



State Medical Board of Ohio

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December 11, 2002

Kenneth N. Michaelis, L.M.T.
9181 Baker Road
St. Louisville, OH 43071

Dear Mr. Michaelis:

Please find enclosed certified copies of the CORRECTED Entry of Order; the Report and Recommendation of Sharon W. Murphy, Attorney Hearing Examiner, State Medical Board of Ohio; and an excerpt of draft Minutes of the State Medical Board, meeting in regular session on December 11, 2002, including motions approving and confirming the Findings of Fact and Conclusions of the Hearing Examiner, and adopting an amended Order.

Section 119.12, Ohio Revised Code, may authorize an appeal from this Order. Such an appeal must be taken to the Franklin County Court of Common Pleas.

Such an appeal setting forth the Order appealed from and the grounds of the appeal must be commenced by the filing of a Notice of Appeal with the State Medical Board of Ohio and the Franklin County Court of Common Pleas. Any such appeal must be filed within fifteen (15) days after the mailing of this notice and in accordance with the requirements of Section 119.12, Ohio Revised Code.

THE STATE MEDICAL BOARD OF OHIO

Anand G. Garg, M.D.
Secretary

AGG:jam
Enclosures

CERTIFIED MAIL RECEIPT NO. 7000 0600 0024 5151 0193
RETURN RECEIPT REQUESTED

Cc: Elizabeth Y. Collis, Esq.
CERTIFIED MAIL RECEIPT NO. 7000 0600 0024 5151 0186
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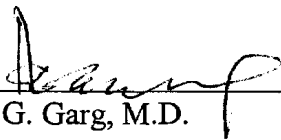
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CERTIFICATION

I hereby certify that the attached copy of the CORRECTED Entry of Order of the State Medical Board of Ohio; Report and Recommendation of Sharon W. Murphy, State Medical Board Attorney Hearing Examiner; and excerpt of draft Minutes of the State Medical Board, meeting in regular session on December 11, 2002 including motions approving and confirming the Findings of Fact and Conclusions of the Hearing Examiner, and adopting an amended Order; constitute a true and complete copy of the Findings and Order of the State Medical Board in the Matter of Kenneth N. Michaelis, L.M.T., as it appears in the Journal of the State Medical Board of Ohio.

This certification is made by authority of the State Medical Board of Ohio and in its behalf.

(SEAL)



Anand G. Garg, M.D.
Secretary

December 11, 2002

Date

BEFORE THE STATE MEDICAL BOARD OF OHIO

IN THE MATTER OF

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KENNETH N. MICHAELIS, L.M.T.

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CORRECTED ENTRY OF ORDER

This matter came on for consideration before the State Medical Board of Ohio on December 11, 2002.

Upon the Report and Recommendation of Sharon W. Murphy, State Medical Board Attorney Hearing Examiner, designated in this Matter pursuant to R.C. 4731.23, a true copy of which Report and Recommendation is attached hereto and incorporated herein, and upon the modification, approval and confirmation by vote of the Board on the above date, the following Order is hereby entered on the Journal of the State Medical Board of Ohio for the above date.

It is hereby ORDERED that:

- A. **SUSPENSION:** The certificate of Kenneth N. Michaelis, L.M.T., to practice massage therapy in the State of Ohio shall be SUSPENDED for a period of at least 180 days.
- B. **CONDITIONS FOR REINSTATEMENT OR RESTORATION:** The Board shall not consider reinstatement or restoration of Mr. Michaelis' certificate to practice massage therapy unless all of the following conditions have been met:
 1. **Application and Fees:** Mr. Michaelis shall submit an application for reinstatement or restoration, accompanied by appropriate fees, if any.
 2. **Demonstration of Compliance with Terms Imposed by the Court:** Mr. Michaelis shall demonstrate to the satisfaction of the Board that he is in full compliance with all terms imposed by the United States District Court for the Southern District of Ohio in *United States of America vs. Kenneth N. Michaelis*, Case No. CR2-00-115.

3. **Successful Completion of Both Portions of the Massage Therapy Examination:** Mr. Michaelis shall successfully complete the Basic Sciences and Limited Branch portions of the Massage Therapy Examination and that he otherwise meets all statutory and regulatory requirements.
4. **Absence from Practice:** In the event that Mr. Michaelis has not been engaged in the active practice of massage therapy for a period in excess of two years prior to the submission of his application for reinstatement or restoration, the Board may exercise its discretion under Section 4731.222, Ohio Revised Code, to require additional evidence of Mr. Michaelis' fitness to resume practice.

C. **PROBATION:** Upon reinstatement or restoration, Mr. Michaelis' certificate shall be subject to the following PROBATIONARY terms, conditions, and limitations for a period of at least three years:

1. **Requests for Modification:** Mr. Michaelis shall not request modification of the terms, conditions, or limitations of probation for at least one year after imposition of these probationary terms, conditions, and limitations.
2. **Laws in Ohio and Terms of Criminal Probation:** Mr. Michaelis shall obey all federal, state and local laws, all rules governing the practice of massage therapy in Ohio; and all terms imposed by the United States District Court for the Southern District of Ohio in *United States of America vs. Kenneth N. Michaelis*, Case No. CR2-00-115.
3. **Appearances:** Mr. Michaelis shall appear in person for interviews before the full Board or its designated representative during the third month following the month in which probation becomes effective, provided that if the effective date is on or after the 16th day of the month, the first personal appearance must occur during the fourth month following. Subsequent personal appearances must occur every third month thereafter, upon Mr. Michaelis' request for termination of the probationary period, and/or as otherwise requested by the Board.

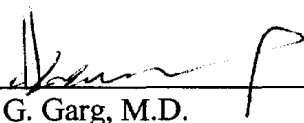
If an appearance is missed or is rescheduled for any reason, ensuing appearances shall be scheduled based on the appearance date as originally scheduled. Although the Board will normally give him written notification of scheduled appearances, it is Mr. Michaelis' responsibility to know when personal appearances will occur. If he does not receive written notification from the Board by the end of the month in which the appearance should have occurred, Mr. Michaelis shall immediately submit to the Board a written request to be notified of his next scheduled appearance.

4. **Quarterly Declarations**: Mr. Michaelis shall submit quarterly declarations under penalty of Board disciplinary action or criminal prosecution, stating whether there has been compliance with all the conditions of probation. The first quarterly declaration must be received in the Board's offices on the first day of the third month following the month in which probation becomes effective, provided that if the effective date is on or after the 16th day of the month, the first quarterly declaration must be received in the Board's offices on the first day of the fourth month following. Subsequent quarterly declarations must be received in the Board's offices on or before the first day of every third month.
 5. **Absence from Ohio**: In the event that Mr. Michaelis should leave Ohio for three consecutive months, or reside or practice outside the State, Mr. Michaelis must notify the Board in writing of the dates of departure and return. Periods of time spent outside Ohio will not apply to the reduction of this probationary period, unless otherwise determined by motion of the Board in instances where the Board can be assured that the purposes of the probationary monitoring are being fulfilled.
 6. **Violation of Probation; Discretionary Sanction Imposed**: If Mr. Michaelis violates probation in any respect, the Board, after giving him notice and the opportunity to be heard, may institute whatever disciplinary action it deems appropriate, up to and including the permanent revocation of his certificate.
- D. **TERMINATION OF PROBATION**: Upon successful completion of probation, as evidenced by a written release from the Board, Mr. Michaelis' certificate will be fully restored.
- E. **REQUIRED REPORTING BY LICENSEE TO EMPLOYERS AND HOSPITALS**: Within thirty days of the effective date of this Order, Mr. Michaelis shall provide a copy of this Order by certified mail to all employers or entities with which he is under contract to provide health care services or is receiving training, and the Chief of Staff at each hospital where Mr. Michaelis has privileges or appointments. Further, Mr. Michaelis shall provide a copy of this Order by certified mail to all employers or entities with which he applies or contracts to provide health care services, or applies for or receives training, and the Chief of Staff at each hospital where Mr. Michaelis applies for or obtains privileges or appointments. Further, Mr. Michaelis shall provide this Board with a copy of the return receipt as proof of notification within thirty days of receiving that return receipt.
- F. **REQUIRED REPORTING BY LICENSEE TO OTHER STATE LICENSING AUTHORITIES**: Within thirty days of the effective date of this Order,

Mr. Michaelis shall provide a copy of this Order by certified mail, return receipt requested, to the proper licensing authority of any state or jurisdiction in which he currently holds any professional license. Mr. Michaelis shall also provide a copy of this Order by certified mail, return receipt requested, at the time of application to the proper licensing authority of any state in which he applies for any professional license or reinstatement of any professional license. Further, Mr. Michaelis shall provide this Board with a copy of the return receipt as proof of notification within thirty days of receiving that return receipt.

EFFECTIVE DATE OF ORDER: This Order shall become effective immediately upon the mailing of notification of approval by the Board.

(SEAL)



Anand G. Garg, M.D.
Secretary

December 11, 2002

Date

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**REPORT AND RECOMMENDATION
IN THE MATTER OF KENNETH N. MICHAELIS, L.M.T.**

The Matter of Kenneth N. Michaelis, L.M.T., was heard by Sharon W. Murphy, Attorney Hearing Examiner for the State Medical Board of Ohio, on September 17, 2002.

INTRODUCTION

I. Basis for Hearing

- A. By letter dated July 10, 2002, the State Medical Board of Ohio [Board] notified Kenneth N. Michaelis, L.M.T., that it had proposed to take disciplinary action against his certificate to practice massage therapy in this state. The Board based its proposed action on allegations that, on or about May 11, 2001, in the United States District Court, Southern District of Ohio, Mr. Michaelis had pleaded guilty to, and was found guilty of, one felony count of Introduction of an Unapproved Drug [Laetrile] into Interstate Commerce, in violation of 21 United States Code, Sections 331(b) and 355(a)(2), and 18 United States Code, Section 2.

The Board further alleged that Mr. Michaelis' guilty plea and/or the judicial finding of guilt constitute "[s]elling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes or a plea of guilty to, a judicial finding of guilt of, or a judicial finding of eligibility for treatment in lieu of conviction of, a violation of any federal or state law regulating the possession, distribution, or use of any drug,' as those clauses are used in R.C. 4731.22(B)(3)[; and/or] '[a] plea of guilty to, a judicial finding of guilt of, or a judicial finding of eligibility for intervention in lieu of conviction for, a felony,' as that clause is used in R.C. 4731.22(B)(9)."

Accordingly, the Board advised Mr. Michaelis of his right to request a hearing in this matter. (State's Exhibit 1A).

- B. On July 22, 2002, Elizabeth Y. Collis, Esq., submitted a written hearing request on behalf of Mr. Michaelis. (State's Exhibit 1B).

II. Appearances

- A. On behalf of the State of Ohio: Betty D. Montgomery, Attorney General, by Mark A. Michael, Assistant Attorney General.
- B. On behalf of the Respondent: Elizabeth Y. Collis, Esq.

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EVIDENCE EXAMINED

I. Testimony Heard

Presented by the Respondent

1. Philip E. Binzel, D.O.
2. Kenneth N. Michaelis, L.M.T.

II. Exhibits Examined

A. Presented by the State

1. State's Exhibits 1A-1M: Procedural exhibits.
2. State's Exhibit 2: Certified copies of documents pertaining to Mr. Michaelis maintained by the United States District Court for the Southern District of Ohio in *United States of America vs. Kenneth N. Michaelis*, Case No. CR2-00-115.

B. Presented by the Respondent

Respondent's Exhibits A-D: Letters written to the Board in support of Mr. Michaelis.

SUMMARY OF THE EVIDENCE

All exhibits and transcripts of testimony, even if not specifically mentioned, were thoroughly reviewed and considered by the Hearing Examiner prior to preparing this Report and Recommendation.

