of the questions this committee has itself posed to us, I urge you to wait until the necessary national action, now commited, has taken place.

For New Jersey to carry out the same functions, it would be necessary to increase substantially the present appropriation for a testing unit and to expand the scope of Statutes to include testing for efficacy. For were we not to expand the scope of testing in this way, we would essentially be putting the New Jersey Department of Health's seal of approval on a drug that may have no therapeutic value at all. Or because of limited capability, we might be putting our stamp of approval on a substance that is not safe if one overdoses, or if taken by a young child.

U. S. District Judge Luther Bohanon, U. S. District Court for the Western District of Oklahoma, issued a class action order on April 8, 1977, enjoining FDA and the U. S. Customs from impeding or preventing the importation and subsequent interstate shipment provided a practicing licensed physician submits an affidavit attesting the patient is a terminally ill cancer patient. That order of April 8, 1977, was modified on May 10, 1977, to specify the language of the affidavit and to limit the quantity imported to six months' supply which would be 750-500 mg. tablets and 1500 ml. of injectable liquid. The Federal decree stated by Judge Bohanon makes no reference to the prescribing or manufacturing of Laetrile.

The bill sponsored by Assemblyman Gregorio would extend the federal court order to include the manufacturing, introduction or delivery for intra-State commerce. Thus A-3295 give the Department of Health responsibilities it is not currently exercising, and far exceeds the court order.

Now that some of the concerns of the Department of Health has been articulated and in the process I have answered, I hope, several of your questions I will address myself to some of the other questions raised by your committee:

1) What is or is not permitted with regard to the use of prescription importation or manufacture of Laetrile (Amygdalin Vitamin B-17) in New Jersey, in light of the FDA ban, court decisions, and the existing laws of the State.

The State of New Jersey now abides by FDA regulation because of our own limited capability for testing new drugs as I expressed earlier in my testimony. However, Judge Bohanon's ruling provides some guidelines for the limited distribution and use of Laetrile in New Jersey.

2) Why has the FDA banned Laetrile <u>as a drug</u> when the substance is also referred to as a vitamin and is, in fact, found in many foods? How does Laetrile as a "drug" differ from Laetrile as a vitamin? May not Laetrile be sold, and consumed, as a "food" under existing law and regulations?

Laetrile although often referred to by its proponents as a vitamin does not fit into that definition either. According to Dorland's Medical Dictionary, a vitamin is an organic substance that occurs in food and is necessary for the metabolic functioning of the body, e.g. the absence of vitamin C in the diet causes scurvey. There

is no indication that Laetrile is essential for the metabolic functioning of the body.

Conversely Laetrile because it is promoted as a pallative and often cure for the treatment of cancer in humans is classified as a drug in accordance with New Jersey Statute 24:1-1. Both the Federal and State Administration consider Laetrile a drug and subject to the provision of a new drug application. As such, appropriate scrutiny under a new drug application is required.

3) Do State laws to "legalize" Laetrile make any difference? If so, what difference?

Legalizing Laetrile does make a difference. Through legalization Laetrile is being given the sanction of the state and it is that very sanction that enhances its credibility and could further encourage the use of Laetrile as a substitute for therapeutic techniques for cancer control and even cure that are known to be effective, e.g. cervical cancer discovered at an early stage and treated promptly has a very high rate of cure. Where an alternative such as Laetrile is undertaken initially in the hope that surgery or radiation therapy can be avoided, the tragic loss of time can be a matter of life or death. I would be doing my own sex a disservice if I supported any speculative remedy that could by inadvertence and delay, lead to unnecessary death. It is this essential fact that is nowhere stated to the patient who signs the

waiver, the only requirement for use of Laetrile contained in A-3295. The patient merely acknowledges that he or she is aware of the fact that Amygdalin has not been approved as a treatment or cure by the federal Food and Drug Administration, and the prescription label must bear only this message.

Nor does the bill state that the patient must be terminally ill. Therefore by legalizing Laetrile and providing for its manufacture within the State, we in effect, are providing access to a drug that has no proven efficacy and make possible its use for any patient no matter how early the stage of cancer or conceivably, no matter what the disease or its response to proven measures for cure. If the Department of Health has a responsibility for safeguarding the health of the people of the State, then we must go on record as having deep concern about the legalization of Laetrile. Freedom of choice implies that the patient is completely cognizant of the results of his or her action. Substituting Laetrile which would be readily available for any cancer patient, in an early or advanced stage, can deceive the patient about the freedom of choice issues long enough to make it too late. Nowhere is there any requirement that conventional therapeutic techniques be employed along with Laetrile.

4) Your question 10 asks about a medical consensus, rejected by Laetrile proponents, that cancer is a disease of the spread of malignant cells. Some Laetrile supporters contend that it is a system-wide condition, with local manifestations,

that reflects a vitamin or nutritional deficiency. Is there any consensus today about the causes of Cancer among medical scientists or within organizations like the National Cancer Institute?

