

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

In the matter of )  
 ) Docket No. 77N0048  
A Rulemaking Proceeding )  
Concerning Laetrile )

DECLARATION OF SAMUEL C. KLAGSBRUN, M.D.

Samuel C. Klagsbrun, M.D., does hereby declare and state as follows:

1. I am a psychiatrist licensed to practice in the State of New York.

2. I am a graduate of the City College of New York and the Jewish Theological Seminary. In 1962, I received the degree of Doctor of Medicine from the University of Chicago School of Medicine. Thereafter, I spent one year as a rotating intern at the Michael Reese Hospital in Chicago, Illinois and received the Intern of the Year Award.

3. In 1966, I completed my psychiatric residence at Yale-New Haven Hospital. From 1966 to 1968, I was an instructor of psychiatry at the Yale University School of Medicine and, concurrent with that position, served as Chief of Psychiatry at the United States Naval Submarine Base in New London, Connecticut, holding the rank of Lt. Commander.

4. In 1968, I became Director of the Psychiatric Division of the Emergency Room at St. Luke's Hospital in New York City. At that time, I also was appointed Instructor of Psychiatry at the College of Physicians and Surgeons (Columbia University School of Medicine).

5. I was instrumental in establishing a Psychiatric Day Hospital at St. Luke's, as well as that hospital's Psychosomatic Service facilities. I became Director of that service gaining experience and knowledge in the area of cancer and its emotional impact on patients and their families.

6. My publications include a paper entitled "Cancer Emotions and Neuroses" which appeared in the American Journal of Psychiatry. I am a member of the Public Education Committee of the American Cancer Society, New York City Division, and am a member of the Board of Directors of the American Cancer Society, New York City Division. I also have been invited to become a member of the American Cancer Society's Committee on Rehabilitation.

7. As part of my professional practice, I have been extensively engaged in providing psychotherapy to cancer patients and their families on an individual and group basis. During the last two years, I have spent nearly two-thirds of my time working with Dr. Cicely Saunders at St. Christopher's Hospital in London dealing with the physical and emotional care of dying patients. I have begun a service, similar to that which I observed at St. Christophers, at St. Luke's. This service, called "The Hospice at St. Lukes", has been in existence for nearly two years. There, we provide psychotherapy and physical care for cancer patients facing a critical point in life, as well as treating the patients' family and friends. Based on this experience, I will now address myself to the psycho-social issues raised by the potential availability of Laetrile to cancer patients.

8. Cancer patients who "choose" to use Laetrile immediately remove themselves from the realm of orthodox medical treatment. This "choice" is one made out of desperation and on the basis of hearsay and ill-founded information, rather than on any scientifically proven grounds. Such a "choice" results in a disruption of the normal avenues of communication between patients and their physicians and deprives the patients of any opportunity for treatment with advanced

methods discovered following the decision to turn to Laetrile.

9. Patients who resort to Laetrile are avoiding their critical need to face reality. The decision to use Laetrile is, in essence, an attempt "magically" to avoid the reality of cancer. Though there is no need to beat patients over the head with this reality, there is every need to help patients realistically deal with their illness so that constant decisions leading to appropriate treatment in each phase of the disease can be made. At each stage of the disease, cancer patients must critically reevaluate decisions regarding their own lives, as well as their family's. The decision to use Laetrile is often accompanied with wishful thinking and avoidance of reality, such that proper and reasoned decisions are never made.

10. There are severe familial and social pressures which often provide the primary stimulus for the patients' decision to use Laetrile. These pressures very frequently come from individuals whose well-meaning reaction to the frustration of seeing their loved ones deteriorate with cancer is to urge them to seek out any desperate measure which, in their own minds, may help. These individuals, frustrated and angered by what they perceive as orthodox medicine's inability to cure loved relatives, express these emotions by urging the patients to turn to "magical" substances. Thus, instead of helping the patients deal with their own reality, the relatives and friends of the cancer victim, in effect, often attempt to deny the existence of the disease by advocating the use of Laetrile.

11. A decision to use Laetrile is often an expression of the tendency on the part of cancer victims and their family to choose the least physically traumatic treatment for cancer. Conventional anti-cancer treatment brings about a host of uncomfortable and often severe side effects.

Given a choice, which includes on one end of the spectrum radiation therapy, with its nausea and possible skin burns, as well as weakness, and chemotherapy with its nausea, vomiting and pain, and, on the other end, Laetrile, which has no major side effects, many patients choose Laetrile. But, this choice is based on the fear of discomfort from conventional therapy rather than on the basis of any therapeutic effectiveness of Laetrile.

12. In the event that cancer patients were led to believe that society has accepted the legitimacy of Laetrile, then more of them would resort to its use. Permitting Laetrile to be used by any population of cancer victims would have the correlative effect of creating the misimpression in the minds of other cancer victims that the drug is, in fact, safe and effective for a broader population. Thus, to permit even such limited societal acceptance of Laetrile would lead many naive and unknowing people to choose that form of therapy which has the least severe side effects. Such a reaction is only to be expected from the average person and, therefore, requires a societal decision to protect such persons and their families from making an easy, but fatal, choice in a desperate situation.

13. The decision to use Laetrile indicates that, at the subconscious level, patients and their families have given up on conventional therapy and, in fact, have accepted the inevitability of death. On the more superficial level, patients choosing Laetrile are persons who believe that they do not require the use of sophisticated, anti-cancer treatments. This reflects an ambivalence which many patients feel at the time they are required to make decisions about cancer therapy. If patients can maintain denial about the seriousness of their cancer, then they can permit themselves

to experiment with a bizarre apricot-extract, such as Laetrile.

