Informed **OPINION** 

# Laetrile

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LAETRILE (amygdalin or vitamin  $B_{17}$ ), unlike krebiozen, its sister drug of the 1950's, continues to have its advocates. During the early part of 1977, some 20 state legislatures considered bills designed to legalize Laetrile (personal communication from C. Dahle, American Cancer Society, California Division, Inc., San Francisco). In California, Senate Bill 245 was introduced to legalize the administration of Laetrile and, in addition, to make it legal to combine this drug with "any vitamin, mineral, enzyme, or any food for special dietary use deemed adjunctive or necessary to Laetrile therapy when prescribed by a physician and surgeon."1 Also, this bill would legalize the manufacturing of the drug. Pressure groups behind this movement have been reported elsewhere<sup>2</sup> and data proving it is not a vitamin<sup>3</sup> but a quack cancer drug<sup>4</sup> have appeared earlier in this journal. Lacking firm evidence that Laetrile is beneficial in the treatment of persons with cancer, one can only assume that it is the profit motive that keeps this nostrum in the public eye. Indeed the profits accruing to smugglers and sellers of the drug are reported to be substantial.<sup>5</sup>

As a part of the propaganda program mustering support for Laetrile, it has been suggested that: (1) no progress has been made in cancer treatment for the past two decades, therefore why not try Laetrile,<sup>6</sup> (2) Laetrile has never been truly tested in this country because the American Cancer Society and other elements of the "establishment" wish to suppress cancer cures for fear of going out of business,<sup>7</sup> (3) Laetrile is completely harmless and nontoxic and in a free society patients should be permitted to treat themselves with any harmless medication they believe effective<sup>8</sup> and (4) it is legal in many countries and patients outside the United States benefit significantly from treatment with it.<sup>7</sup>

The net effect of these claims has been to rally modest support from a broad base of the American public, including physicians. The latter group, in general, have supported the legalization of Laetrile if for no other reason than to remove the profit motive<sup>9</sup> and to provide some hope for terminally ill cancer patients who are frustrated by the inability to receive a drug that they believe may be effective.

In this paper, I will review the scientific data refuting these widely held concepts and then will cover a few issues that portray the negative impact Laetrile's legalization will have on the quality of medicine and health care in our country.

### Support for Laetrile Lacks Credibility

Contrary to the statement that no progress has been made in cancer treatment for the past two decades, Recent Trends in Survival of Cancer Patients<sup>10</sup> shows that substantial progress has been made in all 17 tumor types indexed. The percent increase in five-year survival rates ranges from 0 for one disease only (histiocytic lymphoma in males) to 700 percent for acute lymphocytic leukemia in females. The average increase in fiveyear survival for all patients was 75 percent.

This statement on Laetrile was adopted unanimously by the Cancer Advisory Council of the State of California on May 11, 1977. The material used in this article was offered in testimony against SB 245 before the California State Health and Welfare Committee on March 30, 1977 and before the California Board of Medical Quality Assurance on April 15, 1977. In these hearings Dr. Lewis represented the California Medical Association.

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Progress reflected by these nationwide studies may be directly attributable to improvements in cancer detection, improvements in surgical techniques, and implementation of higher energy radiation therapy. In some cases such as childhood acute leukemia, these data also reflect progress in chemotherapy. Nevertheless, the major advances in the past decade in chemotherapy are yet to be adequately recorded by this survey. For instance, at present histiocytic lymphoma is being successfully treated with a 48 percent complete remission rate and most of these patients do not relapse.<sup>11</sup> In addition, these figures do not reflect totally the impact on survival and cure of the multidisciplinary approach to the cancer patient. Most surely with an updating of the end-result studies we can anticipate even higher percentages of improvement for each cancer cell type. On the other hand, no data have ever been published showing that Laetrile is useful in any type of cancer. Rather the data suggest that Laetrile is a nontreatment for this highly lethal group of diseases.