There presently is a consensus that there is no single cause of cancer. It is believed that the causes may be multiple depending on the cancer site. There are several theories about the cause of cancer which are accepted as having validity in the scientific community. Certainly today we have statistically tracked the incidence of cancer and know some of the conditions in the environment and in the working place that tend to produce cancer. Should we be permitting our citizens a false sense of security that might come from giving them uncontrolled access to an unproven substance, rather than spending our efforts and dollars on prevention and community control programs where we know the causes?

To sum up, the ready availability of Laetrile can only serve to encourage its exploitation. To quote Senator Kennedy when he asks, "Laetrile is it a useful addition to armamentarium against cancer or is it a useless compound which has gained some acceptance because of the vulnerability of the people who decide against it?"

5) In your question #8 you ask what likelihood is there of a <u>national</u> solution to the Laetrile problem, whether through a change in the FDA's position or through federal legislation? Should

the State of New Jersey wait until the issue is resolved at the national level? I have already urged you to wait because I feel there is now definitely going to be a national effort to do the necessary research.

Intensive research on the federal level can provide some answers. In June, appearing before a Congressional committee, Dr. Guy Newell, Acting Director of the NCI, promised to begin this research. New Jersey lacks this capacity. Therefore, I have strongly urged you to postpone action on Laetrile legislation. You must allow and encourage the kind of research that Senator Kennedy has committed himself to see undertaken--immediate, well organized, thorough research, and only then make an informed judgment about making Laetrile available.

There is something important at stake. Your actions here today do carry considerable weight in the well-being of cancer patients. The weight is not alone that of allowing those who choose this avenue to have Laetrile available, but you also bear the responsibility for putting the weight of your office and the Legislature behind a remedy that not only may be worthless but may delude some patients because of the ease of treatment to seek this cure instead of proven therapy until it is too late. It is not a simple issue of freedom of choice. New Jersey's proposed laws certainly do not provide for informed consent.

To quote from the Philadelphia Inquirer of June 23, 1977, "Full Freedom of Choice, however, suggests that the public be given easy commercial access to, for example, the more than 30,000 other substances which the researchers at Sloan-Kettering alone have tested and found ineffective in cancer therapy.

That freedom of choice is simply the freedom to be confused, and the freedom to be exploited by the astronomically profitable enterprise of cynical salesmen of false hope."

Question # 7 asks about countries, or for that matter even other states, where Laetrile may now be freely used.

The proponents of Laetrile will no doubt enumerate the many States that have enacted Laetrile legislation in recent months. Even perfunctory scrutiny of these laws indicates the more restrictive nature of their content. In New Jersey we would possibly have the most wide open piece of legislation being considered to date.

What the proponents of Laetrile fail to point out is that in eight or nine states, Laetrile bills have died in Legislative Committees. Most recently, June 27, in Massachusetts.

Perhaps one of the greatest fallacies being circulated by the proponents of Laetrile is that Israel permits the use of Laetrile when in fact it is illegal in that country.

In closing, I would like to read the resolution adopted at the last meeting of the Public Health Council on July 11 and sent to the Governor. Remember, the membership of the Council is made up of consumers as well as professionals.

July 15, 1977

The Honorable Brendan T. Byrne
Governor of New Jersey
State House
Trenton, NJ 08625

Dear Governor Byrne:

After careful consideration of the merits of Laetrile in the treatment of cancer, at a Public Health Council meeting on June 13, 1977, we recommend that you not sign any legislation which would make the use or manufacture of this drug legal in the State of New Jersey.

The search for a cure for cancer has been a long and arduous one and substantial progress has been made in many areas of scientific research. Unfortunately, Laetrile has not been demonstrated to be of any value in the treatment of tumors in animals or humans. After meticulous review, the FDA, the National Cancer Institute, the American Medical Association, the American Cancer Society and Memorial-Sloan-Kettering Cancer Center have not substantiated any claims which justify using this substance as an anti-cancer agent. To legalize its use, in the face of this overwhelming negative data, will endanger the lives of patients, who lured by non-scientific promises, refuse scientifically proven beneficial treatments and turn to this useless substance. False hope is a cruel panacea for cancer sufferers.

We strongly feel that the maintenance of unimpeachable medical standards is a necessity and that Laetrile represents a serious compromise of these standards.

We suggest that you join with your colleague, Governor Hugh Carey, in protecting citizens from this potentially harmful legislation.

Seven of the eight Public Health Council members were present at the meeting and unanimously agreed to this Resolution.

Sincerely,

Jane B. Robinson, Chairman

Members Present:
Rodger J. Winn, M.D.
Anita O. Leone
Harry J. Robinson, M.D.
John J. Cane, D.D.S.
Paul R. Jackson
Michael S. Kachorsky

STATEMENT

BY

WILLIAM J. EVANS, M.D.