1. Kenneth N. Michaelis, L.M.T., testified that he has a high school education. Mr. Michaelis took a massage therapy course in 1985, and is licensed to practice massage therapy in Ohio. Mr. Michaelis testified that he has not practiced massage therapy in over ten years. He stated that he is the president of Holistic Alternatives, a corporation located in Newark, Ohio, that sells dietary supplements, vitamins, minerals, and herbs. He stated that Holistic Alternatives primarily does business over the Internet, by mail, or by phone. (Hearing Transcript [Tr.] at 45-46).

Mr. Michaelis testified that the business was started by his father in the early 1970s. It was then known as A.O. Supply Company. Mr. Michaelis became involved in the business when he was thirteen years old. Mr. Michaelis stated that his father passed away in 1994, and that

Mr. Michaelis has been running the business since that time. Mr. Michaelis changed the name of the business to Holistic Alternatives. (Tr. at 46-47).

Mr. Michaelis testified that one of the products that was sold by A.O. Supply Company and Holistic Alternatives was Laetrile. (Tr. at 48-49).

2. On July 18, 2000, an Indictment was filed in the United States District Court, Southern District of Ohio, in *United States of America vs. Kenneth N. Michaelis*, Case No. CR2-00-115. The allegations set forth in the Indictment included the following:
 - a. The United States Food and Drug Administration [FDA] is charged with ensuring that a drug is safe, effective, and properly labeled for its intended use, before that drug can be legally marketed in interstate commerce. Accordingly, a drug's manufacturers and re-packagers are required to comply with applicable provisions of the Federal Food, Drug, and Cosmetic Act [FD&C Act] 21 U.S.C. §321(g).
 - b. "Laetrile," "Amygdalin," "Kemdaline," and "Vitamin B-17," [among others], [hereinafter collectively described as "Laetrile"] that were intended for use in the cure, mitigation, treatment, or prevention of cancer are drugs within the meaning of 21 U.S.C. §321(g).
 - c. The FD&C Act prohibits the introduction of new drugs into interstate commerce, unless the new drugs are the subject of an approved marketing or investigational application.
 - d. A drug is a "new drug" if it is "not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof * * *."
 - e. "Laetrile was not generally recognized as safe and effective by qualified experts for the treatment of cancer and there were no approved marketing or investigational applications on file with FDA for Laetrile."
 - f. From at least August 1994 through January 2000, Mr. Michaelis was doing business either as AO Supply in Newark, Ohio, or as Holistic Alternatives in St. Louisville, Ohio. Through these organizations, Mr. Michaelis did the following:
 - i. obtained injectable and tablet forms of Laetrile from Mexico and repackaged them;
 - ii. provided commercial size quantities of Laetrile to other businesses in the United States;

- iii. distributed Laetrile to consumers throughout the United States “with the intention to cure, mitigate, treat, or prevent cancer”; and
- iv. “with intent to defraud and mislead the FDA,” shipped Laetrile to companies in other states.

(State’s Exhibit [St. Ex.] 2 at 1-21).

- 3. On May 11, 2001, Mr. Michaelis pleaded guilty to, and was found guilty of, one felony count of Introduction of an Unapproved Drug [Laetrile] into Interstate Commerce, in violation of 21 United States Code, Sections 331(b) and 355(a)(2), and 18 United States Code, Section 2. (St. Ex. 2 at 22-29).

Moreover, on May 11, 2001, the United States Attorney for the Southern District of Ohio filed a Complaint for Permanent Injunction, seeking to permanently enjoin Mr. Michaelis from performing a number of acts, including the following:

- a. introducing new drugs or misbranded drugs into interstate commerce; or holding for sale, manufacturing, repackaging or distributing Laetrile; unless certain conditions had first been met;
- b. promoting or advertising that Laetrile is “safe and/or effective in the cure, mitigation, treatment, or prevention of any disease * * *”; and
- c. introducing misbranded drugs into interstate commerce.

In addition, the Complaint for Permanent Injunction sought to authorize the FDA to inspect Mr. Michaelis’ place of business and his business records to ensure compliance with the injunction, with costs to be borne by Mr. Michaelis. (St. Ex. 2 at 30-36). Mr. Michaelis consented to the terms of the injunction without contest. Accordingly, the court granted a Consent Decree of Permanent Injunction. (St. Ex. 2 at 37-45).

On October 30, 2001, the court sentenced Mr. Michaelis to imprisonment for six months, to be served at the Ralph W. Alvis House in Columbus, Ohio. Moreover, the court ordered that, upon release from imprisonment, Mr. Michaelis would be placed on supervised release for a term of one year, the first six months of which Mr. Michaelis would be confined to his home with electronic monitoring. Further, the court ordered Mr. Michaelis to pay a monetary penalty in the amount of \$10,000.00. (St. Ex. 2 at 46-52).

- 4. Philip E. Binzel, D.O., testified at hearing on behalf of Mr. Michaelis. Dr. Binzel testified that he had received his degree in osteopathy from St. Louis University in St. Louis, Missouri. He completed a year of internship and a year of general practice residency at Christ Hospital in Cincinnati, Ohio. In 1955, Dr. Binzel entered private practice as a family

physician in Washington Courthouse, Ohio. He remained there until his retirement from the practice of medicine in 1992. (Tr. at 16-17).

Dr. Binzel testified that, during the first eighteen years of his practice, he had treated cancer patients in the traditional manner, with surgery, radiation, and chemotherapy. He stated that he "got the same results than everybody else did - - almost all of them died." (Tr. at 21-22).

Dr. Binzel stated that, in the 1950s, a number of physicians and scientists, including Dr. Ernst Krebs, embarked in research directed toward preventing metastatic disease through the use of a nutritional program based on vitamins, enzymes, Laetrile, and diet. The diet consisted primarily of raw fruits and raw vegetables, and limited amounts of animal protein. Dr. Binzel testified that the research concluded that Laetrile could be effective in supporting the body's defense mechanisms in controlling the spread of cancer in the body. It did not conclude that Laetrile would cure cancer or make a tumor disappear, but merely stated that Laetrile would be beneficial in preventing metastasis. (Tr. at 21-22).

Binzel testified that Laetrile is a concentrated form of nitrilosides, which can be found in raspberries, blackberries, blueberries, and strawberries. He stated that there are about 1,500 foods that contained nitrilosides. Dr. Binzel testified that there has been a lot of misinformation about Laetrile disseminated, most often by the FDA. Dr. Binzel stated that the FDA claims that Laetrile doesn't work because it doesn't make a tumor "magically disappear." Dr. Binzel agreed that Laetrile does not make tumors disappear, restating that it is beneficial as part of a nutritional program geared toward preventing metastatic disease. (Tr. at 20-22, 35).

Dr. Binzel stated that, during the last eighteen years of his practice, he had incorporated a nutritional program for his cancer patients, which was based on the findings of Dr. Krebs and others. Dr. Binzel testified that his nutritional program consisted of moderate amounts of vitamins, enzymes, Laetrile and diet. Dr. Binzel explained that the nutritional program was not designed to treat the existing tumor. Treatment of the existing tumor was a determination to be made by the patient and the patient's oncology physician. Dr. Binzel testified that his treatment was directed toward preventing spread of the cancer. He stated that his nutritional program was dedicated to supporting the body's defense mechanisms. Therefore, Laetrile alone was of no benefit. Only Laetrile combined with the enzymes, vitamins, and diet would be of value. (Tr. at 22-26, 41-42).

Dr. Binzel testified that the quantity and quality of life for the cancer patients on his nutritional program was far superior to that experienced by patients undergoing only surgery, radiation, and/or chemotherapy. He said that the difference was "absolutely amazing." Dr. Binzel added that, "With all the hassle that I went through for the use of Laetrile, if I had not been absolutely convinced that my patients were considerably better off with that than they were with the other, I wouldn't have done it." (Tr. at 23).

Dr. Binzel testified that numerous studies have been released which argue against the use of Laetrile. Dr. Binzel stated that the only basis for the conclusion that Laetrile should not be used is the belief that Laetrile is toxic and that Laetrile does not work, i.e. it does not make the tumor disappear. (Tr. at 39-41). Dr. Binzel acknowledged that Laetrile contains cyanide, and that hydrogen cyanide can be harmful to patients. Nevertheless, Dr. Binzel testified that the only cyanide that is released from Laetrile is the cyanide radical, which is an entirely different compound than hydrogen cyanide. Dr. Binzel testified that he had had cyanide levels drawn on many of his patients who were taking Laetrile, and none had an elevated cyanide level. (Tr. at 33-34).

Dr. Binzel testified that he would use a drug or product in his treatment of cancer even if he knew that the FDA did not approve of it. Moreover, Dr. Binzel acknowledged that his opinion regarding Laetrile is a minority opinion in the United States. (Tr. at 38, 44). Finally, Dr. Binzel testified that, in approximately 1975, he had been investigated by the Board based on his use of Laetrile with patients. He stated that he had had a meeting with Board representatives, but that "nothing was ever done." (Tr. at 28, 31-32).

5. Dr. Binzel testified that he has known Mr. Michaelis since Mr. Michaelis was nine or ten years old. Dr. Binzel testified that he had been a friend of Mr. Michaelis' parents. Dr. Binzel testified that Mr. Michaelis' father had started a company that supplied vitamins, enzymes and other nutritional supplements. Moreover, the company had sold nutritional supplements of better quality and at better prices than any drug store or health supplement supplier. Dr. Binzel testified that, for these reasons, he had instructed his patients to contact Mr. Michaelis' father for the purchase of Laetrile. (Tr. at 18-19).

Dr. Binzel testified that, in the early 1970s, a local federal judge had ruled that any person could purchase Laetrile so long as that person signed an affidavit stating that they wanted Laetrile and so long as a physician also signed the affidavit. Dr. Binzel testified that he had used the affidavit system for many years. When he did, he had sent the completed affidavits to Mr. Michaelis or his father. (Tr. at 20, 32).

Dr. Binzel testified that Mr. Michaelis was simply a supplier of nutritional supplements. Dr. Binzel stated that it is his belief that Mr. Michaelis did not advise patients as to what supplements to purchase; nor did he advise patients as to the dosage or the manner in which the supplements should be taken. Dr. Binzel testified that he held this belief because patients had routinely presented their questions to Dr. Binzel. Furthermore, on occasion, when patients requested information from Mr. Michaelis, Mr. Michaelis had called Dr. Binzel for instructions. (Tr. at 19, 30). Nevertheless, Dr. Binzel later testified that Mr. Michaelis had called him with questions regarding other vitamins and enzymes, not with questions regarding Laetrile. (Tr. at 37-38).

6. Mr. Michaelis testified that he has never before been convicted of a crime, although he has been investigated by the government more than once. Mr. Michaelis explained that, in the

early 1970s, his father had started A.O. Supply Company, which had supplied Laetrile and other nutritional supplements. Mr. Michaelis further explained that, in July 1977, the FDA, with federal marshals and search warrants, raided his father's business. During the raid, the FDA seized Laetrile, Laetrile records, dietary supplements, vitamins and other things. (Tr. at 54-55).

Mr. Michaelis' father filed an action in federal court against the FDA. The federal court ruled in favor of Mr. Michaelis' father, and held that it is not illegal to possess Laetrile. The court further ordered the FDA to return all of the seized items to Mr. Michaelis' father and to pay a monetary settlement to Mr. Michaelis' father. Finally, the court dismissed all charges against Mr. Michaelis' father. Mr. Michaelis testified that the business never ceased operating, and continued in the same manner after the raid as it had before the raid. (Tr. at 54-55).

Mr. Michaelis further testified that, in 1989, the business was operating in the same manner that it had in 1977. Nevertheless, in June 1989, the FDA again raided the business. Mr. Michaelis testified that, despite the fact that the raid had been covered extensively by the press, the FDA took no action after the raid. The FDA did not even issue a "cease and desist" letter. Moreover, the family heard nothing from the FDA, and the FDA did not communicate in any way with the Michaelis' legal counsel. Accordingly, the business continued to operate as it had before. (Tr. at 55-57).

In May 1993, the business was again raided by the FDA. The FDA seized books, records, Laetrile and other things. Again, nothing happened. The business continued to operate as it had before. In 1994, Mr. Michaelis' father passed away, and Mr. Michaelis took over the business. (Tr. at 46-47, 58).