Contrary to the statement that Laetrile has never been adequately tested,<sup>7</sup> the record shows it has been investigated extensively.<sup>12-25</sup> The conclusion of each study has been that Laetrile is totally worthless. The development and identification of effective chemotherapeutic agents in cancer rely upon studies showing activity of the proposed chemotherapeutic agent in animal tumor systems, as well as in Phase I and II clinical studies. In such systems Laetrile has been found to be inactive. The following summarizes animal and clinical studies on Laetrile:

• In 1953 the first article appeared in the literature using Laetrile in animal trials.<sup>12</sup> Four separate studies were reported utilizing C1300 neuroblastoma tumor in A-mice, acute lymphatic leukemia in DBA line 2 mice, Crocker sarcoma 180 tumors in mice and ear tumors in mice. None of these tumors responded to Laetrile.

• Data from the National Cancer Institute's Testing Program on Laetrile summarized in 1975 included studies done in 1957, 1960, 1969, 1973 and 1975.<sup>13</sup> In these investigations, Laetrile was either tested alone or in combination with its cyanide cleaving enzyme, beta-glucosidase. The following tumor types were investigated for response to Laetrile treatment: carcinoma 775, sarcoma 180, leukemia L1210, Walker 256 carcinoma, lymphoid leukemia P388, B16 melanoma, Lewis lung carcinoma and Ridgway osteogenic sarcoma. "In each of the tests . . . , the compound failed to produce a reproducible antitumor effect."<sup>13</sup>

• As part of the McNaughton Foundation's submission for an investigational new drug application in 1970, other animal studies were reported.14 These had been done by the Scind Research and Development Company, Inc. of San Francisco, California. These studies were carried out on the L1210 mouse leukemia, the S180 tumor, CA755 adenocarcinoma and Walker 256 tumor systems. Waldemar R. Gustavson, Executive Vice President, Scind Research and Development, in a letter to Mr. McNaughton dated October 18, 1968, stated "We are in a position to draw the following conclusions: (1) Laetrile when administered without beta-glucosidase has little or no effect upon the transplanted rodent tumor systems tested, (2) beta-glucosidase when administered without Laetrile has no effect upon the transplanted tumor system tested, (3) Laetrile when administered in conjunction with beta-glucosidase has a highly significant effect upon the tumor system tested" (emphasis theirs). "We are pleased to state that the above is in accordance with predictions by the McNaughton Foundation." Again, therefore, Laetrile by itself was shown to be ineffective. Why it appeared active when combined with beta-glucosidase is not known. When these studies were repeated by others, this beneficial effect was not confirmed.13,15,16

• By 1975 the Arthur D. Little Company had studied Laetrile in L1210, P388, B16 and the Walker 256 tumor systems.<sup>15</sup> Again, Laetrile failed to show a positive effect. The combination of Laetrile plus beta-glucosidase resulted in potentiation of amygdalin's toxicity. In that same year, the Southern Research Institute reported on their studies with the Lewis lung tumor, the Ridgway osteogenic sarcoma and the P388 tumor. They reached the same conclusions—Laetrile was without antitumor activity.<sup>16</sup>

• In 1976 the Washington University School of Medicine investigated the effect of Laetrile alone on the B16 tumor and the BW5147 AKR leukemia and confirmed again that Laetrile was inactive in these systems.<sup>17</sup>

• Recently studies from Sloan-Kettering Institute using transplantable and spontaneous murine tumors have been reported by C. Chester Stock.<sup>18</sup> These studies again show no response. "We have tested amygdalin at high doses, 1,000 mg/k/day, in over a dozen transplantable tumor

systems and one induced tumor system without seeing any action against the tumors. The chemotherapeutic agents effective in clinical cancer have had or would have had their activities detected in one or more of those systems." This report corrects the controversial report "leaked" to the press in 1973 suggesting Sugiura's studies at Sloan-Kettering showed Laetrile to be beneficial.<sup>19</sup> Dr. Stock, in commenting on follow-up studies to Sugiura's preliminary investigations, goes on to state, "Subsequent experiments, in some of which Dr. Sugiura participated, some conducted in conjunction with Dr. Daniel Martin of the Catholic Medical Center of Brooklyn and Queens and some which were independent by other investigators in our Institute, showed that the initial results were not consistently observable. In some experiments there were more metastatic mice in the treated than in the control mice. In the latest experiment in which Dr. Sugiura read the lungs of the mice without knowing what treatment they had received, there was essentially no difference found between the treated and control groups. In summary, not even the spontaneous mammary tumor experiments offer me encouragement to recommend amygdalin for clinical trial."18