BUREAU OF DRUGS

FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH, EDUCATION AND WELFARE

BEFORE THE

INSTITUTIONS, HEALTH, AND WELFARE COMMITTEE

NEW JERSEY STATE SENATE

HACKENSACK, NEW JERSEY

JULY 19, 1977

Mr. Chairman:

I should like to begin with a statement:

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

The statement I have just read was made by then-Commissioner James Goddard twelve years ago; in reading it to you I have substituted one name--Laetrile---for another--Krebiozen. Only some of the people in this hearing room will recall that Krebiozen was "the" cancer fraud of the late 1950's and early 1960"s. Its sponsorship by Dr. Andrew C. Ivy, a distinguished physiologist at the University of Illinois School of Medicine, gave it substantial credibility among cancer patients; and despite the universal skepticism with which it was treated by the scientific community and organized medicine, thousands of cancer victims eagerly sought the drug and thousands of doctors prescribed it as an investigational drug--at a cost of $9.00 per ampoule.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

When one hears testimonials from such patients, it is difficult not to be resentful at their exploiters. It is a deplorable suggestion that this Government should, on the falsely applied issue of "freedom of choice" stand aside and allow them to be exploited by the purveyors of a therapy that is of unproven merit, and even of uncertain identity.

Let me emphasize, for a moment, our views as it relates to legislative action being taken by some States to legalize the use of Laetrile in the prevention or cure of cancer.

In any State where Laetrile is legalized, a great number of cancer victims in that State could be irreparably harmed, both by spending large sums of money for this drug and by foregoing known effective treatments that are now available for many forms of cancer, especially in early stages. We hope that your State will not legitimize this exploitation of a tragic disease. The shipment of Laetrile from or into your State is now illegal under Federal law and passage of State legislation would not alter this situation. Passage of this legislation will not protect sponsors, promoters, distributors, dispensers, or sellers of Laetrile from applicable civil or criminal sanctions under the Federal Food, Drug, and Cosmetic Act.

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

The Medical Society of New Jersey

EXECUTIVE OFFICES

315 WEST STATE STREET, TRENTON, NEW JERSEY TELEPHONE 394-3154

REPLY TO P. O. BOX 904, TRENTON, NEW JERSEY, 08605

July 14, 1977

The Honorable Alexander J. Menza
Chairman, Senate Institutions,
Health and Welfare Committee
State of New Jersey
State House, Room 318-A
Trenton, New Jersey 08625

Re: Senate Bill #3289
Assembly Bill #3295

Dear Senator Menza:

The concern over laetrile as evidenced by the above bills and the daily publicity on the topic is a matter of vital importance to all the people of New Jersey.

Unfortunately, it will not be possible for me or members of my Committee to appear at the hearing you have scheduled for July 19, 1977.

As physicians who specialize in the care of cancer patients we are constantly searching for new methods and medications to treat and control cancer. Laetrile is a chemical substance well known to the medical community. It has no known therapeutic effect on cancer or any other disease. It can be toxic if taken in excessive doses. The major danger, however, is that the legalization of it may deter patients from seeking forms of treatment which can be and are known to be effective such as chemotherapy, surgery, and radiation therapy.

To legalize and promote the use of a placebo medication for patients with proven malignancies is in our judgement, an unwise course to follow.

Respectfully submitted,

Roy Forsberg, M.D.
Chairman, Committee on Cancer Control

RF:jg
cc; Michael Bruinooge, Committee Aide
State of New Jersey

HAROLD E. BUTTRAM, M.D.

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July 18, 1977

Concerning Laetrile Testing,
Open letter to Senator Edward Kennedy

At the present time there is a growing wave of public opinion calling for a very basic re-evaluation of present approaches to cancer therapy in the United States. In spite of the fact that many billions of dollars have been poured into cancer research, the benefits of the customary methods of medical therapy are coming under increasing question and doubt.

In June of this year an American Cancer Society official stated that there has been no dramatic reduction in death rate from breast cancer in the past four decades. At a recent conference on environmental carcinogenesis in Houston, sponsored by the American Cancer Institute, American Cancer Society and other organizations, the statement was made that current medical treatment in this country has had little impact on death rate from cancer. Hardin Jones, recognized as an authority in medical statistics, has stated that survival rates for cancer patients have not improved during the era of chemotherapy and radiation with the exception of the childhood leukemias and Hodgkins disease.

In recent years we have witnessed a mass exodus of cancer patients from the United States to foreign countries for alternative therapies which are illegal or unavailable here. Within the United States, for good or ill, there has evolved an underground railroad for cancer patients, in some respects reminiscent of the underground railroad during the days of slavery for escaped slaves seeking freedom.

In order to bring this question into proper focus, it should be explained that two distinct and separate approaches in cancer therapy are emerging upon the present day scene:

(1) Standard or orthodox medical therapy, based largely on the use of toxic-type drugs, radiation, and surgery.

(2) Biological therapy* directed at the building or stimulating of the body's own immune systems and resistance against cancer, the restoring of normal and healthy body organ functions, and the cleansing from the body of carcinogenic toxins.