In 1998, the FDA raided Mr. Michaelis' business. Mr. Michaelis testified, however, that the business was operating in the same manner as it had over the past twenty years. Nevertheless, Mr. Michaelis testified that the charges which resulted in his conviction had arisen from the 1989 raid. (Tr. at 58-59).

Mr. Michaelis testified that, before the last raid, he had run the business from his home. At that time, most of the Laetrile had been stored in a warehouse. He had kept a small amount in his home, in order to respond to telephone orders. He stated that he usually kept the Laetrile on a shelf in his office. At times however, he had hidden it, in hopes that, in case of a raid, the Laetrile would not be discovered. He stated that he had done so because, each time the FDA raided the business, they seized thousands of dollars worth of Laetrile and did not return it. Therefore, Mr. Michaelis had hidden it to avoid the loss. (Tr. at 73-76).

Mr. Michaelis testified that, after his conviction, he had served his prison sentence at Alvis House, a halfway house in Columbus, from December 24, 2001, through June 21, 2002. At the time of hearing, Mr. Michaelis was being monitored and confined to his home but for work and church. He stated that he is allowed to leave his home from 6:45 a.m.

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until 6:45 p.m., Monday through Friday, in order to go to work. He is also allowed to go to church on Sunday. He is not allowed to go anywhere else without special permission. (Tr. at 53-54).

When asked what had been the basis for his conviction, Mr. Michaelis testified that, in his opinion, a lot of the government activity surrounding Laetrile is political. He stated that, in the 1950s, the government had banned bitter almond trees in the United States because almonds contain the richest amounts of Laetrile. He stated that the controversy has continued over the years. Nevertheless, Mr. Michaelis acknowledged that the indictment had charged him with introducing "an unapproved new drug into interstate commerce." Mr. Michaelis testified that there is no law that defines Laetrile either as new or as a drug but, nonetheless, the FDA claims that it is a "new drug." (Tr. at 62-63).

Mr. Michaelis testified that it is not illegal to possess Laetrile; nor it is illegal to sell Laetrile in Ohio. In addition, it is not illegal to purchase Laetrile from another state or from another country to have it sent to Ohio. Mr. Michaelis further testified that the State of Arizona defines Laetrile as a "dietary supplement." Therefore, Holistic Alternatives legally imported Laetrile from Mexico into Arizona. He added that imported Laetrile routinely passes customs clearance and FDA clearance, even after the 1998 raid. (Tr. at 60-61).

Mr. Michaelis explained that the generic name of Laetrile is amygdalin. He further explained that Dr. Ernst Krebs, one of the original researchers on the use of Laetrile, had coined the name Laetrile, and had also identified the product as Vitamin B-17. Mr. Michaelis does not know if it has ever been approved as a vitamin by the FDA. (Tr. at 79-80).

Mr. Michaelis testified that, because the Laetrile he purchased was from Mexico, the original labels were in Spanish. Mr. Michaelis created new labels in English. In his new labels, he identified the product as "amygdalin [Vitamin B-17]" and noted that it should be taken "as a dietary supplement one tablet daily or as otherwise directed." (Tr. at 79-80).

Mr. Michaelis testified that, over the years, there has been a lot of media attention directed at Laetrile. He explained that opponents of Laetrile argue that proponents claim that Laetrile is a cure for cancer. Mr. Michaelis testified that he has never claimed or believed that Laetrile is a cure for cancer. He stated that he has been attending seminars on Laetrile since he was a teenager. At the seminars, physicians and scientists repeatedly taught that Laetrile is not a cure for cancer. Therefore, he has always been very careful not to create that impression with his business. (Tr. at 81-83).

Mr. Michaelis testified that virtually all of the customers who purchased Laetrile were referred to him by a physician. He added that most physicians learned of his business by "word of mouth," from physicians like Dr. Binzel who regularly sent patients to Holistic Alternatives. (Tr. at 48-49, 80-81).

Mr. Michaelis testified that A.O. Supply Company and Holistic Alternatives had been “major players” nationally in the Laetrile business. Mr. Michaelis testified that Holistic Alternatives has been hurt by his inability to sell Laetrile. He stated that the sale of Laetrile had constituted 70 to 80% of his business’ income. Prior to his conviction, his business had had a gross income of \$400,000 per year. Of that, Mr. Michaelis had earned approximately \$60,000 annually. (Tr. at 84-86, 88).

Mr. Michaelis testified that, before his conviction, he had not had any reason to believe that he could be convicted of a crime for the operation of his business. He had based his belief, in part, on the fact that the business had been raided so many times and no charges had been filed. Moreover, he was aware that customs and FDA officials knew that Laetrile was coming into the country and neither agency had prevented it. In addition, Mr. Michaelis stated that his father had sued the FDA in federal court and won. Finally, Mr. Michaelis testified that the government never once issued Holistic Alternatives a cease and desist order, telling them that their conduct was illegal. Finally, Mr. Michaelis testified that, if it had been made clear to him that his conduct was illegal, he would not have continued to sell Laetrile. (Tr. at 65, 67-68, 71).

7. Mr. Michaelis testified that he has never used the “L.M.T.” designation after his name in relation to his business. He stated that customers did not know that he was a licensed massage therapist. Mr. Michaelis testified that he did not want customers to assume any medical knowledge on his part, because he did not want to give the impression that he was in the business of setting up nutritional or medical programs. (Tr. at 51).

Mr. Michaelis testified that he hopes to retain his massage therapy license because his business is no longer as successful as it once had been. He stated that he has been considering taking refresher courses and reentering the profession. (Tr. at 67).

8. Mr. Michaelis submitted letters written by his customers in his support. (Respondent’s Exhibits [Resp. Exs.] A-D).
9. As noted by the State, one of Mr. Michaelis’ customers wrote that Mr. Michaelis “has helped me immensely as to proper dosage and use of supplements when I requested his assistance.” Nevertheless, the author does not specifically refer to Laetrile. (Tr. at 98; Resp. Ex. D).

FINDINGS OF FACT

1. On May 11, 2001, in the United States District Court, Southern District of Ohio, Mr. Michaelis pleaded guilty to, and was found guilty of, one felony count of Introduction of an unapproved drug [Laetrile] into interstate commerce, in violation of 21 United States Code, Sections 331(b) and 355(a)(2), and 18 United States Code, Section 2.

STATE MEDICAL BOARD
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2. On October 30, 2001, the court sentenced Mr. Michaelis to imprisonment for six months and, upon release from imprisonment, supervised release for a term of one year. Further, the court ordered Mr. Michaelis to pay a monetary penalty in the amount of \$10,000.00.

CONCLUSIONS OF LAW

1. The conduct of Kenneth N. Michaelis, L.M.T., as described in Findings of Fact 1, constitutes “[s]elling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes or a plea of guilty to, a judicial finding of guilt of, or a judicial finding of eligibility for treatment in lieu of conviction of, a violation of any federal or state law regulating the possession, distribution, or use of any drug,” as those clauses are used in Section 4731.22(B)(3), Ohio Revised Code.
2. Mr. Michaelis’ guilty plea and/or the judicial finding of guilt, as described in the Findings of Fact, constitute “[a] plea of guilty to, a judicial finding of guilt of, or a judicial finding of eligibility for intervention in lieu of conviction for, a felony,” as that clause is used in Section 4731.22(B)(9), Ohio Revised Code.

PROPOSED ORDER

It is hereby ORDERED that:

- A. **SUSPENSION:** The certificate of Kenneth N. Michaelis, L.M.T., to practice massage therapy in the State of Ohio shall be SUSPENDED for a period of at least 180 days.
- B. **CONDITIONS FOR REINSTATEMENT OR RESTORATION:** The Board shall not consider reinstatement or restoration of Mr. Michaelis’ certificate to practice massage therapy unless all of the following conditions have been met:
 1. **Application and Fees:** Mr. Michaelis shall submit an application for reinstatement or restoration, accompanied by appropriate fees, if any.
 2. **Demonstration of Compliance with Terms Imposed by the Court:** Mr. Michaelis shall demonstrate to the satisfaction of the Board that he is in full compliance with all terms imposed by the United States District Court for the Southern District of Ohio in *United States of America vs. Kenneth N. Michaelis*, Case No. CR2-00-115.
 3. **Absence from Practice:** In the event that Mr. Michaelis has not been engaged in the active practice of massage therapy for a period in excess of two years prior to the submission of his application for reinstatement or restoration, the Board may exercise

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its discretion under Section 4731.222, Ohio Revised Code, to require additional evidence of Mr. Michaelis' fitness to resume practice.

C. **PROBATION:** Upon reinstatement or restoration, Mr. Michaelis' certificate shall be subject to the following PROBATIONARY terms, conditions, and limitations for a period of at least three years:

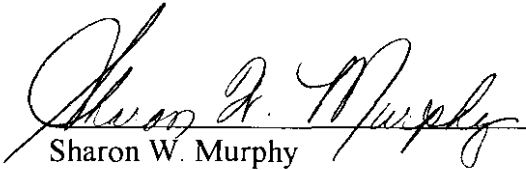
1. **Requests for Modification**: Mr. Michaelis shall not request modification of the terms, conditions, or limitations of probation for at least one year after imposition of these probationary terms, conditions, and limitations.
2. **Laws in Ohio and Terms of Criminal Probation**: Mr. Michaelis shall obey all federal, state and local laws, all rules governing the practice of massage therapy in Ohio; and all terms imposed by the United States District Court for the Southern District of Ohio in *United States of America vs. Kenneth N. Michaelis*, Case No. CR2-00-115.
3. **Appearances**: Mr. Michaelis shall appear in person for interviews before the full Board or its designated representative during the third month following the month in which probation becomes effective, provided that if the effective date is on or after the 16th day of the month, the first personal appearance must occur during the fourth month following. Subsequent personal appearances must occur every third month thereafter, upon Mr. Michaelis' request for termination of the probationary period, and/or as otherwise requested by the Board.

If an appearance is missed or is rescheduled for any reason, ensuing appearances shall be scheduled based on the appearance date as originally scheduled. Although the Board will normally give him written notification of scheduled appearances, it is Mr. Michaelis' responsibility to know when personal appearances will occur. If he does not receive written notification from the Board by the end of the month in which the appearance should have occurred, Mr. Michaelis shall immediately submit to the Board a written request to be notified of his next scheduled appearance.

4. **Quarterly Declarations**: Mr. Michaelis shall submit quarterly declarations under penalty of Board disciplinary action or criminal prosecution, stating whether there has been compliance with all the conditions of probation. The first quarterly declaration must be received in the Board's offices on the first day of the third month following the month in which probation becomes effective, provided that if the effective date is on or after the 16th day of the month, the first quarterly declaration must be received in the Board's offices on the first day of the fourth month following. Subsequent quarterly declarations must be received in the Board's offices on or before the first day of every third month.

5. **Absence from Ohio**: In the event that Mr. Michaelis should leave Ohio for three consecutive months, or reside or practice outside the State, Mr. Michaelis must notify the Board in writing of the dates of departure and return. Periods of time spent outside Ohio will not apply to the reduction of this probationary period, unless otherwise determined by motion of the Board in instances where the Board can be assured that the purposes of the probationary monitoring are being fulfilled.
 6. **Violation of Probation; Discretionary Sanction Imposed**: If Mr. Michaelis violates probation in any respect, the Board, after giving him notice and the opportunity to be heard, may institute whatever disciplinary action it deems appropriate, up to and including the permanent revocation of his certificate.
- D. **TERMINATION OF PROBATION**: Upon successful completion of probation, as evidenced by a written release from the Board, Mr. Michaelis' certificate will be fully restored.
- E. **REQUIRED REPORTING BY LICENSEE TO EMPLOYERS AND HOSPITALS**: Within thirty days of the effective date of this Order, Mr. Michaelis shall provide a copy of this Order by certified mail to all employers or entities with which he is under contract to provide health care services or is receiving training, and the Chief of Staff at each hospital where Mr. Michaelis has privileges or appointments. Further, Mr. Michaelis shall provide a copy of this Order by certified mail to all employers or entities with which he applies or contracts to provide health care services, or applies for or receives training, and the Chief of Staff at each hospital where Mr. Michaelis applies for or obtains privileges or appointments. Further, Mr. Michaelis shall provide this Board with a copy of the return receipt as proof of notification within thirty days of receiving that return receipt.
- F. **REQUIRED REPORTING BY LICENSEE TO OTHER STATE LICENSING AUTHORITIES**: Within thirty days of the effective date of this Order, Mr. Michaelis shall provide a copy of this Order by certified mail, return receipt requested, to the proper licensing authority of any state or jurisdiction in which he currently holds any professional license. Mr. Michaelis shall also provide a copy of this Order by certified mail, return receipt requested, at the time of application to the proper licensing authority of any state in which he applies for any professional license or reinstatement of any professional license. Further, Mr. Michaelis shall provide this Board with a copy of the return receipt as proof of notification within thirty days of receiving that return receipt.