• Limited studies have also been conducted with three dogs and one cat with naturally occurring tumors (personal communication with W. D. Hardy, Memorial Sloan-Kettering Cancer Institute, May 1977). No antitumor effect was observed when Laetrile was administered at a dose of 100 mg per kg of body weight per day given intravenously six days per week for five weeks. The cat with mammary adenocarcinoma and two dogs with mammary adenocarcinomas were treated for five and six weeks respectively. One dog with renal carcinoma was treated for two weeks. It was found that 1 mg per kg of body weight per day of Laetrile given to healthy dogs intraperitoneally was tolerated well, while an oral dose of 100 mg per kg was lethal within three days.

In summary, Laetrile has failed as an active chemotherapeutic agent in the usual acceptable animal tumor screens that classically have been utilized to identify potentially active anticancer drugs. From this, one would predict that Laetrile would be inactive in man. Clinical studies in humans published to date tend to confirm this impression:

• In January of 1953 the Cancer Commission in California obtained clinical data on 44 patients with cancer who had been treated with Laetrile.<sup>12</sup>

Supposedly these data were selected to show the beneficial effect of this drug. At the time of the report, 19 had died of their disease. Seven were lost to follow-up and had cancer at the time they left the study. Seventeen patients were still alive, six of whom may have had static disease, eight had progressive disease, and three were terminal. One patient had no evidence of cancer. She was a woman with preinvasive epidermoid carcinoma of the uterus. This was initially diagnosed on biopsy, but on rebiopsy was not verified. None of these 44 patients had objective evidence of control of cancer under treatment with Laetrile alone. These patients in whom stabilization of disease was seen were receiving other forms of chemotherapy or had received radiation. In nine of the 19 patients who had died by the time of the report, autopsy studies were done and tissues examined by five different pathologists. They all agreed that there was no evidence of any chemotherapeutic effect on the tumor at the time of autopsy.

• In 1957, Dr. Navarro, an Assistant Professor of Biochemistry from Manila, published results of Laetrile in 14 patients with cancer.<sup>20</sup> These cases were published without controls and no evidence of prolongation of life was offered. In that same year, Dr. Navarro reported on 83 patients he had treated with Laetrile.<sup>21</sup> The length of survival of his patients ranged from 7 to 24 months. No evidence was provided that this was an extension of life for these patients. In both of his articles, Dr. Navarro stressed that "Laetrile is hydrolyzed by the hydrochloric acid in the stomach; hence, it should never be given by mouth."

• In 1962 an attending surgeon at Jersey City Medical Center, Dr. John Morrone, published a brief report of ten patients treated in the United States with Laetrile. His conclusions were that there was a possible regression of tumor in some of these patients. His data were incomplete as no data were provided on the effects of Laetrile on overall survival.<sup>22</sup>

• In 1970 the Contreras Clinic assembled 702 cases treated with Laetrile.<sup>23</sup> Of these, 62 patients died within the first three weeks of treatment. No explanation is given for the cause of death in these patients, although it is impled that death was secondary to cancer. Dr. Contreras thought that several types of cancer might be treatable with Laetrile with response rates between 30 and 35 percent. These so-called responsive tumors included cancer of the prostate, lung, breast and

uterus, and lymphoma. After one year of treatment, however, only 23 of the 702 patients (approximately 3 percent) appeared to have benefited from Laetrile treatments. Of some concern in his report was the fact that 3.6 percent of the patients died of undetermined causes. Dr. Contreras himself noted that one patient after taking 6 grams of Laetrile orally experienced acute intoxication with vomiting, dizziness, slight cyanosis and headache. In addition, other patients had an allergy to this substance. From his data, one can only conclude that any responses patients might have experienced with Laetrile were indeed exceedingly brief.