14. Cancer patients are usually very, very frightened individuals to whom normal judgment is no longer available. Therefore, the concept of "Freedom of Choice", as it applies to cancer patients, is ludicrous. Cancer patients act out of irrational fear which expresses itself in many poor judgments. Patients end up making "Choices" which, in the circumstances of every day life, would be censored very carefully by their rational side. "Freedom of Choice," therefore, as applied to cancer patients or their desperate families, has a completely different connotation than it would otherwise have. It is similar to the kind of "freedom of choice" which a child in playing with matches ought not to have made available to him. It is a "freedom of choice" which allows for the choice of death over possible life and one which is made on the basis of fear, rather than calm, dispassionate medical evaluation.

15. Some of the most vociferous proponents of Laetrile are the survivors of cancer victims who died although being treated with Laetrile. This reaction can be understood because such persons, whether they are family members or friends, have to justify the deceased's use of Laetrile by suggesting that the patients were considerably helped by the drug, that their lives were prolonged to a significant extent, or, at the least, that they did not suffer a great deal of pain during treatment with the drug. To do otherwise would require them to acknowledge that they made a mistake and misled the patients or that they went along with decisions which were clearly erroneous. Living with that kind of guilt is very difficult and the advocacy of Laetrile is a way of avoiding it.

16. Use of the term "terminally ill" is inappropriate when dealing with an individual cancer patient. Although specific forms of cancer may have a statistically expectable mortality rate, that rate is meaningless when applied to an individual patient. Oncologists are all familiar with experiences where severe cancers, which were statistically considered to be hopeless, have, in some small percentages of cases, undergone a sudden remission. It would be tragic to condemn any individual cancer patient to death because, as a statistical matter, that patient's particular form of cancer may not be curable.

17. A decision to allow patients who are diagnosed as having a cancer which, as a statistical matter is expected to lead to their death, would move all such patients away from orthodox therapy and condemn even the individual patient whose cancer may unexpectedly move into remission to Laetrile, a worthless and ineffective drug. In addition, such a decision would thereafter remove the patients from the possibility of receiving continuing chemotherapy or radiation therapy which could enhance the effects of any remission. Most physicians have undergone the experience of predicting the moment of death and have been unexpectedly and repeatedly proven wrong to a considerable degree. The prolongation of life, therefore, becomes a goal, not simply for the sake of prolongation, but also to render patients available to either a recent advance in chemotherapy or simply to enhance the quality of the time left available to the patients. Thus, it is impossible to conclusively determine that a particular cancer patient is "terminally ill" until the moment of that patient's death.

18. Although I am not aware of any study on the personality of Laetrile users, my impression as a clinician is that the population which lends itself to the use of Laetrile exhibits infantile characteristics (I do not intend use of that term to have any condescending connotation) and is more magically oriented than other populations may be. They appear to be suggestible to a greater degree than others. The mature approach to cancer treatment lies in recognizing the reality of the problem and playing every percentage point available within the realistic range of expectations to enhance the quality of life, its longevity, and patients' availability to the most recent discoveries in the treatment of cancer. This requires that patients remain in the hands of a good doctor; that they maintain good communications; and that they be as healthy and mobile as is possible under the circumstances. So long as patients lean in the direction of magical treatment, they will likely delay other forms of therapy or will give up on such other forms of therapy at an early stage.

19. My experience at the "Hospice at St. Lukes" is that when cancer victims are made to feel comfortable, painfree, and when all the resources for living as full a life as possible are made available to them, the patients, without exception, remain hopeful, comfortable, relaxed, and available for any new treatment methods which become available. This patient population never speaks of magical cures such as Laetrile, or miracles, or of any infantile wishes. In short, when there exists a good rapport with patients, they remain adult and choose to conduct their affairs realistically. In the same way that parental authority sometimes must withstand the angry onslaught of a child who has been denied access to some favorite outlet for the sake of the growth of that child, so too does society have a responsibility for those of us who become impaired in judgment and infantile in action, and whose decisions are likely to be harmful to ourselves and to others.

20. A popular argument for the use of Laetrile is that it serves the function of a "placebo". In other words, it is suggested that Laetrile makes the patients feel better because they think they are getting better and, therefore they should be allowed to use the drug. The problem with such a notion is that the safety and effectiveness of Laetrile as a placebo must be evaluated in terms of its relationship to the patients' ability to deal realistically with their cancer. Even in a group of patients who, as a statistical matter, may be considered terminally ill, use of Laetrile as some kind of a "placebo" has, as discussed above, the effect of telling each individual patient that he should give up on conventional therapy. Surely, where the possibility of remission exists, however remote, use of a drug such as Laetrile in lieu of conventional therapy cannot be considered safe and effective placebo treatment for any population of cancer patients.

21. It is important to remember that in the public's mind, as well as in the mind of the medical community, cancer has a different psychological impact than virtually any other disease. The fears, the primitive reactions, and the sense of being overwhelmed which accompany the discovery of cancer create reactions in all of us which are more infantile, more magical, and more bizarre than our reactions to any other kind of disease. We, therefore, need all the help we can get when facing cancer. That help includes realistic and toughminded decisions which prevent us from fooling ourselves needlessly by using worthless substances such as Laetrile.

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Samuel C. Klagsbrun, M. D. Dated:

I hereby verify under penalty of perjury that the foregoing facts are true and correct to the best of my knowledge.

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Samuel C. Klagsbrun, M.D.