EFFECTIVE DATE OF ORDER: This Order shall become effective immediately upon the mailing of notification of approval by the Board.


Sharon W. Murphy
Attorney Hearing Examiner



State Medical Board of Ohio

77 S. High St., 17th Floor • Columbus, OH 43215-6127 • (614) 466-3934 • Website: www.state.oh.us/med/

EXCERPT FROM THE DRAFT MINUTES OF DECEMBER 11, 2002

REPORTS AND RECOMMENDATIONS

Dr. Somani announced that the Board would now consider the findings and orders appearing on the Board's agenda.

Dr. Somani asked whether each member of the Board had received, read, and considered the hearing record, the proposed findings, conclusions, and orders, and any objections filed in the matters of: Wallace C. Adamson, M.D.; Robin Rae Adamson, P.A.; Brijesh Arya, M.D.; John A. Frenz, M.D.; Jitander N. Kalia, M.D.; Anthony W. Kitchen, M.D.; Joseph Robert Mannino, Jr., D.O.; Kenneth N. Michaelis, L.M.T.; Gary R. Rochon, M.D.; and Michael Carmen Staschak, M.D. A roll call was taken:

| | | |
|------------|----------------|-------|
| ROLL CALL: | Mr. Albert | - aye |
| | Dr. Egner | - aye |
| | Dr. Talmage | - aye |
| | Dr. Bhati | - aye |
| | Dr. Buchan | - aye |
| | Dr. Somani | - aye |
| | Ms. Sloan | - aye |
| | Dr. Davidson | - aye |
| | Dr. Agresta | - aye |
| | Dr. Garg | - aye |
| | Dr. Steinbergh | - aye |
| | Mr. Browning | - aye |

Dr. Garg advised that he has not read the materials in the matters of Wallace C. Adamson, M.D., Robin Rae Adamson, P.A., and Jitander N. Kalia, M.D.

Dr. Somani asked whether each member of the Board understands that the disciplinary guidelines do not limit any sanction to be imposed, and that the range of sanctions available in each matter runs from dismissal to permanent revocation. A roll call was taken:

| | | |
|------------|-------------|-------|
| ROLL CALL: | Mr. Albert | - aye |
| | Dr. Egner | - aye |
| | Dr. Talmage | - aye |

- Dr. Bhati - aye
- Dr. Buchan - aye
- Dr. Somani - aye
- Ms. Sloan - aye
- Dr. Davidson - aye
- Dr. Agresta - aye
- Dr. Garg - aye
- Dr. Steinbergh - aye
- Mr. Browning - aye

Dr. Somani noted that, in accordance with the provision in Section 4731.22(F)(2), Revised Code, specifying that no member of the Board who supervises the investigation of a case shall participate in further adjudication of the case, the Secretary and Supervising Member must abstain from further participation in the adjudication of these matters.

Dr. Somani stated that, if there were no objections, the Chair would dispense with the reading of the proposed findings of fact, conclusions and orders in the above matters. No objections were voiced by Board members present.

The original Reports and Recommendations shall be maintained in the exhibits section of this Journal.

.....

KENNETH N. MICHAELIS, L.M.T.

Dr. Somani directed the Board's attention to the matter of Kenneth N. Michaelis, L.M.T. He advised that objections were filed to Hearing Examiner Murphy's Report and Recommendation and were previously distributed to Board members.

Dr. Somani continued that a request to address the Board has been timely filed on behalf of Dr. Michaelis. Five minutes would be allowed for that address.

Mr. Michaelis was accompanied by his attorney, Elizabeth Y. Collis.

Ms. Collis advised that she knows that the Board members have reviewed the objections she submitted. She and Mr. Michaelis do support the Report and Recommendation.

Mr. Michaelis thanked the Board for allowing him to address it before making its final determination on his case. He has been licensed in Ohio since 1985. He has not worked as a massage therapist for about twelve to 13 years. He would like to retain his license so that he may start to practice massage again some time in the future, should he choose to do so.

Mr. Michaelis stated that, as the Board well knows from reading the transcript of his hearing, he has run the family business for the past 22 years or so. The current name of the business is "Holistic Alternatives, Inc." Through this business he sells dietary supplements to both individuals and professionals. This is strictly a mail order business, where orders are taken over the telephone or the website. They have never had a store-front or walk-in store like GNC or Wal-Mart. In general, the only contact he has with customers is through the mail, by telephone, or through e-mail. His family has been in this business since 1972, and he's worked part-time in the business since its inception when he was about 13 years old.

Mr. Michaelis continued that in 1977, after high school, he became more involved in the business. In 1980 he took over the day-to-day management of the business. From 1972 until the year 2000 the family business sold Laetrile and other dietary supplements to customers. In 1977, when his father ran the business, he was raided by the Food and Drug Administration (FDA). No criminal charges were filed against him, but he did initiate and win a legal battle with the FDA. The federal judge ruled that Laetrile is legal to possess and ordered the FDA to return the seized Laetrile because it was seized illegally. In 1989, while he was managing the business, they were again raided by the FDA and Laetrile was confiscated. No criminal charges were filed, nor were he or his company provided with any information from the Government that it was illegal to either possess or sell Laetrile. They received no "cease and desist" letter from the Government or any communication from the Government whatsoever, and they continued to sell Laetrile openly. Due to financial considerations, no suit was issued to force the FDA to return the seized merchandise in 1989, and no forfeiture papers were filed by the Government, as required by law, to allow them to retain any materials seized. However, the Laetrile and other records were never returned.

Mr. Michaelis continued that, following the raid in 1989, they did begin to store the Laetrile off premises and stored, out of sight, the small amount they kept in their business location. In 1993 the business was again raided by the FDA, but, again, no charges were filed, nor was he or the company warned by the Government not to sell Laetrile. Cease and desist letters were issued by the FDA, and once again, all seized items were retained by the Government, even though no forfeiture papers were filed or procedures followed. Based on advice from legal counsel, the company continued to do business as usual and continued to sell Laetrile to customers openly.

Mr. Michaelis stated that he has never advised customers how to use Laetrile, or advised customers that Laetrile is a cure for cancer or anything else. He's also never used his credentials as a massage therapist on any literature, stationery or documentation connected with the family business, because he did not want customers to assume that because he was licensed by the State Medical Board or had some title after his name that he was qualified to advise them on the use of Laetrile or anything else. He never held himself out to customers as anything other than a salesman of dietary supplements, including Laetrile. When he signs his name to any letters written either personally or as manager of the business, he never uses the title, L.M.T., or any other title. He never advises customers that Laetrile is a cure for cancer or anything else, since he firmly believes that it is not a cure for cancer. He does believe that, in conjunction with a healthy diet and lifestyle changes, Laetrile can aid in helping to build the immune system, which he believes can help one's overall well-being. Customers who contacted him in the business to purchase Laetrile were referred to him by a treating physician with whom they had already consulted regarding the use of nutrition

and Laetrile. If he was contacted by someone who did not have a physician but wanted to purchase Laetrile, he would refer them to a physician who had experience with nutrition and the use of Laetrile.

Dr. Somani advised Mr. Michaelis that he had one more minute. He added that the Board has much of the information he is providing now.

Mr. Michaelis stated that at no time did he ever provide direction for the dosage of Laetrile to individuals seeking personal health advice. In January 1998, Holistic Alternatives, Inc. was again raided by the FDA. After consultation with legal counsel, he continued to do business as usual; however, this time, in August 2000, he was charged with a felony count of introduction of an unapproved drug, specifically Laetrile, in interstate commerce. Although he was never criminally charged in the past and was running the business in the same manner that he had been for 20 years, this time, without having been issued a cease and desist letter, he was charged with a felony. He entered into a plea agreement that specified one year probation; however, instead he was sentenced to serve six months in a halfway house and is currently serving the last three weeks of six months on home confinement, which permits him to go to work every day but requires him to return home by 6:45 p.m. He was also sentenced to a one year probation, which ran concurrent with six months of home confinement.

Mr. Michaelis stated that it is not illegal to purchase or possess Laetrile in the United States. In the past, others have imported and shipped Laetrile to his business, even following the raid in 1998. In accordance with advice from legal counsel, he personally arranged to have Laetrile imported into the United States. Laetrile was imported into the United States through licensed brokers in Arizona. The Laetrile was imported as a dietary supplement and was cleared by both U.S. Customs and the U.S. Food and Drug Administration. Following the indictment in August 2000, he stopped selling Laetrile. Since Laetrile was a large percentage of his business and since the remaining customers cannot be adequately serviced due to his six months absence in a halfway house from December 24, 2001 to June 21, 2002, the business has suffered financially. Mr. Michaelis stated that he would like to retain his license to practice as a massage therapist in case he chooses to take some refresher courses and supplement his income in the future by doing massage. He's supportive of the Hearing Examiner's recommendation or for any shorter suspension period for his license. He would like to be able to retain his license to practice as a massage therapist.

Dr. Somani asked whether the Assistant Attorney General wished to respond.

Mr. Michael advised that Mr. Michaelis pled guilty to a felony count of introduction of an unapproved drug into interstate commerce. This is a felony under the federal code. While Mr. Michaelis seems to state that it was legal to possess Laetrile, he admitted that he had been hiding it to keep the Government from finding it, as they would come and raid his business. In fact he had hidden it offsite. He also had hidden it in his house, as noted in the Report and Recommendation. Mr. Michael stated that, to clarify that point, it was hidden inside a furnace that Mr. Michaelis had in his basement. He clearly knew that there was something wrong with his business of distributing Laetrile throughout the United States, and he admitted that his company was a major player in the United States, one of two that he named, as far as the distribution of Laetrile. Mr. Michael stated that it is also quite clear that Mr. Michaelis was well familiar as to what

people were using Laetrile for in the treatment of cancers, as opposed to simply a dietary supplement. Mr. Michael stated that the State supports Ms. Murphy's Report and Recommendation.

DR. AGRESTA MOVED TO APPROVE AND CONFIRM MS. MURPHY'S PROPOSED FINDINGS OF FACT, CONCLUSIONS, AND ORDER IN THE MATTER OF KENNETH N. MICHAELIS, L.M.T. DR. STEINBERGH SECONDED THE MOTION.

Dr. Somani stated that he would now entertain discussion in the above matter.

Dr. Agresta stated that he would support the Proposed Order. He believes it is fair, considering the circumstances and information the Board has.

Dr. Steinbergh also supported the Report and Recommendation, but added that she would like to require Mr. Michaelis to pass the entire massage therapy examination, as Mr. Michaelis has been out of practice for ten years.

DR. STEINBERGH MOVED TO AMEND THE PROPOSED ORDER TO REQUIRE MR. MICHAELIS TO PASS BOTH THE BASIC SCIENCES AND LIMITED BRANCH PORTIONS OF THE BOARD'S MASSAGE THERAPY EXAMINATION AS A CONDITION FOR REINSTATEMENT OF HIS LICENSE. DR. BHATI SECONDED THE MOTION.