• In 1970 Hans Nieper of Germany wrote on 35 cases of patients with cancer treated with Laetrile.<sup>24</sup> In contrast to Dr. Navarro,<sup>20,21</sup> Dr. Nieper felt that orally given Laetrille was considerably more effective than the intravenously administered preparation. Reading through his case reports, there may be five or six of his 35 patients that had some objective improvement. Since these patients were receiving other therapies in addition to Laetrile, it is difficult, if not impossible, to know which agent should be credited with any objective response. One patient with a brain tumor was made decidely worse with Laetrile; in addition, some patients experienced nausea following ingestion of the drug and some noted increase in nerve pain.

• In 1970, the McNaughton Foundation submitted an investigational new drug (IND) application for the clinical study of Laetrile. The animal studies reported in this application have been alluded to earlier.<sup>14</sup> In addition, clinical data were submitted. These data were considered insufficient to warrant the issuing of an IND license. One year later an ad hoc committee of oncology consultants for the review and evaluation of amygdalin appointed by the Food and Drug Administration reviewed this application and stated "Clinical material on the present IND 6734 does not fulfill minimal requirements for such decisions as to human efficacy. This committee would welcome the opportunity to review such material, including case reports, which will substantiate claims in an effort to assist the proper evaluation of amygdalin MF."25 To date no such cases have been submitted to the Food and Drug Administration.

These human data parallel the animal tumor screen data that failed to show a beneficial response to Laetrile. This confirms the validity of the animal screen approach to the selection of potentially active chemotherapeutic agents.

In hopes of collecting additional data from clinics that presently prescribe Laetrile, one of my associates wrote to Dr. Contreras of Mexico, Dr. Hans Nieper of Germany and Dr. Navarro of the Philippines. Responses from all three Laetrile proponents have been received. Each letter reads essentially the same; they have no new data.

Contrary to being completely harmless and nontoxic, Laetrile is a poison. Amygdalin (Laetrile) contains cyanide, a respiratory enzyme poison. In humans, 200 mg of cyanide is toxic. Three grams of Laetrile contains 180 mg of cyanide. Cyanide is released from amygdalin in the presence of beta-glucosidase. If one ingests foods containing beta-glucosidase with Laetrile tablets, cyanide is cleaved and evidence of cyanide poisoning occurs. Quoting from Harrison's textbook Principles of Internal Medicine, "The cyanide ion is an exceedingly potent and rapid acting poison . . . . Parts of many plants also contain substances such as amygdalin which release cyanide on digestion. Among these are the seeds of certain stone fruits (choke cherry, pin cherry, wild black cherry, peach, apricot, bitter almond), cassava roots, etc. . . . As little as 300 mg of potassium cyanide may cause death."26 Examples of toxicity and fatalities follow:

• In 1942 in the American Journal of Medical Science, four cases of cyanide poisoning following ingestion of seeds were reported in Indians in the western United States.<sup>27</sup>

• In 1960 four cases of cyanide poisoning were reported from France following the ingestion of amygdalin.<sup>28</sup>

• In 1961, again in the French literature, a case of a 4-year-old French girl was reported who became comatose after consuming ground-up peach seeds.<sup>29</sup>

• In 1964 the experience at Children's Hospital in Ankara, Turkey was reported, again pointing to the hazardous effect of ingestion of kernels of bitter almond. They reported nine cases of cyanide intoxication which required admission of the patients to hospital; two of these patients died. The poisoning was identified as being secondary to the ingestion of apricot seeds. The incidence of cyanide poisoning secondary to ingestion of apricot seeds was essentially the same as that of poisoning secondary to salicylates.<sup>30</sup>

• In 1965 a fatal case of cyanide poisoning was reported following ingestion of bitter almonds.<sup>31</sup>

• In 1969 a similar but nonfatal case of cyanide poisoning was reported following the ingestion of bitter almonds.<sup>32</sup>

• In 1972 an article was published in the foreign literature of another fatal case of cyanide poisoning following the ingestion of amygdalin.<sup>33</sup>