There is now a great deal of scientific evidence that cancer results from a breakdown of the body's immune systems, including the so-called T-lymphocyte system. German researchers have shown a deficiency of pancreatic enzymes in cancer patients. Cancer is almost always accompanied by a breakdown in other organ functions as well. Although the toxic-type drugs and radiation

*By definition, the term "biological therapy" refers to the therapeutic use of substances native to the processes of life.

given in treatment of cancer may reduce the size of the tumor and possibly bring temporary remission, in so doing they may also cripple the body's immune systems, thereby ultimately lowering resistance to the cancer. Whereas surgery, radiation and chemotherapy may be of benefit, and in some cases curative to the patient, the LONG TERM CONTROL OF CANCER MUST DEPEND ON THE BODY'S OWN IMMUNE SYSTEMS.

Many foreign countries have had a great deal more freedom for innovative types of medical research than the United States, controlled as we are by a bureaucratic health-care system. As a result of their greater freedom, other countries, particularly Germany and Austria, may be many years ahead of us in developing more effective means of cancer therapies. In Germany and Austria, all patients are given the option of conventional cancer therapy, biological therapy or a mixture of the two. Hans Nieper of Germany has claimed a very striking improvement in survival statistics in those patients receiving biological therapies after initial conventional treatments of surgery, radiation or chemotherapy. Karl Ransberger, also of Germany, has cited a study done on 3,000 women with surgical mastectomies for breast cancer. Reportedly this study showed an 84% improvement in three-year survival for those women given biological therapy following the mastectomy as compared with those who did not receive biological therapy.

Senator Kennedy, I am sure you will agree that the scientific brainpower in this country is second to none, but we have a system in which innovative research has been stifled and discouraged and this can only lead to stagnation.

In regards to laetrile itself, I would like to make three comments:

(1) Aside and apart from the medical merits of laetrile, it has become a focal point for the broader issue of health freedom. A great deal of emotionalism associated with the controversy is not so much concerning laetrile as it is with health freedom. Increasing numbers of Americans, very likely at this point a majority, are coming to feel that health freedom is just as basic to the rights of a free people as other freedoms guaranteed in the Bill of Rights of the United States Constitution.

(2) The second observation is that laetrile is not a form of chemotherapy in the treatment of cancer but is a form of biological therapy which acts by stimulating the body's own immune systems, in ways as yet not fully understood. As a form of biological therapy, it simply will not work unless combined with a total support program of nutrition and supplements, and in some cases a change of personal living habits, all designed to cleanse the body of carcinogenic toxins, to restore normal body organ function and to stimulate innate immune systems of the body. For this reason I am very skeptical that any clinical study by the National Cancer Institute with laetrile will show any success, BECAUSE THEY ARE MISSING THE ENTIRE POINT OF LAETRILE THERAPY.

(3) In my opinion, cancer research in this country in some respects at least, is headed in the wrong direction. As already stated, no long-term therapy for cancer will ever be successful unless at the same time it restores body tissues and organs to health and reactivates the immune systems. Again in my opinion, significant scientific advances in cancer therapy in the future will be in the realm of biological therapies.

Thomas Edison, in the invention of the electric light, had to perform many hundreds of experiments before he found a combination of materials and conditions that worked. What if he had stopped his work on the electric light after three or four failures, saying that he had tested the electric light and proved that it didn't work? The present position of the F.D.A. and N.C.I. on laetrile is much the same.

In an article entitled THE AMERICAN CANCER SOCIETY MEANS WELL, BUT THE JANKER CLINIC MEANS BETTER, (Esquire Magazine, April, 1976) Patrick M. McGrady, Jr., reported on a visit to the Janker Cancer Clinic and Hospital in Bonn, Germany where, according to the article, data shows 70% full or partial remission of patients treated at the clinic, of whom 76,000 have been treated since 1936. McGrady makes the following comments:

> "These results are more stunning even than the statistics would seem to show because, whereas most compilations of remissions refer to newly diagnosed, primary treatments, the Janker successes are almost entirely achieved upon patients who have been through one therapeutic mill or another and been jilted by other doctors. This fact makes their win-loss ratio almost flabbergasting.

"I persuaded a steely-eyed nullifidían American cancer-specialist friend to join me on a second visit to the Janker Clinic. If anyone could scare out the bugs from under the chips, he could. I secretly wanted to be proved wrong.

"Here was a private hospital (one hundred and ten beds) with no government or foundation subsidy that seemed to have developed better cancer treatments than the best of those available anywhere else in the world.-----

"Here were two men, Scheef and his boss, hospital director Dr. Hans Hoefer-Janker, who were largely responsible for developing four of the most potent anti-cancer agents known to the medical world.

"This German hospital seemed just too good to be true. If only my doctor friend would dampen my fervor, he would reaffirm what I wanted to believe: that the best cancer care is available only in the United States of America. ------

"Regrettably, my friend was absolutely perfervid in his enthusiasm for the Janker's staff and techniques. In the few days he spent working alongside Drs. Hoefer and Scheef, he experienced a clinical freedom he said he had never known in the United States. I say 'regrettably' because his comparisons terrified him. If he were to praise publicly what amounted to a refutation of the bureaucratic system he worked under, it would cost him dearly. He asked that I not mention his name, and I agreed.