Dr. Steinbergh stated that the Proposed Order does allow the Board to require Mr. Michaelis to present additional evidence of his fitness to resume practice. She would require him to pass the massage therapy examination, as it is given at this time by the Medical Board, accompanied by appropriate fees for taking the examination.

Dr. Buchan stated that he believes that Mr. Michaelis understands, once and for all, what this is all about. The suspension is appropriate, and Dr. Steinbergh appropriately amended the Order.

A vote was taken on Dr. Steinbergh's motion to amend:

| | | |
|-------|----------------|-----------|
| Vote: | Mr. Albert | - abstain |
| | Dr. Egner | - aye |
| | Dr. Talmage | - aye |
| | Dr. Bhati | - aye |
| | Dr. Buchan | - aye |
| | Mr. Browning | - aye |
| | Ms. Sloan | - aye |
| | Dr. Davidson | - aye |
| | Dr. Agresta | - aye |
| | Dr. Garg | - abstain |
| | Dr. Steinbergh | - aye |

The motion carried.

DR. BHATI MOVED TO APPROVE AND CONFIRM MS. MURPHY'S PROPOSED FINDINGS OF FACT, CONCLUSIONS, AND ORDER, AS AMENDED, IN THE MATTER OF KENNETH N. MICHAELIS, L.M.T. DR. STEINBERGH SECONDED THE MOTION. A vote was taken:

| | | |
|-------|----------------|-----------|
| Vote: | Mr. Albert | - abstain |
| | Dr. Egner | - aye |
| | Dr. Talmage | - aye |
| | Dr. Bhati | - aye |
| | Dr. Buchan | - aye |
| | Mr. Browning | - aye |
| | Ms. Sloan | - aye |
| | Dr. Davidson | - aye |
| | Dr. Agresta | - aye |
| | Dr. Garg | - abstain |
| | Dr. Steinbergh | - aye |

The motion carried.



State Medical Board of Ohio

77 S. High St., 17th Floor • Columbus, OH 43215-6127 • (614) 466-3934 • Website: www.state.oh.us/med/

July 10, 2002

Kenneth N. Michaelis, L.M.T.
9181 Baker Road
St. Louisvillle, Ohio 43071

Dear Mr. Michaelis:

In accordance with R. C. Chapter 119., you are hereby notified that the State Medical Board of Ohio intends to determine whether or not to limit, revoke, permanently revoke, suspend, refuse to register or reinstate your certificate to practice massage therapy, or to reprimand or place you on probation for one or more of the following reasons:

- (1) On or about May 11, 2001, in the United States District Court, Southern District of Ohio, you pleaded guilty to, and were found guilty of, one (1) felony count of Introduction of an unapproved drug [Laetrile] into interstate commerce in violation of 21 United States Code, Sections 331(b), 355(a)(2) and 18 United States Code, Section 2.

On the above felony count, you were sentenced, on or about October 30, 2001, to be imprisoned for six (6) months; upon release from imprisonment, you shall be on supervised release for a term of one (1) year. Further, you were required to pay a criminal monetary penalty in the amount of \$10,000.00.

The conduct underlying your above plea of guilty, and the subsequent finding of guilt, is set forth in detail in the Indictment, Plea Agreement and Judgment in a Criminal Case, copies of which are attached hereto and incorporated herein.

Your guilty plea and/or the judicial finding of guilt, as alleged in paragraph one (1) above, individually and/or collectively, constitute “[s]elling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes or a plea of guilty to, a judicial finding of guilt of, or a judicial finding of eligibility for treatment in lieu of conviction of, a violation of any federal or state law regulating the possession, distribution, or use of any drug,” as those clauses are used in R. C. 4731.22(B)(3).

Further, your guilty plea and/or the judicial finding of guilt, as alleged in paragraph one (1) above, individually and/or collectively, constitute “[a] plea of guilty to, a judicial finding of guilt of, or a judicial finding of eligibility for intervention in lieu of conviction for, a felony,” as that clause is used in R. C. 4731.22(B)(9).

Pursuant to R. C. Chapter 119., you are hereby advised that you are entitled to a hearing in this matter. If you wish to request such hearing, the request must be made in writing and must be received in the offices of the State Medical Board within thirty (30) days of the time of mailing this notice.

Mailed 7-11-02

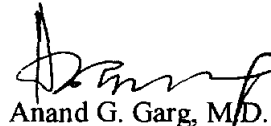
You are further advised that, if you timely request a hearing, you are entitled to appear at such hearing in person, or by your attorney, or by such other representative as is permitted to practice before this agency, or you may present your position, arguments, or contentions in writing, and that at the hearing you may present evidence and examine witnesses appearing for or against you.

In the event that there is no request for such hearing received within thirty (30) days of the time of mailing of this notice, the State Medical Board may, in your absence and upon consideration of this matter, determine whether or not to limit, revoke, suspend, refuse to register or reinstate your certificate to practice massage therapy or to reprimand or place you on probation.

Please note that, whether or not you request a hearing, R. C. Section 4731.22(L), effective March 9, 1999, provides that "[w]hen the board refuses to grant a certificate to an applicant, revokes an individual's certificate to practice, refuses to register an applicant, or refuses to reinstate an individual's certificate to practice, the board may specify that its action is permanent. An individual subject to a permanent action taken by the board is forever thereafter ineligible to hold a certificate to practice and the board shall not accept an application for reinstatement of the certificate or for issuance of a new certificate."

Copies of the applicable sections are enclosed for your information.

Very truly yours,


Anand G. Garg, M.D.
Secretary

AGG/jag
Enclosures

CERTIFIED MAIL # 7000 0600 0024 5139 9422
RETURN RECEIPT REQUESTED

Ralph W. Alvis House (North)
1755 Alum Creek Drive
Columbus, Ohio 43207-1708

CERTIFIED MAIL # 7000 0600 0024 5139 9415
RETURN RECEIPT REQUESTED

Rick J. Abraham, Esq.
Abraham Law Offices
24 N. High Street
Columbus, OH 43215-3423

CERTIFIED MAIL #7000 0600 0024 5139 9392
RETURN RECEIPT REQUESTED

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

FILED
KENNETH J. MURPHY
CLERK
00 JUL 18 PM 4:30

U.S. DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

CR2 00 115 (1)
JUDGE SARGUS

UNITED STATES OF AMERICA,

: Case No.
: Judge

PLAINTIFF,

:

vs.

: 18 U.S.C. § 2
: 18 U.S.C. § 371
: 21 U.S.C. § 331(a)
: 21 U.S.C. § 331(d)
: 21 U.S.C. § 331(p)
: 21 U.S.C. § 333(a) (2)
: 21 U.S.C. § 355(a)

KENNETH N. MICHAELIS

:

DEFENDANT .

:

:

I N D I C T M E N T

THE GRAND JURY CHARGES:

I CERTIFY THAT THIS IS A
TRUE AND CORRECT COPY OF THE
ORIGINAL FILED IN MY OFFICE
ON July 18, 2000
KENNETH J. MURPHY, CLERK
BY: Betha Baird
Deputy Clerk
DATE: July 9, 2002

I N T R O D U C T O R Y A L L E G A T I O N S

At all times relevant to this Indictment:

The Food and Drug Administration's Regulation of Drugs

1. The United States Food and Drug Administration ("FDA") was the federal agency within the United States Department of Health and Human Services ("DHHS") charged with the responsibility for protecting the health and safety of the American public by ensuring that drugs were safe and effective and properly labeled for their intended uses before they could be legally marketed in interstate commerce. In order to legally market a drug in

interstate commerce, the drug's manufacturer and re-packager were required to comply with all applicable provisions of the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), 21 U.S.C. § 321, et seq., and its implementing regulations.

Misbranded Drugs

3. The FD&C Act defined a drug to include articles intended for use in the cure, mitigation, treatment, or prevention of disease in man or other animals or intended to affect the structure or any function of the human body. 21 U.S.C. § 321(g).

4. Substances known as:

a) "Laetrile," "laetrile," "Amygdalin," "Amigdaline B-17," "Amygdalina," "Kemdaline," "Kemdaline S," "B-17," and "Vitamin B-17," (hereinafter collectively and individually described as "Laetrile") that were intended for use in the cure, mitigation, treatment, or prevention of cancer were drugs within the meaning of the FD&C Act, 21 U.S.C. §§ 321(g)(1)(B) and (C);

Unapproved New Drug

7. The FD&C Act also prohibited causing the introduction or delivery for introduction into interstate commerce or introducing or delivering for introduction into interstate commerce new drugs that were not the subject of an approved marketing or

investigational application. 21 U.S.C. §§ 331(d) and 355.

"Approved marketing or investigational applications" included new drug applications ("NDAs"), abbreviated new drug applications ("ANDAs") and investigational new drug applications ("INDs"). 21 U.S.C. § 355.

8. A drug was a "new drug" if it was "not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof" 21 U.S.C. § 321(p)(1).

9. Laetrile was not generally recognized as safe and effective by qualified experts for the treatment of cancer and there were no approved marketing or investigational applications on file with FDA for Laetrile.

Defendants

11. Defendant KENNETH N. MICHAELIS, a resident of Licking County, Ohio, was doing business, from at least August, 1994, until January 1996, as AO Supply, 12176 Eddyburg Road, Newark, OH. From on and after January, 1996, through at least January, 2000, defendant KENNETH N. MICHAELIS was doing business as defendant HOLISTIC ALTERNATIVES, INC. ("HOLISTIC ALTERNATIVES"), 9181 Baker Road, St. Louisville, OH.

12. Defendant HOLISTIC ALTERNATIVES was a company owned and operated by defendant KENNETH N. MICHAELIS. At first through AO Supply and later through defendant HOLISTIC ALTERNATIVES, defendant KENNETH N. MICHAELIS, without medical or pharmaceutical credentials, was and continued to be in the business of, among other things: 1) obtaining and repackaging injectable and tablet forms of Laetrile from Mexico;

4) providing

commercial size quantities of Laetrile to
other businesses in the United States; and 5) distributing Laetrile
in interstate commerce to consumers
throughout the United States, all with the intention to cure,
mitigate, treat, or prevent cancer.

**INTRODUCTION INTO INTERSTATE COMMERCE
OF AN UNAPPROVED NEW DRUG (LAETRILE)**

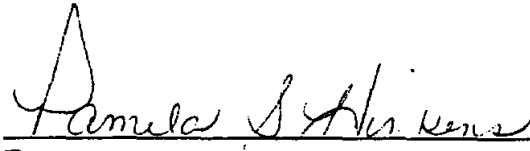
1. The Introductory Allegations in paragraphs 1, 3, 4, 7, 8, 9, 11 and 12 of this Indictment are incorporated by reference herein.

2. On or about the following dates as set forth for each count, within the Southern District of Ohio, and elsewhere, defendants KENNETH N. MICHAELIS and HOLISTIC ALTERNATIVES did, with intent to defraud and mislead the FDA, introduce and deliver for introduction into interstate commerce and cause to be introduced and delivered into interstate commerce the new drug Laetrile, as described below, which drug was not the subject of an approved marketing or investigational application on file with FDA:

| COUNT | DATE | ITEM |
|-------|---------|--|
| | | |
| 4 | 8/14/97 | Shipment to "unindicted co-conspirator Company G" in Rochester, MN, from "unindicted co-conspirator Laboratory KS" in California of 600 10 cc. ampules of "amygdalin" and 10,000 500 mg. tablets of "amygdalin." |

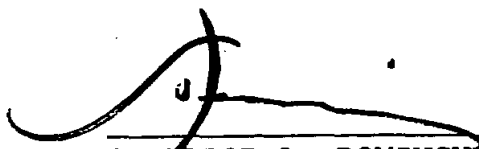
All in violation of 21 U.S.C. §§ 331(d), 355(a) and 333(a)(2),
and 18 U.S.C. § 2.

A True Bill.