• In September of 1972, in California Morbidity, a weekly report from the Bureau of Communicable Disease Control, a case of cyanide poisoning was reported following ingestion of apricot kernels purchased from a health food store.<sup>34</sup> The story is indeed most informative. "A man and his wife purchased a two-pound bag of apricot kernels at a local health food store. They soaked some 30 kernels with dried apricots in distilled water overnight and the following day pureed the ingredients in a blender. The resulting concoction was bitter and took some effort to swallow. About an hour after drinking the mixture, the wife complained of abdominal discomfort, tachycardia, and feeling strange. She drank some water and vomited. Within minutes of his wife's onset, the husband became symptomatic also and complained of headache, lightheadedness, tachycardia, a generally strange sensation, and impaired vision . . . 'as if looking through frosted glass.' He felt impending doom. They were rushed to the emergency room of a nearby hospital. Vomiting was successfully induced, and after several hours of observation they were released. For the next three days the husband complained of insomnia and tinnitus. The wife had diarrhea which abated in one day. Both recovered fully."

• In November of 1975 a case of cyanide poisoning associated with forceful vomiting, headache, flushing, heavy perspiration, dizziness and faintness was reported in a man who had ingested 48 apricot kernels.<sup>35</sup>

• In December of that same year, another case of cyanide poisoning following ingestion of apricot kernels was reported in California. In this case a woman ate a "handful" of apricot kernels purchased at a "nutrition center" in Santa Clara County and within 30 minutes headache, rapid heart rate, a light-headedness, flushing and generalized weakness developed. Cyanide was identified in her serum.<sup>36</sup>

• In reading the literature from the Laetrile proponents, one cannot help but be impressed with the variety of toxic effects this drug produces, including fall in blood pressure,<sup>21,22</sup> itching,<sup>20,22</sup> free hemoglobin in the urine, hemorrhage

into the gastrointestinal tract and the tumor,<sup>20</sup> fever,<sup>20.21</sup> and occasionally an increase in neuritis.<sup>24</sup> Also reported are vomiting, dizziness, slight cyanosis and headache.<sup>23</sup> When Laetrile is injected with beta-glucosidase, other side effects are seen, such as coughing, a sense of suffocation and pain in the lumbar region.<sup>21</sup> I have recently spoken with one of my patients who has been to the Contreras Clinic and she tells me that she too experienced nausea when taking oral Laetrile. Another patient has told me that several persons at the Contreras Clinic had serious reactions to Laetrile injections, including diarrhea, vomiting and high fevers.

• As regards chronic toxicity, we really have no data. There are statements that neuritis is made worse by administration of Laetrile;<sup>24</sup> this suggests that it may be chronically toxic to the nervous system. This has been adequately shown in Africa following cassava root ingestion. Cassava root contains an amygdalin-like substance which leads to severe nervous system dysfunction.<sup>37</sup> Long-term ingestion of this cyanogenic compound has also been postulated to be goitrogenic.<sup>38</sup>

• Another area of toxicity that is of considerable concern is the effects on fetuses. A teratogenic effect of Laetrile was suggested by the McNaughton Foundation in their 1970 IND application.<sup>14</sup> In these investigations pregnant rats were fed 5 or 25 mg per kg of body weight per day of Laetrile orally. Offspring of these rats were then studied for deforming effects of Laetrile. In rats given no Laetrile, one fetus was found to have a kidney abnormality. In rats receiving 5 mg per kg of Laetrile orally, one fetus was found to have a kidney defect, and two fetuses with abnormal kidneys were found in rats fed 25 mg per kg orally. In addition, one fetus from the group receiving 5 mg per kg orally had hydrocephalus. These findings would suggest that this drug may have an adverse effect on a developing fetus, and although it might not be as bad as thalidomide, additional studies are needed before this drug could be released for human consumption by pregnant patients.

• Some have suggested that, if legalized, Laetrile should be used only on hopelessly ill patients with cancer. These patients, however, present special problems which have not been adequately investigated. For instance, the acute toxicity of Laetrile in tumor-bearing animals is much greater than is the acute toxicity of Laetrile in non-tumorbearing animals.<sup>14</sup> This suggests that the more tumor that is present, the more toxic the Laetrile becomes. Consequently, in patients with far advanced cancer extreme toxicity might occur when Laetrile is given. In addition, these patients invariably have liver and renal damage either secondary to the tumor or to some metabolic dysfunction associated with their basic disease process. Laetrile is detoxified by rhodenase which is found in high levels in the liver. Is this same high level found in a cancerous liver? We have no data on this. The water-soluble benzaldehyde and cyanide moieties are excreted by the kidney. What is the effect of kidney failure on Laetrile's toxicity? Again, the data are not available.

In summary, Laetrile has a myriad of toxic effects in man and in some cases ingestion of amygdalin is fatal. It is hard to reconcile these facts with the cry of the Laetrile advocates that Laetrile should be legalized because this is a free country and freedom of choice demands that nontoxic drugs, even though not efficacious, be available to all who wish them.

If use of Laetrile is legalized for terminally ill patients, it will be used soon by patients with potentially curable disease as well. These patients, because of the adverse publicity that proponents of Laetrile have given to standard effective therapy (cutting, burning and poisoning), will be diverted from beneficial therapies to ineffective Laetrile. Ineffective treatment for early disease preempts ethical physicans' opportunities to cure cancer. According to a conversation\* with Robert Bradford, President, Committee for Freedom of Choice in Cancer Therapy, Inc., fully 50 percent of patients going to practitioners who prescribe Laetrile have early disease. When asked if he meant by this that patients with Stage I Hodgkin disease, isolated breast tumors or small neoplastic colon polyps were receiving Laetrile, the answer was "Yes, isn't that wonderful!" It is also true that patients who are seen by Laetrile doctors do not undergo standard staging procedures nor do they receive accepted forms of treatment plus Laetrile. Patients seen in the medical oncology clinics at the Sacramento Medical Center confirm this. Those of our patients who have received Laetrile illegally in Mexico or California have not been properly

If states choose to make Laetrile a legal drug for terminally ill patients, it is only natural that patients will assume that if it is good for the terminally ill, it will be good for the minimally ill, and then finally it should be released for prophylaxis against cancer. Therefore, initial legalization, even though it may be highly restrictive, will soon lead to indiscriminate use of this drug since the proponents of Laetrile have been quite vocal in recent years proclaiming this as a prophylactic drug against cancer. Furthermore, legalization of Laetrile for the terminally ill suggests that critically ill patients are not entitled to our usual consumer protection laws; these laws prevent the use of worthless drugs in the treatment of disease.

In small doses, orally given Laetrile may not be harmful, but when ingested with uncooked foods such as fresh apples, sweet almonds or bean sprouts—which contain the beta-glucosidase enzyme—cyanide may be released, with the patient suffering the effects of cyanide poisoning (personal communication with Eric E. Conn, PhD, Professor of Biochemistry, University of California, Davis, April 1977).

Contrary to Laetrile proponents, this drug is not legal and freely prescribed in many countries. In 1975 and 1976 the following countries were contacted by Dr. Sherwood Lawrence, Executive Secretary, Cancer Advisory Council, Department of Health, State of California: Israel, Australia, Greece, Belgium, United Kingdom and India. Each of these countries had been reported at one time or another to have legalized Laetrile.<sup>6</sup> Responses from the Secretaries of Health or the equivalent from each of these countries stated that Laetrile was not legal and that no applications had been made to legalize it. In view of the proximity of Mexico to the United States and of the commonly held belief that it is widely utilized in that country, it is pertinent to quote from a letter dated August 21, 1975, from the Secretary of Health and Assistance of Mexico to Dr. Lawrence. The translation states that the direct selling of amygdalin to the general public is prohibited; it is available only to investigators, hospitals or clinics with the intention of continuing investigations; it was only permitted to be advertised as an "analgesic in some forms of lung cancer." They further state that Laetrile's analgesic effect is not comparable to that of narcotics. Recently the Mexican government has moved to terminate the

<sup>\*</sup>At a meeting on October 25, 1976, in the offices of Governor Brown of California, attended by myself, Sherwood Lawrence, MD (Executive Secretary, Cancer Advisory Council, Department of Health), and two members of the Committee for Freedom of Choice in Cancer Therapy, Inc., including Mr. Bradford.

production of Laetrile because it has not been shown to be of value as a cancer remedy and it is this claim that accounts for the sale and exportation of amygdalin in Mexico (personal communication from the United States Embassy in Mexico to Secretary of State, Washington, D.C., April 1977).

# The Negative Impact of Laetrile's Legalization

Bills such as those being promulgated in California formalize a new type of physician, one who practices "holistic medicine." Such a person is freed from ethical standards and made immune to prosecution as long as he practices within his confined field. Senate Bill 245, amended April 14, 1977, in effect legalizes the introduction of ineffective treatments for human disease.<sup>1</sup> This runs counter to the practice of ethical medicine and also strikes at the very heart of our solid research programs and broad-based medical education system, which attempts to bring effective therapies to the forefront.

It seems incongruous at a time when our gross national product devotes 8.3 percent to health care delivery that we would be considering the interjection of worthless treatments into clinical medicine. This will only raise costs and, of course, with the delay in treatment associated with Laetrile's administration, patients will be appearing with more advanced disease for standard therapy. The latter type of patient is certainly more costly to manage than is a patient with early disease.

The federal government, through the Kefauver-Harris Drug Amendments of 1962, prevents the interstate shipment of drugs that are merely safe but ineffective. State legislatures at this moment are attempting to circumvent this consumer protection law by providing for the manufacture, sale, prescription and use of Laetrile within state confines. Consequently the protection afforded us by the federal government through the Kefauver-Harris Drug Amendments becomes null and void. This suggests that many of the nostrums of the past decades may once again be manufactured and distributed on druggist shelves.

The State of California, through its Board of Medical Quality Assurance, attempts to provide continued surveillance of the qualty of medicine that is practiced within the state. Organized medicine has become active in Professional Standards Review Organizations (PSRO) in an attempt to upgrade the quality of medicine. Bills legalizing Laetrile and other worthless remedies essentially emasculate Boards of Medical Quality Assurance and make meaningless PSRO activities. The passage of Laetrile legalization bills makes it impossible to protect the public from the quasiethical and the unethical practitioner.

If a completely useless drug can be promulgated for the treatment of a highly lethal yet potentially curable disease, it is likely that additional useless drugs will find their way into the market place through state legislative actions for treatment of incurable chronic diseases, such as heart disease, diabetes, arthritis and the like. This is definitely a step back into the sordid past of medical history where quacks could be found providing useless devices, services and remedies for a variety of ailments.

Not to be overlooked is the fact that Laetrile as a worthless remedy is a ripoff. From conversations with my patients, I am led to believe that an average patient in California pays approximately \$2,200 for six months of treatment with Laetrile. One of our patients has spent more than \$4,000 for Laetrile treatment over the past 18 months. During this time, while away from standard forms of therapy, her initial Stage III-A nodular sclerosing Hodgkin disease with a greater than 61 percent five-year disease-free interval response rate has progressed to Stage IV-B with a less than 27 percent five-year disease-free response rate.39 Therefore, for a \$4,000 investment in her "nontoxic treatment," she has lost at least a 30 percent chance of being free of disease at five years. Since the tumor now involves her spinal cord and she is paraparetic, she may never walk even if we are successful in arresting her disease at this point.

## Summary

In this report I have examined the facts about Laetrile. I find not a shred of evidence that this drug will play even a minor role in oncology in the future. The drug is toxic, at times highly so; it is teratogenic; it may be goitrogenic; it may cause deaths; and all animal and human cancer studies reported to date have failed to show prolongation in survival or a substantial reduction in tumor size.

Legislation responsive to Laetrile's pressure groups has the real potential of diverting patients with treatable and curable cancer away from the skilled care of competent physicians toward less knowledgeable practitioners who believe more in the propaganda of pro-Laetrile fanatics than in the current data showing real progress in cancer treatment. With the passage of bills legalizing a worthless remedy for a curable disease, we see a precedent being set that will lead to a reorientation of our entire health care services, a reorientation away from efficacious therapies toward useless nostrums. Let us hope our medical and legal professions will see the issues clearly and be guided by facts, not fantasy.

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