"What impressed my friend most was the freedom the Janker staff enjoyed. Hoefer and Scheef control their one hundred forty employees with an enlightened paternalism. Decisions are reached by a rapid concensus. Protocols are revised the moment they are perceived to be ineffectual without any need to kow-tow to government kibitzers, medical societies, do-good propaganda and fund-raising agencies, boards of directors or groups of peer onlookers.

"The Janker Clinic's preemptive focus is the patient. Nothing is permitted to interfere with the primary goal of prolonging the patient's productive life span."

Senator Kennedy, as a public servant who has the best interest of the American public at heart, I would think that you would be concerned with selecting an impartial group of medical experts and sending them to foreign countries such as Germany and Austria. If these countries are achieving superior results in terms of survival rates of cancer patients, then certainly American citizens should not be deprived of these therapies. It would be better still if you yourself would go and survey work being done at cancer centers such as the Janker Cancer Clinic and Hospital.

I would also think that there should be an independent investigation by the legislative branch of government of doctors in America such as John Richardson of California and Paul Wedel of Oregon, doctors who have been involved in laetrile therapy for many years and have had a wealth of clinical experience with laetrile and other related therapies. Personally I believe that history will eventually give these men the credit that is their due as courageous pioneers in opening up new dimensions in the treatment of this dreadful disease.

If and when medical experts are chosen for this work, I believe that they should be free of any ties or obligations to the F.D.A. and National Cancer Institute, which are hopelessly biased against laetrile or other forms of biological therapy. Asking officials of the F.D.A. or N.C.I. to investigate laetrile is much the same as asking a republican to write a democratic party platform, or vice versa.

In all this sordid affair, perhaps the kindest thing that can be said of the officials of the F.D.A. and other bureaucratic agencies involved in the regulation of health care is that they have shown a total lack of vision for the potential value of biological therapies.

Sincerely,

Harold Buttram M.D.

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Brunsvig

Laetrile

ACS POSITION ON LAETRILE ADOPTED BY NATIONAL BOARD OF DIRECTORS, ACS, SAN DIEGO, JUNE 9th

The following recommendations of the Committee on Unproven Methods of Cancer Management and of the Medical and Scientific Committee were adopted today:

1) That, in view of recent developments, the Committee's summary statement expressing the Society's official position on Laetrile, be revised to read as follows:

"A review of all reported material available to the American Cancer Society shows that Laetrile is not effective in the prevention or treatment of cancer in human beings."

2) That, since there is a growing public and legislative interest in Laetrile and in its effect and use, and since the Society has a responsibility for informing the medical profession and the public at large on matters concerning cancer, the American Cancer Society reaffirms its support for the protection of the cancer patient through strict adherence to FDA established methods of scientific testing, and further, that it does not approve of any exceptions to such methods for any particular substance.

JUL 20 1977

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public education/ Q & A on Laetrile

introduction

Laetrile has been touted as a cure for cancer by a handful of promoters off and on for almost 50 years. In recent years increasing numbers of desperate and wishful cancer patients have turned to Laetrile, offered illegally by a small number of practitioners who promise patients cure, control or prevention of cancer. Most recently Laetrile promoters have stepped up a campaign to create an emotional demand for Laetrile. They have turned to the political platform, as they seek legalization of Laetrile through the state courts. While a few state legislatures have succumbed to political pressure and approved the manufacture and distribution of laetrile, this has not been because of its medical effectiveness. It has none.

> Laetrile has been totally rejected as having any benefit whatsoever in cancer after some 20 years of testing and investigation by medical scientists. It is banned as an ineffective and unsafe therapy by the Food and Drug Administration.

This pamphlet is intended to answer some of the questions most likely to arise concerning the background and current situation surrounding Laetrile.

WORDS UNDERLINED IN PENCIL ARE IN GLOSSARY.

1. What is Laetrile?

Laetrile is the product name given the chemical amygdalin, a substance that occurs naturally in the pits of apricots, peaches, bitter almonds and in parts of many other plants. The amygdalin used in the production of Laetrile is extracted from apricot pits, and it is currently packaged either in tablet form or in vials of liquid for injection. It was tagged as a cancer remedy as early as the 1920's by its "discoverer," Ernst T. Krebs, a California physician. However his theory of amygdalin's characteristics and action in attacking and destroying cancer cells has long since been disproved by chemical facts as well as medical and scientific tests. Krebs argued that cancer was a single disease, and that a single agent could wipe it out. In fact cancers include some 100 conditions, with any of 50 proven anti-cancer drugs effective only against a few forms of cancer at most.

2. Why has Laetrile been banned by the Food and Drug Administration?

The FDA is empowered to require that all drugs marketed since 1938 meet standards of safety and effectiveness for their intended use. Laetrile, available since the 1950's, has been described by its promoters as recently as 1970 as a drug, with its intended use being to combat cancer cells to bring about a cure, to relieve the pain associated with cancer, to prevent recurrence of cancer, to induce a feeling of well-being in and to prolong the lives of cancer patients. It is also held to prevent cancer.