Foreperson

SHARON J. ZEALEY,
UNITED STATES ATTORNEY


SALVADOR A. DOMINGUEZ (0056232)
First Assistant United States Attorney

FILED

MAY 11 2001

Kenneth J. Murphy, Clerk
Columbus, Ohio

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

UNITED STATES OF AMERICA, :

Plaintiff, :

vs. :

KENNETH MICHAELIS :

Defendant. :

Case No. CR2-00-115

JUDGE MARBLEY

| | |
|--|--------------|
| I CERTIFY THAT THIS IS A TRUE AND CORRECT COPY OF THE ORIGINAL FILED IN MY OFFICE ON <u>May 11, 2001</u> | |
| KENNETH J. MURPHY, CLERK | |
| BY: <u>Beth Aband</u> | Deputy Clerk |
| DATE: <u>July 9, 2002</u> | |

PLEA AGREEMENT

Plaintiff United States of America and defendant KENNETH MICHAELIS hereby enter into the following Plea Agreement pursuant to Rule 11(e) of the Federal Rules of Criminal Procedure:

1. Defendant KENNETH MICHAELIS will enter a plea of guilty to Count Four of the Indictment which charges Defendant KENNETH MICHAELIS with distribution of the unapproved new drug laetrile in interstate commerce with intent to defraud in violation of 21 U.S.C. §§ 331(d), 355(a) and 333(a)(2)

2. Defendant KENNETH MICHAELIS understands that the maximum

penalty that may be imposed pursuant to his plea of guilty to Count Four is a term of imprisonment of three years, one year of supervised release, and a fine of \$250,000

3. Prior to or at the time the defendant is sentenced, the defendant will pay a special assessment of \$100 for Count Four

as required in 18 U.S.C.

§ 3013. This assessment shall be paid by the defendant before sentence is imposed and defendant will furnish a receipt at the time of sentencing. The payments shall be made to the United States District Court, at the Clerk's Office, 85 Marconi Blvd., Columbus, Ohio 43215.

4. The defendant is aware that the defendant's sentence will be imposed in accordance with the United States Sentencing Guidelines and Policy Statements. The defendant is aware that the Court has jurisdiction and authority to impose any sentence within the statutory maximum set forth for the offense to which the defendant pleads guilty. The defendant is aware that the Court has not yet determined a sentence. The defendant is also aware that any estimate of the probable sentencing range under the sentencing guidelines that the defendant may have received from the defendant's counsel, the United States, or the probation office, is a prediction, not a promise, and is not binding on the United

States, the probation office, or the Court. The United States makes no promise or representation concerning what sentence the defendant will receive, and the defendant cannot withdraw a guilty plea based upon the actual sentence.

5. If such plea of guilty is entered, and not withdrawn, and defendant KENNETH MICHAELIS acts in accordance with all other terms of this agreement, the United States Attorney for the Southern District of Ohio agrees to seek leave of Court at the time of sentencing to dismiss Counts One through Three, Counts Five through Nine and Counts Eleven through Sixteen of the Indictment and the United States Attorney for the Southern District of Ohio agrees not to file additional federal criminal or civil charges (except those civil charges referred to in paragraph Eight herein) related to the dismissed counts of the Indictment or based on other similar activities in the Southern District of Ohio occurring prior to the dates set forth in the Indictment and as to which Defendant gives testimony or makes statements pursuant to this agreement.

6. Defendant KENNETH MICHAELIS agrees to provide a complete statement to authorities of the United States, including submitting to a polygraph examination if requested, concerning the distribution of unapproved and misbranded drugs and unregistered drug manufacturing facilities outlined in the Indictment and any other similar activity as to which he may have been a part or as to which he has knowledge prior to the entry of his guilty plea

pursuant to this agreement. Defendant agrees to submit to supplemental debriefings on such matters whenever requested by authorities of the United States, whether before or after the plea is entered.

Pursuant to §1B1.8 of the Federal Sentencing Guidelines, the government agrees that any self-incriminating information so provided will not be used against the defendant in determining the applicable guideline range for sentencing, or as a basis for upward departure from the guideline range.

7. By virtue of the defendant pleading guilty to Count Four of the Indictment in exchange for the dismissal of Counts One through Three, Counts Five through Nine and Counts Eleven through Sixteen of the Indictment herein, the defendant understands that he is not a prevailing party as defined by 18 U.S.C. §3006A (statutory note captioned "Attorney Fees and Litigation Expenses to Defense") and hereby expressly waives his right to sue the United States.

8. The parties enter into the following agreements regarding application of the United States Sentencing Guidelines to this defendant:

8.1 Pursuant to USSG § 5E1.1 (1998) and 18 U.S.C. § 3663 (as amended October 11, 1996), there is no restitution due and owing in this case;

8.2 The provisions of U.S.S.G. § 2N2.1 govern the sentence on

the misdemeanor plea to Count Ten;

8.3 The cross reference to U.S.S.G. § 2F1.1 in U.S.S.G. § 2N2.1(b)(1) is applicable to the sentence on the felony plea to Count Four;

8.4 Special Offense Characteristics under U.S.S.G. § 2F1.1(b)(1) include a loss (including all relevant conduct, not just the count of conviction) of at least \$10,000, but less than \$20,000, so the provisions of U.S.S.G. § 2F1.1(b)(1)(D) apply to this case;

8.5 Defendant has "accepted responsibility" for the offense charged in the Indictment as that term is defined in U.S.S.G. § 3E1.1(a) and is deserving of at least a two point reduction in offense level, and possibly a three point reduction in offense level depending on the final offense level, provided that defendant acknowledges to the government, the Probation Office and the Court the nature and extent of all relevant criminal conduct and continues to deserve this reduction under a reasonable interpretation of the sentencing guidelines.

8.6. Pursuant to U.S.S.G. § 2F1.1(b)(2), defendant is deserving of two points for more than minimal planning;

8.7 Pursuant to U.S.S.G. § 2F1.1(b)(7)(A), defendant is deserving of two points for reckless risk of serious bodily injury;

8.8 With the exception of the fine provisions, no other

provisions of the sentencing guidelines are relevant to defendant's sentence.

Defendant and the United States understand that these recommendations are not binding on the Court and that the final determination of such matters for sentencing purposes rests entirely with the Court.

9. The parties represent and acknowledge that Defendant KENNETH MICHAELIS, in addition to the plea of guilty herein, is also agreeing to the entering of a civil injunction as set forth in a Complaint and Consent Judgment (attached hereto as Exhibit A) to be filed in the Southern District of Ohio simultaneously with this plea agreement.

10. Finally, the United States Attorney for the Southern District of Ohio agrees that if Defendant Kenneth N. Michaelis provides substantial assistance in the investigation or prosecution of others who have committed criminal offenses, the United States Attorney may move the court pursuant to § 5K1.1 of the Federal Sentencing Guidelines and/or Federal Rules of Criminal Procedure, Rule 35(b) for an appropriate departure from the otherwise applicable guideline range for Defendant's sentence and will in connection therewith make known to the Court the nature and extent of Defendant's assistance. Defendant understands that such motion may not be filed until the United States Attorney is satisfied that the Defendant has substantially cooperated. Defendant understands

that whether such motion should be made lies within the discretion of the United States Attorney and that whether and to what extent such motion should be granted are solely matters for determination by the Court.

11. Defendant KENNETH MICHAELIS understands that this agreement does not protect him from prosecution for perjury, should defendant testify untruthfully, or for making false statements, nor does it protect him from prosecution for other crimes or offenses which the United States discovers by independent investigation. Further, should Defendant KENNETH MICHAELIS fail to comply fully with the terms and conditions set forth herein, or should he fail to appear as required for sentencing, this agreement is voidable at the election of the government, in which case defendant KENNETH MICHAELIS shall be subject to prosecution as if the agreement had never been made.

12. It is agreed that if the Court refuses to accept any provision which is binding on the Court, neither party is bound by any of its provisions. Defendant KENNETH MICHAELIS may withdraw his guilty plea, and the United States Attorney for the Southern District of Ohio may proceed with prosecution of the conduct set forth in the Indictment and other similar conduct occurring prior to the date of this agreement without prejudice.

13. No additional promises, agreements, or conditions have been made relative to this matter other than those expressly set

forth herein, and none will be made unless in writing and signed by all parties.

5/11/01
Dated

Kenneth N. Michaelis
KENNETH N. MICHAELIS

ABRAHAM LAW OFFICES

5-11-01
Dated

Rick J. Abraham
RICK J. ABRAHAM (0037723)
Attorney for Defendant

5-11-01
Dated

William J. Abraham
WILLIAM J. ABRAHAM (0009698)
Attorney for Defendant

SALVADOR A. DOMINGUEZ,
UNITED STATES ATTORNEY FOR THE
SOUTHERN DISTRICT OF OHIO

5-11-01
Dated

Deborah A. Solove
DEBORAH A. SOLOVE (0024552)
Assistant United States Attorney

*M
K
O*

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

FILED

MAY 11 2001

Kenneth J. Murphy, Clerk
Columbus, Ohio

UNITED STATES OF AMERICA, :
 :
 PLAINTIFF, :
 :
 vs. :
 :
 KENNETH N. MICHAELIS :
 :
 :
 DEFENDANT. . :

CIVIL NO: **C2 01 450**
JUDGE MARBLEY
COMPLAINT FOR PERMANENT
INJUNCTION
MAGISTRATE JUDGE XMS

The United States of America, plaintiff, by and through its undersigned counsel, respectfully represents to this Honorable Court as follows:

1. In this action for a statutory injunction brought pursuant to the Federal Food, Drug, and Cosmetic Act (FDC Act), 21 U.S.C. § 332(a), plaintiff, the United States of America, seeks to permanently enjoin defendants Kenneth N. Michaelis, an individual from violating:

a. 21 U.S.C. § 331(d), by introducing or delivering for introduction or causing the introduction or delivery for introduction into interstate commerce of new drugs within the meaning of 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355(a) nor exempt from approval pursuant to 21 U.S.C. § 355(i); and

I CERTIFY THAT THIS IS A TRUE AND CORRECT COPY OF THE ORIGINAL FILED IN MY OFFICE ON May 11, 2001
KENNETH J. MURPHY, CLERK
BY: Beth Baird
Deputy Clerk
DATE: July 8, 2002

b. 21 U.S.C. § 331(a), by introducing or delivering for introduction or causing the introduction or delivery for introduction into interstate commerce of drugs that are misbranded within the meaning of 21 U.S.C. §§ 352(c), 352(f)(1), 352(f)(2), 352(o), and 353(b)(1).

2. This Court has jurisdiction over this action pursuant to 21 U.S.C. § 332(a), and 28 U.S.C. §§ 1331, 1337, and 1345.

3. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and (c).

5. Defendant Kenneth N. Michaelis, an individual, is the president of Holistic Alternatives and has overall responsibility for, and authority over, all operations of the firm, including, but not limited to, the receipt, processing, packing, repacking, labeling, holding, and distribution of drug products. Mr. Michaelis performs his duties as president of Holistic Alternatives at the firm's Newark, Ohio place of business.

VIOLATIONS OF THE FDC ACT

6. Defendants have been and are engaged at 9181 Baker Road, Newark, Ohio, in receiving, packing, repacking, labeling, holding, and distributing in interstate commerce various products made from or containing amygdalin (also known as laetrile and

"Vitamin B-17"), including injectable amygdalin and amygdalin tablets (hereinafter, "amygdalin products")

Defendants' injectable amygdalin and amygdalin tablets are manufactured in Mexico.

7. Defendants' amygdalin products are drugs within the meaning of 21 U.S.C. § 321(g)(1)(B) because, as indicated in their accompanying labeling and promotional materials and in statements by defendants, they are articles intended for use in the cure, mitigation, treatment, and prevention of human disease, namely cancer.

8. Defendants' amygdalin products are new drugs within the meaning of 21 U.S.C. § 321(p)(1) because they are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, namely for the treatment of cancer.

9. There is not now, nor has there ever been, an approved new drug application filed with the United States Food and Drug Administration (FDA) pursuant to 21 U.S.C. § 355(b) or (j) for defendants' amygdalin products. Further, defendants' amygdalin products are not exempt under 21 U.S.C. § 355(i) from the premarket approval requirement. Therefore, defendants' amygdalin products are unapproved new drugs within the meaning of 21 U.S.C. § 355(a).

10. Defendants' amygdalin

are misbranded within the meaning of: (1) 21 U.S.C. § 352(f)(1), because their labeling fails to bear adequate directions for use; (2) 21 U.S.C. § 352(f)(2), because their labeling failed to bear such adequate warnings against use in those pathological conditions, and by children where its use might have been dangerous to health, and against unsafe dosage and methods and duration of administration and application, in such manner and form, as were necessary for the protection of users; and (3) 21 U.S.C. § 352(o), because they were manufactured, prepared, propagated, compounded, or processed in an establishment in any state not duly registered with FDA pursuant to 21 U.S.C. § 360.

11. One of defendants' drugs, injectable amygdalin, is also misbranded under 21 U.S.C. § 352(c) in that information required by or under authority of the FDC Act to appear on the label or labeling is not in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use because it is written in Spanish.

12. Defendants violate 21 U.S.C. § 331(d) by introducing or delivering for introduction or causing the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of 21 U.S.C. § 355, as set forth herein.

13. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction or causing the introduction or delivery for introduction into interstate commerce of misbranded drugs, as set forth herein.

14. Plaintiff is informed and believes that, unless enjoined by this Court, defendants will continue to violate 21 U.S.C. §§ 331(a) and (d) in the manner alleged herein.

WHEREFORE PLAINTIFF PRAYS:

I. That defendants, and Kenneth N. Michaelis, an individual, and each and all of their agents, representatives, employees, and attorneys, and any and all persons in active concert or participation with any of them, be permanently enjoined from directly or indirectly doing or causing to be done any of the following acts:

A. Introducing or delivering for introduction or causing the introduction or delivery for introduction into interstate commerce, holding for sale after shipment in interstate commerce, manufacturing, labeling, packing, repacking, processing, or distributing injectable amygdalin, amygdalin tablets, or any similar product containing or purporting to contain amygdalin, laetrile, or Vitamin B-17,

which, when recommended for use in the treatment of cancer is a new drug, or any other drug product that is a "new drug" within the meaning of 21 U.S.C. § 321(p), unless and until:

1) an approved new drug application filed pursuant to 21 U.S.C. § 355 is in effect for such drug product; or

2) an investigational new drug application filed pursuant to 21 U.S.C. § 355(i) and 21 C.F.R. Part 312 is in effect for such drug product and the drug product is distributed and used solely for the purpose of conducting clinical

investigations in accordance with the investigational new drug application;

B. Promoting, advertising, or representing that amygdalin, laetrile, Vitamin B-17, or any other product containing or purporting to contain amygdalin, laetrile, or Vitamin B-17 is safe and/or effective in the cure, mitigation, treatment, or prevention of any disease, unless and until an approved new drug application authorizing such representations is in effect for such product;

C. Introducing or delivering for introduction or causing the introduction or delivery for introduction into interstate commerce of any drug that is misbranded within the meaning of 21 U.S.C. §§ 352(c), 352(f)(1), 352(f)(2), 352(o), or 353(b)(1); and

D. Packing, repacking, labeling, or holding for sale any drug in any manner that causes such drug to become misbranded within the meaning of 21 U.S.C. §§ 352(c), 352(f)(1), 352(f)(2), 352(o), or 353(b)(1) while it is held for sale after shipment of one or more of its components in interstate commerce.

II. That FDA be authorized pursuant to this injunction to inspect defendants' place of business, facilities, and all records relating to the receipt, packing, repacking, labeling, holding, and distribution of any drug, including components, to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by defendants at the rates prevailing at the time the inspections are performed.

III. That the Court grant plaintiff its costs and such other relief as the Court deems just and proper.

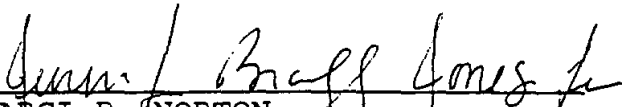
Dated this 11th day of May 2001.

Respectfully submitted,

SALVADOR A. DOMINGUEZ (0056232)
UNITED STATES ATTORNEY



DEBORAH A. SOLOVE (0024552)
Assistant United States Attorney
Two Nationwide Plaza
280 N. High St., 4th Floor
Columbus, Ohio 43215
(614) 469-5715



MARCI B. NORTON
Special Assistant United States
Attorney and Associate Chief
Counsel for Enforcement, US FDA
5600 Fishers Lane, Room 6-89, GCF-1
Rockville, MD 20857
(301) 827-1189

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

FILED
KENNETH J. MURPHY
CLERK

01 MAY 30 AM 8:03

U.S. DISTRICT COURT
SOUTHERN DIST. OHIO
EAST. DIV. COLUMBUS

K
5/30/01

UNITED STATES OF AMERICA, :
 :
 PLAINTIFF, :
 :
 vs. :
 :
 KENNETH N. MICHAELIS, and :
 :
 :
 DEFENDANT . :

CIVIL NO: **C2 01 450**

JUDGE MARBLEY

CONSENT DECREE OF
PERMANENT INJUNCTION
MAGISTRAL JUDGE KING

The United States of America, plaintiff, having filed a
Complaint for Permanent Injunction against defendant

Kenneth N. Michaelis, an individual, and the defendants having
appeared and having consented to the entry of this Decree without
contest and before any testimony has been taken, and the United
States of America having consented to this Decree:

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that:

1. This Court has jurisdiction over the subject matter of
this action, and has personal jurisdiction over all parties to this
action.

I CERTIFY THAT THIS IS A
TRUE AND CORRECT COPY OF THE
ORIGINAL FILED IN MY OFFICE
ON MAY 30, 2001
KENNETH J. MURPHY, CLERK
BY: B. W. Baird
Deputy Clerk
DATE: July 9, 2002

J

2. The Complaint for Injunction states a cause of action against the defendants under the Federal Food, Drug, and Cosmetic Act (FDC Act), 21 U.S.C. §§ 301-97.

3. Defendants and each and all of their agents, representatives, employees, attorneys, successors and assigns, and any and all persons in active concert or participation with any of them, who have received actual notice of this Decree by personal service or otherwise, are hereby permanently restrained and enjoined pursuant to 21 U.S.C. § 332(a), from directly or indirectly doing or causing to be done any of the following acts:

A. Introducing or delivering for introduction into interstate commerce, holding for sale after shipment in interstate commerce, manufacturing, processing, packing, repacking, labeling, promoting, or distributing amygdalin, laetrile, "Vitamin B-17", or any similar product containing or purporting to contain amygdalin, laetrile, "Vitamin B-17," or any other drug product

that is a new drug, as defined in 21 U.S.C. § 321(p), unless and until:

(1) an approved new drug application filed pursuant to 21 U.S.C. § 355 is in effect for such drug product; or

(2) an investigational new drug application filed pursuant to 21 U.S.C. § 355(i) and 21 C.F.R. Part 312 is in effect for such drug product and the drug product is distributed and used

solely for the purpose of conducting clinical investigations in accordance with the investigational new drug application.

B. Introducing or delivering for introduction into interstate commerce any drug that is misbranded within the meaning of 21 U.S.C. §§ 352(c), 352(f)(1), 352(f)(2), 352(o), or 353(b)(1).

4. All drug products containing or purporting to contain amygdalin, laetrile, or "Vitamin B-17" that are in the possession, custody, or control of defendants or their agents, representatives, employees, or attorneys, as of the date of entry of this Decree shall be destroyed at defendants' expense and under supervision of the U.S. Food and Drug Administration (FDA).

5. Duly authorized representatives of FDA shall be permitted, as FDA deems necessary and without prior notice, to make inspections of defendants' facilities, and all equipment, finished and unfinished materials and products, containers, labeling, and other promotional material therein, to take photographs and video recordings, and to examine and copy all records relating to the receipt, packing, repacking, labeling, promotion and distribution of any of defendants' products to ensure continuing compliance with the terms of this Decree. Such inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. Such inspection authority granted by this Decree is apart from, and in addition to, the authority to make inspections under the FDC Act, 21 U.S.C. § 374.

red
reasonable
and
good faith
das
to
atg

6. The parties agree that state and/or federal governmental authorities, including but not limited to FDA, may conduct surveillance, including undercover buys, as they deem necessary and without notice, to monitor compliance with this decree.

7. Upon written notification from FDA, defendants shall immediately cease and discontinue receiving, packing, repacking, labeling, holding, and distributing any article, if FDA notifies the defendants in writing that their receiving, packing, repacking, labeling, holding, or distributing of such article is in violation of this Decree or the FDC Act. Any such cessation of operations shall go into effect without further order from this Court and, defendants shall not resume receiving, packing, repacking, labeling, holding, or distributing the article(s) that are the subject of FDA's notification until FDA notifies defendants in writing that defendants appear to be in compliance with the FDC Act and the requirements of this Decree.

8. Upon written notification from FDA, defendants shall institute recalls or take any other action(s) as FDA deems necessary or appropriate to ensure that the articles defendants receive, pack, repack, label, hold, and distribute, or have received, packed, repacked, labeled, held, or distributed, are in compliance with the FDC Act. Any such recall shall be conducted by defendants in accordance with the recall procedures set forth in 21

C.F.R. Part 7. All costs of recalls, including the FDA supervisory costs, shall be borne by defendants in accordance with ¶ 9.

9. Defendants shall pay the costs of all inspections, supervision, reviews, examinations, and analyses conducted pursuant to this Decree at the standard rates prevailing at the time these activities are performed. As of the date of this Decree, the standard rates are as follows: \$62.19 per hour or fraction thereof per representative for inspection work; \$74.53 per hour or fraction thereof per representative for analytical work; \$0.345 per mile for travel expenses; and \$ 110.00 per day per person for subsistence expenses. In the event that the standard rates generally applicable to FDA supervision, inspection, review, examination, or analysis are modified, these rates shall be adjusted accordingly without further order of the Court.

10. Should plaintiff bring, and prevail in, a civil or criminal contempt action arising out of a violation of the terms of this Decree, defendants shall, in addition to other remedies, reimburse plaintiff for attorneys' fees, expert witness fees, investigational expenses, travel expenses incurred by witnesses, administrative and court costs, and any other costs or fees, including overhead, related to such enforcement proceedings.

11. Within ten (10) days of the date of entry of this Decree, defendants shall serve a copy of this Decree upon each of their agents, representatives, employees, attorneys, successors and

assigns, and upon any and all persons in active concert or participation with any of them.

12. Within ten (10) days of the date of entry of this Decree, defendants shall post a copy of this Decree in all of the employee common areas at all of their facilities, including the facility at 9181 Baker Road, Newark, Ohio, and shall ensure that the Decree remains posted for a period of no less than twelve (12) months. Within thirty (30) days of the date of entry of this Decree, defendants shall provide to FDA and to plaintiff's attorneys an affidavit of compliance stating the fact and manner of compliance with the provisions of this paragraph and identifying the names and positions of all persons upon whom this Decree has been served.

13. Defendants shall notify FDA in writing, at least twenty (20) days before any change in ownership, character, or name of their business, including reorganization, bankruptcy, assignment, or sale resulting in the emergence of a successor business or corporation, or any other change in the structure or identity of such business, or the sale or assignment of any business assets, such as buildings, equipment, or inventory that may affect obligations arising out of this Decree. Defendants shall serve a copy of this Decree on any prospective successor or assign within twenty (20) days prior to such sale or change in business, and shall furnish FDA and plaintiff's attorneys with an affidavit of

compliance with this paragraph within fifteen (15) days prior to such sale or change in business.

14. Defendants shall address all communications with FDA required under this Decree to the Director, Cincinnati District Office, Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio, 45237-3097, and shall reference this case by name and civil action number in such communications. A copy of all such communications shall be provided to Special Agent Greg Goneconto, Office of Criminal Investigations, Food and Drug Administration, 4041 Powder Mill Road, Suite 200, Calverton, MD 20705.