The FDA holds that: "Even though it has been known, tested and used for more than 25 years, no valid scientific evidence has ever been found that suggests Laetrile has any potential value in cancer management." The FDA position further states that Laetrile, being ineffective against cancer, is also unsafe.. in that its use interferes with competent diagnosis and treatments of known and proven value. In 1963 Laetrile was banned by the FDA, and its manufacture, distribution and sale in interstate commerce is illegal.

3. Is Laetrile, in itself, safe for use?

Objections raised by the FDA, the American Cancer Society and others who have investigated the properties of Laetrile also concern its actual make-up. Amygdalin belongs to a class of substances capable of releasing cyanide, a deadly poison, when acted upon by certain of the body's enzymes. When injected, Laetrile appears to avoid enzyme action and is evidently excreted in the urine, intact, unchanged. This means it is probably "safe" in that no cyanide has been released; but it also refutes arguments that Laetrile has done any "work" whatsoever. When taken orally, in tablet form, Laetrile can be acted upon, releasing cyanide, during the digestive process and in combination with certain foods. Cyanide poisoning can take place, and such cases are being increasingly reported.

4. Why the current controversy over Laetrile...How did it get this far?

Laetrile has been the subject of vigorous promotion and intensive propaganda by several groups among its advocates. They use films,

pamphlets and visits to cancer patients to promote Laetrile. They hold mass meetings and rallies, and seek to cultivate media representatives and politicians. Combined with this is a campaign of denunciation against orthodox treatment methods (surgery, radiation and chemotherapy are tagged "cut, burn and poison" and constitute "three approved paths to the graveyard," according to one pamphlet), and against the scientific community. These Laetrile groups charge a conspiracy among the "powers" in medicine...of trying to block Laetrile in order to protect their "lucrative monopoly" of "the cancer business."

Current cancer treatment is saving one out of three cancer patients and this could be one out of two if early diagnosis and prompt and adequate treatment were universal. Research is constantly improving the three main forms of cancer treatment:

*Modern surgery gets better results with less radical operations than in the past. Moreover, improved procedures and advancements in pre-and post-operative care provide greater safety and effectiveness for even the most aggressive surgery. New antibiotics reduce the risk of infection.

*Radiation therapy has fewer side effects today and can be used for cure or considerably prolong life and restore comfort to the cancer patient. Improved radiotherapy techniques make it possible to treat internal tumors without excessive damage to overlying tissues. This permits cure not only of many localized early cancers but also some advanced tumors not suited to surgical removal.

*Chemotherapy now utilizes some 50 drugs and another 500 are under study. Many are employed following surgery or radiation to prevent recurrence of of breast, bone and other cancers. Eleven tumors formerly considered incurable are now controlled by drugs - e.g. acute leukemia in children,

advanced malignant melanoma, Hodgkin's disease, testicular carcinoma. And advanced cancers of the colon-rectum are responding to combined drug treatments.

5. Isn't Laetrile now being called a vitamin? *

Although initially characterized as a drug, Laetrile is now described by its promoters as "a natural vitamin and food supplement, vitamin B_{17}." One principal Laetrile advocate states that it is no longer being promoted as a specific anti-cancer agent, but is "the crown jewel in the diadem of metabolic therapy," and that it must be administered by a "trained metabolic holistic physician." Metabolic therapy and holistic physician are terms

* Kansas City hearings, as reported in Medical World News of 5/30/77.

describing a treatment approach in which the patient must be perceived as a functioning whole, and all his physical and chemical processes must be maintained in proper balance.

Vitamins are defined as organic substances that occur in small amounts in many foods, and which are necessary for normal metabolic functioning in the body. Their absence causes certain diseases to afflict the body. The FDA, various nutritionists and other scientists report: There is no evidence that Laetrile is an essential nutrient, that it promotes any vital bodily process, or that lack of amygdalin is linked to any disease, including cancer.

6. What is happening in the state courts, and how will this affect the FDA ban on Laetrile?

A growing number of states are legislating the legalization of Laetrile -- chiefly on the grounds that it should be available to individuals if it is a treatment of choice agreed upon between the patient and his physician. "Freedom of choice" has been the central view expressed in state approval. But as many cancer experts and other medical scientists protest, it involves the introduction of an unproven therapy by means of legislative action, without a clinical, scientific evaluation. A leading cancer researcher points out that "Every anti-cancer drug ever shown to work in humans was first proved to have an effect on some animal cancer -- but not Laetrile."[*1] Some physicians who consider Laetrile a quack therapy nonetheless call for its legalization -- to take away, as one expressed it, "the clamor for the forbidden fruit."[*2]

*1 Daniel S. Martin, M.D., New York Times Op-ed, 6/3/77 50x

*2 Quote from Dr. Franz J. Inglefinger, editor of New England Journal of

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The position of the FDA is that the prohibition on Laetrile will stand. Any efforts to import, any interstate movement, of Laetrile or Laetrile ingredients, such as apricot pits, will be subject to raids and seizures. Any attempts at Laetrile manufacture are open to raids and seizures. The FDA further declares it will vigorously fight the legalization by establishing an investigative study record in support of its ban.

7. Haven't a number of physicians and many cancer patients claimed that Laetrile is an effective anti-cancer substance?

The claims that Laetrile successfully cures or controls cancer have come primarily from the handful of physicians and other persons who are actively involved in promoting, marketing and administering Laetrile -- along with a corps of treated patients who swear by the substance. Essentially reports of Laetrile's effectiveness consist of endorsements and testimonials by those treated -- that pain and other symptoms have lessened, that they feel better; and observations by their Laetrile practitioners that the patients feel well, are relieved of pain and other symptoms, and have increased energy.

Cases of successful treatment have been cited by Laetrile practitioners -- but documentation, medical records, treatment plan, tests and other essentials of an acceptable case history have been absent. Where outside attempts have been made to follow up on some of these"successful" cases, it has been found that no documentation exists that the patient ever had cancer in the first place; and in those patients where there was objective improvement,

it has been found that the patient received orthodox treatment in addition to Laetrile. Other cited patients could not be traced, were dead, or had advancing cancer. Most often Laetrile patients refuse to grant permission to study their Laetrile treatment records.

There have been no controlled animal studies reported by Laetrile practitioners. They have presented no case studies of Laetrile-treated patients that offer controls or documentation, or objective proof of improvement that meet standards of procedure acceptable in U.S. medical science today.

8. What about independent or impartial testing of Laetrile?

There have been several controlled and extensive animal test series done to evaluate Laetrile at leading cancer research centers. The tests were done on animal systems which had been earlier proven able to detect active anti-cancer properties in the scores of drugs which have shown demonstrable value.

. The National Cancer Institute of the National Institutes of Health conducted series of Laetrile tests on five separate occasions between 1957 and 1975. Its report stated no evidence of benefit in the treatment or prevention of cancer.

. New York City's Memorial Sloan-Kettering Cancer Center conducted an exhaustive series of tests on Laetrile during the period 1973 to 1977. Its conclusion was that Laetrile has no effect one way or another on cancer.

. Four independent animal studies testing Laetrile were done at other cancer research centers in 1975 -- all of which found no evidence of Laetrile's effectiveness against cancer.

Major cancer research centers have not tested Laetrile in human cancer patients because chemical analyses of amygdalin's properties as well as the testing of Laetrile in animals have shown no evidence that it would be of benefit. Human experimentation would be considered unethical, in that all anti-cancer drugs shown to work in humans were first proved to have an effect on some animal cancer.

9. Is Laetrile now going to be tested in human cancer patients?

The National Cancer Institute and the Memorial Sloan-Kettering Cancer Center have announced that they are considering testing Laetrile in cancer patients. Both institutions emphasize they are willing to perform these tests not because of any scientific justification, but in recognition of the social and political climate now surrounding Laetrile. They emphsize they still consider Laetrile ineffective, but are willing to obtain hard facts for the benefit of practicing physicians and cancer patients.

They suggest:

. A double-blind study to be made at several institutions -- where some patients receive the drug being tested (Laetrile) while another group gets an inactive substance, called a placebo. Neither the patients or their doctors (hence the term "double-blind") know who is getting what. The patients and results would be evaluated in terms of observable patient improvement.

. The studies would not endanger participating cancer patients in that they would all receive cancer treatments recognized as effective, with either Laetrile or the placebo being given in addition.

. A study be made in which some 10,000 patients who have been treated with Laetrile are traced, determining what kinds of cancers they had, what other treatments, if any, they received, and their survival rate.

. The data from the various studies be reviewed by a committee of scientists and lay people to eliminate possible claims of bias.

. Laetrile and placebos be tested in patients for whom all accepted forms of treatment have been tried with no effect, or in those for whom there are no accepted effective therapies.

10. What is the "freedom of choice issue surrounding Laetrile?

Freedom of choice, as it is used by Laetrile promoters, urges that patients and practitioners consult together to decide the treatments they patient will receive -- regardless of whether the scientific community regards the therapy as effective, and without interference from the government. This issue is often combined -- in Laetrile propaganda, although not in their legal efforts -- with the conspiracy argument. This charges that the medical, scientific and research "powers" are working together to prevent the riddles of cancer from being solved, and to prevent useful remedies from reaching the market.

In practice of course, patients who want Laetrile, even if it is legalized, will have to find physicians willing to prescribe or give it -- a list particularly short if Laetrile is selected as the only treatment acceptable to the patient.* Several reputable physicians have indicated that although they would never recommend

* Dr. Ingelfinger, cited earlier.

Laetrile, if asked to administer it by a patient, they would do so for those who had advanced and untreatable cancer, or in combination with other accepted treatments.

11. What is the objection to Laetrile as a placebo in hopeless cases?

On the surface, there is nothing wrong with giving a person a substance which will do him no harm. Just as Laetrile has not been proven effective, it has not been proven harmless. In addition, a placebo in medical care is given by the physician as a medication, even if the purpose is only to comfort or please the patient. The patient has the psychological comfort of receiving "treatment."

In the view of the American Cancer Society and many other individuals and organizations in the field of health care, legalization of Laetrile even as a placebo treatment supports the make-believe that it is a legitimate therapy. It leads to the further danger that it will be chosen as an alternative therapy, over proven cancer treatments. It is also not acceptable for "hopeless" or terminal patients, in that nobody can be sure a given patient will not recover, live longer than expected, become responsive to a given therapy, or have a remission of disease -- using treatments known to be of benefit in cancer.

Who judges that a patient is hopeless or terminal? The patient? An enquolefied M.D.? The law? (kaak)

12. Who Are The Supporters of Laetrile?

Promotion of Laetrile is carried on primarily by four organizations.

*The National Health Federation, a promoter of health foods.

*The International Association of Cancer Victims and Friends, founded in 1963 by a California cancer patient. Although the Association claimed on their founder's death in 1969 that the "autopsy showed no cancer cells present," her death certificate states that she died of far advanced metastatic carcinoma of of breast to abdomen. This group uses meetings, movies to promote the use of Laetrile and publishes the Cancer News Journal.

*The Cancer Control Society which is a group which broke away from the International Association in 1973. Their stated objectives are to force the government to allow freedom of choice in cancer therapy and to provide information of cancer and its treatment. It publishes a Cancer Control Journal.

*The Committee for Freedom of Choice in Cancer Therapy, founded in 1973, by Robert Bradford, a physicist who feels efforts to regulate Laetrile are an invasion of privacy and interference with individual freedom. He has been convicted by a federal jury for smuggling Laetrile from Mexico.

13. Do the proponents of Laetrile make money from it?

Those who peddle it do, and some have become wealthy through selling the useless substance.

14. What is the position of Laetrile in other countries?

Laetrile has become an issue in Canada and Mexico, because both countries experienced active promotion of Laetrile by certain individuals, were the sites of Laetrile manufacture; and these centers of Laetrile activity drew many hopful cancer patients, large numbers of them from the United States. Both countries have now banned Laetrile. Investigations in the Soviet Union* and preliminary tests in Israel have declared Laetrile ineffective. There is a Laetrile clinic in Hanover, Germany, which apparently draws a substantial number of Americans. The status of Laetrile in other countries is not known to the American Cancer Society.

15. How does the American Cancer Society respond to the possibility of widespread legalization of Laetrile?

The American Cancer Society, along with the Food and Drug Administration and all major cancer centers and cancer researchers totally reject Laetrile as a substance of any benefit in the treatment of cancer. Legalization will introduce an unproven therapy, will defraud the public, can endanger the lives of countless persons...and can open the door once again to countless, worthless "remedies."

It is the Society's position that the public has a right to protection in an area -- medical treatment -- where they cannot have sufficient knowledge to protect themselves against quackery. This is what the licensing of physicians is about; why we have drug standards and restrictions, why there are accreditation standards for hospitals, why we have consumer protection activity and legislation. A patient can refuse treatment, can seek another

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* According to Dr. Martin's editorial cited earlier.

(more)

professional opinion. And a patient has the right to be protected...to know that he is dealing with qualified professionals and institutions, that techniques and drugs which may be used are those that have been approved or might reasonably be thought to be of benefit -- according to reputable standards of medical science today.

For further information on Laetrile, please call your Division of the American Cancer Society.

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glossary

Amygdalin - a chemical containing sugar and cyanide elements, it is found and occurs naturally in the pits of apricots, peaches, bitter almonds, in the leaves of cherry laurel and plum trees, and in over a thousand other plant elements. It can release hydrogen cyanide when acted upon by certain enzymes.

Benign - generally meaning kind; in medical science it means not malignant, not cancerous.

Bias - a particular viewpoint which prevents fair consideration of a question or issue.

Chemotherapy - treatment by use of drugs.

Controls, controlled studies - in the scientific approach, controls are a group of test subjects which are not receiving the treatment/being evaluated, for means of comparison. Controlled studies are those in which a control group is used.

Cyanide - an extremely poisonous gas.

Enzymes - complex substances which originate from living cells and are capable of action which causes chemical changes, such as in digestion or fermentation.

Holistic - describing a person, view or technique which sees the person or thing as a whole -- which is more than the sum of its parts.

Metabolic - describing all the physical and chemical processes building and maintaining an organism or person, including the changes which release energy for use by the organism or person.

Metastatic carcinoma - cancer which has spread.

Nutrient - any substance which provides nourishment to the body.

Organic - Made up of, or coming from, living matter, animal or plant.

Orthodox - approved or conventional.

Placebo - taken from the Latin meaning "I will please,", a placebo is an inactive substance given to comfort a patient psychologically; given to provide or as a comparison in tests of another substance, in controlled studies.

Remission - the temporary decrease or disappearance of signs and symptoms of disease.