15. All decisions conferred upon FDA in this Decree shall be vested in the discretion of FDA. FDA's decisions shall be final and shall be reviewed, if necessary, by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A).

16. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be hereafter necessary or appropriate.

17. Defendants shall bear their own costs, including attorneys' fees, of this action and for compliance with this Decree.

IT IS SO ORDERED:

Dated: This 11th day of May, 2001.

5600 Fishers Lane, Room 6-89,
GCF-1
Rockville, MD 20857
(301) 827-1189
Attorney for Defendants

EXHIBIT 1

EXHIBIT 2

FILED
KENNETH J. MURPHY
01 OCT 30 PM 2:51
U.S. DISTRICT COURT
SOUTHERN DIST. OHIO
EAST. CANTON, OHIO

UNITED STATES DISTRICT COURT

Southern District of Ohio

UNITED STATES OF AMERICA

JUDGMENT IN A CRIMINAL CASE

(For Offenses Committed On or After November 1, 1987)

V.

KENNETH N. MICHAELIS

Case Number CR-2-00-115(1)

William Abraham,
Rick Abraham,
Defendant's Attorney

THE DEFENDANT:

 x pleaded guilty to count four (4) of the Indictment.
 pleaded nolo contendere to counts ___ of the Indictment.
 was found guilty on counts ___ of the Indictment after a plea of not guilty.

Title & Section

21 U.S.C. §331(b),355(a)(2) and
18 U.S.C. §2

Nature of Offense

Introduction of an unapproved drug into interstate commerce

Date Offense

Concluded
8/14/91

Count

Numbers
Four

The defendant is sentenced as provided in pages 2 through 7 of this judgment. The sentence is imposed pursuant to the Sentencing Reform Act of 1984.

 The defendant has been found not guilty on counts ___ of the Indictment, and is discharged as to such counts.

 X Counts one (1), two (2), three (3), five (5), six (6), seven (7), eight (8), nine (9), eleven (11), twelve (12), thirteen (13), fourteen (14), fifteen (15), and sixteen (16) of the Indictment are dismissed on the motion of the United States.

IT IS FURTHER ORDERED that the defendant shall notify the United States attorney for this district within 30 days of any change of name, residence, or mailing address until all fines, restitution, costs, and special assessments imposed by this judgment are fully paid.

October 4, 2001

Date of Imposition of Sentence

Signature of Judicial Officer

Algenon L. Marbley
United States Magistrate Judge

Date

Oct. 29, 2001

I CERTIFY THAT THIS IS A TRUE AND CORRECT COPY OF THE ORIGINAL FILED IN MY OFFICE ON Oct 30, 2001
KENNETH J. MURPHY, CLERK
BY: Bethaband Deputy Clerk
DATE: July 9, 2002

Defendant: Kenneth N. Michaelis
Case Number: CR-2-00-115(1)

IMPRISONMENT

The defendant is hereby committed to the custody of the United States Bureau of Prisons to be imprisoned for a total term of SIX (6) MONTHS on count four (4)

The Court makes the recommendation to the Bureau of Prisons that the defendant serve his term of incarceration in the Ralph W. Alvis house, located in Columbus, Ohio.

The defendant is remanded to the custody of the United States Marshal.

The defendant shall surrender to the United States Marshal for this district,
at ____ m. on ____.
 as notified by the Marshal.

The defendant shall surrender for service of sentence at the institution designated by the Bureau of Prisons
before 2 p.m. on ____.
as notified by the United States Marshal.
as notified by the Probation or Pretrial Service Office.

RETURN

I have executed this Judgment as follows:

Defendant delivered on _____ to _____
at _____ with a certified copy of this Judgment.

R. Allen Smith
United States Marshal

By _____
Deputy U.S. Marshal

Defendant: Kenneth N. Michaelis
Case Number: CR-2-00-115(1)

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SUPERVISED RELEASE

Upon release from imprisonment, the defendant shall be on supervised release for a term of ONE (1) YEAR on count four (4). As a special condition of supervised release the defendant shall serve the first SIX (6) MONTHS in home confinement with electronic monitoring. The defendant shall pay the daily cost of electronic monitoring.

Further, the defendant shall provide access to his business and personal financial information to the U.S. Probation Officer upon request.

Further, the defendant shall only store business inventory in his home or in another location approved by the U.S. Probation Officer.

The defendant shall report to the probation office in the district into which the defendant is released within 72 hours of release from the custody of the Bureau of Prisons.

The defendant shall not commit another federal, state, or local crime.

The defendant shall not illegally possess a controlled substance.

For offenses committed on or after September 13, 1994:

The defendant shall refrain from any unlawful use of a controlled substance. The defendant shall submit to one drug test within fifteen (15) days of release from imprisonment and at least two (2) periodic drug tests thereafter, as directed by the probation officer.

The above drug testing condition is suspended based on the court's determination that the defendant poses a low risk of future substance abuse.

The defendant shall not possess a firearm as defined in 18 U.S.C. §921.

If this judgment imposes a fine or restitution obligation, it shall be a condition of supervised release that the defendant pay any such fine or restitution that remains unpaid at the commencement of the term of supervised release in accordance with the Schedule of Payments set forth in the Criminal Monetary Penalties sheet of this judgment.

The defendant shall comply with the standard conditions that have been adopted by this Court (set forth below). The defendant shall also comply with the additional conditions on the attached page.

STANDARD CONDITIONS OF SUPERVISION

- 1) the defendant shall not leave the judicial district without the permission of the court or probation officer;
- 2) the defendant shall report to the probation officer and shall submit a truthful and complete written report within the first five days of each month;
- 3) the defendant shall answer truthful all inquiries by the probation officer and follow the instructions of the probation officer;
- 4) the defendant shall support his or her dependents and meet other family responsibilities;
- 5) the defendant shall work regularly at a lawful occupation unless excused by the probation officer for schooling, training, or other acceptable reasons;
- 6) the defendant shall notify the probation officer ten days prior to any change in residence or employment;
- 7) the defendant shall refrain from excessive use of alcohol;
- 8) the defendant shall not frequent places where controlled substances are illegally sold, used, distributed, or administered;
- 9) the defendant shall not associate with any persons engaged in criminal activity, and shall not associate with any person convicted of a felony unless granted permission to do so by the probation officer;
- 10) the defendant shall permit a probation officer to visit him or her at any time at home or elsewhere and shall permit confiscation of any contraband observed in plain view of the probation officer;
- 11) the defendant shall notify the probation officer within seventy-two hours of being arrested or questioned by a law enforcement officer;
- 12) the defendant shall not enter into any agreement to act as an informer or a special agent of a law enforcement agency without the permission of the court;
- 13) as directed by the probation officer, the defendant shall notify third parties of risks that may be occasioned by the defendant's criminal record of personal history or characteristics, and shall permit the probation officer to make such notifications and to confirm the defendant's compliance with such notification requirement.

Defendant: Kenneth N. Michaelis
 Case Number: CR-2-00-115(1)

CRIMINAL MONETARY PENALTIES

The defendant shall pay the following total criminal monetary penalties in accordance with the schedule of payments set forth on Sheet 5, Part B.

| | | | |
|--------------|-------------------|-------------|--------------------|
| <u>Count</u> | <u>Assessment</u> | <u>Fine</u> | <u>Restitution</u> |
| Four | \$100.00 | \$10,000.00 | |

If applicable, restitution amount ordered pursuant to plea agreement.....\$ _____

| | | | |
|----------------|----------|-------------|-------|
| <u>Totals:</u> | \$125.00 | \$10,000.00 | \$-0- |
|----------------|----------|-------------|-------|

FINE

The above fine includes costs of incarceration and/or supervision in the amount of \$ _____
 The defendant shall pay interest on any fine of more than \$2,500, unless the fine is paid in full before the fifteenth day after the date of judgment, pursuant to 18 U.S.C. §3612(f). All of the payment options on Sheet 5, Part B may be subject to penalties for default and delinquency pursuant to 18 U.S.C. §3612(g).

The court has determined that the defendant does not have the ability to pay interest and it is ordered that:

- The interest requirement is waived.
- The interest requirement is modified as follows:

RESTITUTION

The determination of restitution is deferred in cases brought under Chapters 109A, 110, 110A, and 113A of Title 18 for offenses committed on or after 09/13/1994, until _____. * An Amended Judgment in a Criminal Case will be entered after such determination.

The defendant shall make restitution to the following payees in the amounts listed below.

If the defendant makes a partial payment, each payee shall receive an approximately proportional payment unless specified otherwise in the priority order or percentage payment column below.

| <u>Name of Payee</u> | <u>Total Amount of Loss</u> | <u>Amount of Restitution Ordered</u> | <u>Priority Order or Percentage of Payment</u> |
|----------------------|---------------------------------|--|--|
| <u>Totals</u> | \$ | \$ | |

* Findings for the total amount of losses are required under Chapters 109A, 110, 110A, and 113A of Title 18 for offenses committed on or after September 13, 1994.

Defendant: Kenneth N. Michaelis

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SCHEDULE OF PAYMENTS

Payments shall be applied in the following order: (1) assessment; (2) restitution; (3) fine principal; (4) cost of prosecution; (5) interest; (6) penalties.

Payment of the total fine and other criminal monetary penalties shall be due as follows:

A in full immediately; or

B \$10,125.00 immediately, balance due (in accordance with C, D, or E); or

C not later than _____; or

D In the event the entire amount of criminal monetary penalties imposed is not paid prior to the commencement of supervision, the U.S. probation officer shall pursue collection of the amount due, and shall request the court to establish a payment schedule if appropriate; or

E in _____ (e.g. equal, weekly, monthly, quarterly) installments of \$ _____ over a period of _____ years to commence _____ days after the date of this judgment.

Special instruction regarding the payment of criminal monetary penalties:

The defendant shall pay the cost of prosecution.

The defendant shall forfeit the defendant's interest in the following property to the United States:

Unless the court has expressly ordered otherwise in the special instructions above, if this judgment imposes a period of imprisonment payment of criminal monetary penalties shall be due during the period of imprisonment. All criminal monetary penalty payments are to be made to the United States District Court, Office of the Clerk, 85 Marconi Boulevard, Room 260, Columbus Ohio 43215 except those payments made through the Bureau of Prisons' Inmate Financial Responsibility Program.

Defendant: Kenneth N. Michaelis
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STATEMENT OF REASONS

The court adopts the factual finding and guideline application in the pre-sentence report.

OR

The court adopts the factual findings and guideline application in the pre-sentence report except The Court departs two (2) levels pursuant to 2F1.1(b)(1) Note 9 of the U.S. Sentencing Guidelines which provides that a loss need not be determined with precision and that the Court need only make a reasonable estimate of the loss given.

Guideline Range Determined by the Court:

Total Offense Level: 11

Criminal History Category: 1

Imprisonment Range: 8 to 14 months

Supervised Release Range: 1 year

Fine Range: \$3,000.00 to \$30,000.00

Fine waived or below the guideline range because of inability to pay.

Total Amount of Restitution: \$ 0

Restitution is not ordered because the complication and prolongation of the sentencing process resulting from the fashioning of a restitution order outweighs the need to provide restitution to any victims, pursuant to 18 U.S.C. §3663(d).

For offenses that require the total amount of loss to be stated, pursuant to Chapters 109A, 110, 110A, and 113A of Title 18, restitution is not ordered because the economic circumstance of the defendant do not allow for the payment of any amount of a restitution order, and do not allow for the payment of any or some portion of a restitution order in the foreseeable future under any reasonable schedule of payments.

Partial restitution is ordered for the following reasons:

The sentence is within the guideline range, that range does not exceed 24 months, and the court finds no reason to depart from the sentence called for by application of the guidelines.

OR

The sentence is within the guideline range, that range exceeds 24 months, and the sentence is imposed for the following reasons:

OR

The sentence departs from the guideline range

upon motion of the government, as a result of defendant's substantial assistance, the Court departs to a level ____.

for the following reasons: