

HEMATOLOGY-ONCOLOGY MEDICAL GROUP OF ORANGE COUNTY, INC.

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March 17, 1977

Docket #77N-0048

Food and Drug Administration
Rockville,
Maryland 20857

Gentlemen:

In the matter of Laetrile Docket #77N-0048, I am a physician licensed to practice in the State of California. Attached is a copy of my curriculum vitae which details my education, training and experience and contains a list of my publications. I have been in the practice of hematology and oncology in California since September of 1972. During the course of my practice I have treated a number of patients who took Laetrile in Mexico. All of these patients had cancer and had been drawn to Mexico because of the promise of a cure. When it became apparent that the disease progressed inexorably, the patients returned to their home towns and requested orthodox treatment; in most of the cases this was too late to do any good.

One such case was Mrs. P. which I analyzed extensively and documented on video tape. The patient was a 58-year-old white female who was first seen in consultation at St. Joseph Hospital in August of 1973 with a 2-week history of abdominal cramps, nausea and vomiting. A complete G-I series was performed. Barium enema indicated an adenocarcinoma almost completely obstructing the colon at the level of the splenic flexure. SMA-12 and other blood tests were normal at the time as well as hemoglobin, hematocrit and white blood count. Urinalysis was normal. EKG showed a possible old inferior myocardial infarct and left axis deviation. Chest x-ray showed blunted left costophrenic angle. In August of 1973 she had resection of transverse colon and a colostomy with closure of the distal loop of bowel. This showed a well differentiated adenocarcinoma of the large intestine. Lymph nodes were negative for metastatic malignancy and she was believed to have a Duke's Type A. At the time of colostomy a remaining adenocarcinoma was left in situ (histology at the edge of the colostomy showed malignancy.) In September of 1973 she was readmitted for closure of colostomy and also resection of a large piece of colon since adenocarcinoma was still present in the abdomen. At that time she had abnormal liver function tests. This was felt to be secondary to Fluothane anesthesia. She did extremely well. Colostomy was closed, edges were now negative for cancer. She did well until June of 1975

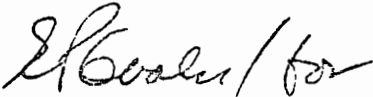
when followup examination showed a chest x-ray to contain two foci which were not present previously and were presumed to be metastatic from cancer of the colon. She was investigated thoroughly in June of 1975. She was worked up thoroughly. Carcino-embryonic antigens were less than 1. SMA-12 revealed alkaline phosphatase increased to 121. Antinuclear factors were 110. Serum protein electrophoresis was normal as was IEP patten (immunoelectrophoresis). IVP showed an extrarenal location of the right renal pelvis with a resultant slight ectasia of the right renal pelvis. This was felt to be a normal anatomic variant. Upper G-I's were normal. Bone scan showed increased activity in the calverium felt to be secondary to hyperostosis frontalis interna and what appeared to be an osteoma in the medial cell of the right frontal sinus. Chest x-ray and tomograms revealed three uncalcified nodules in the left lung, in upper, mid and lower portions of the lung, likely representing metastatic neoplasm. Liver scintigraphy was normal. Spleen showed decreased activity around the splenic hilum. The patient was referred to a pulmonary specialist for possible bronchoscopy; however, this procedure was not performed because it was felt that with a history of cancer of the colon and the nodules which appeared uncalcified and which had not been present previously that this represented a metastasis and that bronchoscopy would be superfluous and perhaps academic. She was then presented to the Tumor Board of St. Joseph Hospital in June of 1975 whose recommendation it was that the patient probably had metastatic cancer from the colon to the lung and that chemotherapy should be undertaken. The patient elected instead to have treatment with Laetrile in Tijuana, Mexico. The patient's husband traveled to Mexico with her and attested (on video tape) that on the first day of contact with the Clinico Del Mar run by Dr. Contreras that no physical examination was done prior to starting on treatment. The patient was merely asked what she was in for and was started right away on the long course of "vitamins and Laetrile." Repeat chest x-ray in that city was done and she was told that the metastases had increased and now she should begin on chemotherapy. The patient, however, decided that since she could get chemotherapy in her home town, she returned for this reason. In December of 1975 she was seen and started on chemotherapy with 5-FU. However, she complained of an episode of weakness in the left lower extremity which she had attributed to a "stroke." Complete neurologic evaluation failed to reveal any abnormalities. She was started on 5-FU and an hour after receiving chemotherapy she again noted recurrent weakness which proceeded to frank paresis of the left upper extremity and the left lower extremity. An EMI scan documented at least five metastatic brain lesions. She then developed marked motor weakness which became progressively worse and she finally expired on January 17, 1976.

In June of 1975 when the patient was discussed and presented to the Tumor Board at St. Joseph Hospital in Orange, California, and was offered chemotherapy, it is, of course, impossible to state with certainty that the course would have been any different from what transpired later had she been started on chemotherapy. What is certain, however, is that she had at that time a 35-40% chance of going into a remission with the Moertel protocol of 5-FU and Methyl CCNU. What is certain is that without chemotherapy and with

Laetrile, she developed increasing metastases, went into no remission, and had rapidly increasing metastases to the brain and expired quickly, approximately four weeks after she had been started on the Moertel program with Methyl CCNU and 5-FU.

In our practice here in Orange County, California, we have been impressed with several patients whose course followed the same route.

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


J.V. Souadjian, M.D.

CURRICULUM VITAE

JACQUES V. SOUADJIAN, M.D.

PERSONAL

Born: December 1, 1933
Married: Joan Bielinis, 1963
Children: Three--Jacques, Jr., age 9, Marie Christin, age 8, Michael, age 4.

Business Addresses: 1. 18102 Irvine Boulevard, Suite 105, Tustin, California 92680
2. University of California (Irvine)
California College of Medicine
Division of Hematology, Department of Medicine
101 City Drive South, Orange, California 92668

Business Phone: 714-838-8151

Home Address: 1777 Warbler Place, Orange, California 92667

Home Phone: 714-998-2936

Citizenship: U.S. (St. Paul, Minnesota, 1969)

EDUCATION AND DEGREES

1951 American University of Beirut, Prep. Section, Beirut, Lebanon.
1951-53 American University of Beirut, Beirut, Lebanon.
1953 General Certificate of Education (Oxford University) at British Consulate, Beirut, Lebanon.
1953-56 French Faculty of Medicine (St. Joseph University), Beirut, Lebanon.
1954 Pre-Med Degree (P.C.B., Degree in Physics, Chemistry and Biology), St. Joseph University, Beirut, Lebanon.
1959-63 M.D. Degree, Ottawa University School of Medicine, Ottawa, Ontario, Canada.
1969 M.Sc. (Medicine), University of Minnesota.

POSTGRADUATE TRAINING

July 1963-July 1964 Rotating Internship, Memorial Hospital of Long Beach, California.
Oct. 1964-Oct. 1967 Fellowship in Internal Medicine, Mayo Graduate School of Medicine, Mayo Clinic, Rochester, Minnesota
Oct. 1967-July 1969 Fellowship in Hematology, Mayo Graduate School of Medicine, Mayo Clinic, Rochester, Minnesota.
July 1969 Master of Sciences in Medicine, University of Minnesota.

LICENSURES AND CERTIFICATION

Licensed: United States (California #A-24891)
Canada (Ontario #23529; Quebec #69-363)

Diplomate, Medical Council of Canada, May 1971.
Diplomate, Certified Specialist in Hematology,
Province of Quebec, 1971.
Diplomate, Federal Licensure Medical Examination (FLEX) 1973

PROFESSIONAL APPOINTMENTS

1959 Laboratory Instructor in Histology and Embryology,
University of Ottawa, Ontario, Canada.

1964 Fellow, Mayo Graduate School of Medicine, Mayo Clinic,
Rochester, Minnesota.

1965 Special Intramural Grant, Mayo Clinic (National Institutes
of Health), Department of Experimental Pathology.

1969 Assistant Professor, Department of Medicine, Section of
Hematology, University of Sherbrooke, Quebec, Canada.

1970 Special Research Grant, Cancer Research, The Medical
Research Council of Quebec.

1972 Assistant Adjunct Professor, University of California,
Irvine, College of Medicine.

July 1974 Clinical Associate Professor of Medicine, University of
California, Irvine, College of Medicine.

ADMINISTRATIVE APPOINTMENTS

1962-63 President, University of Ottawa School of Medicine,
Student Body (by election).

1969 Medical Consultant, University of Sherbrooke Medical Center.

1970 Committee Member, Intern and Resident Medical Curriculum,
University of Sherbrooke Medical Center, Sherbrooke,
Quebec.

1970-72 Chairman, Medical Audit Committee, University of Sherbrooke
Medical Center, Sherbrooke, Quebec, Canada.

1971 Member, Committee on Procedures and Utilization of Nuclear
Material, University of Sherbrooke Medical Center.

1973 Member, Cancer Committee, St. Joseph Hospital, Orange,
California.

1974 Member, Committee on Transfusion Utilization, St. Joseph
Hospital, Orange, California.

1975 Chairman, Cancer Committee, St. Joseph Hospital, Orange, Ca.
President, Orange County Blood Club (by election.)

HONORS AND AWARDS

The Society of Sigma Xi, 1969.
American Medical Association Physicians Recognition Award, 1970-73.

MILITARY SERVICE

Nov. 1956-June 1963 U.S. Army Reserve
1956-57 Active Duty, U.S. National Guard
1957-63 Reserve Duty, U.S. Army

PROFESSIONAL MEMBERSHIPS

The College of Physicians & Surgeons of the Province of Quebec.
The College of Physicians & Surgeons of the Province of Ontario.
The Orange County Medical Society
The California Medical Association
The American Medical Association
The Society of the Sigma Xi.
The American Federation of Clinical Research.
The Canadian Society of Hematology.
The American Society of Hematology.
The International Society of Internal Medicine.
The American Geriatrics Society.
The New York Academy of Sciences.
The American Federation of Clinical Research.
Mayo Clinic Alumnus Society.

PAPERS & LECTURES PRESENTED AT PROFESSIONAL MEETINGS

1. Minnesota Society of Internal Medicine, Duluth, Minnesota, May 1965, (Hypertension in Acromegaly.)
2. American Heart Association, Council on Atherosclerosis, New York, New York, Oct. 1966, (Effect of Estrogen on Spontaneous Atherosclerosis.)
3. American Federation of Clinical Research, Atlantic City, New Jersey, May 1968 (The Thymus and Malignancy.)
4. American Federation of Clinical Research (Mid-West Section), Chicago, Illinois, October 1968 (Influence of Thymic Grafts on Tumor Growths.)
5. The Quebec Society of Laboratory Physicians, Quebec, Canada, May 1970 (Relationship of Thymic Anaerobic Glycolysis in Mice to Genetic Predisposition.)
6. Quebec Clinical Research Society, Mount Orford, Quebec, Canada, September 1970 (Analysis of Thymic Metabolic Products in Experimental Leukemia.)
7. Second International Symposium on Growth Hormone, Milan, Italy, May 1971, (Effect of Growth Hormone on the Thymus.)
8. Tumor Forum, St. Joseph Hospital, November 1972 (The Stauffer Syndrome, Reversible Hepatopathy with Hypernephroma.)
9. Tumor Forum, St. Joseph Hospital, May 1973, (The Spectrum of Diseases Associated with Thymoma.)

LECTURES

1. University of California, Irvine Campus, October 1972 (The Serum Protein Electrophoresis.)
2. Staff Meeting, Tustin Community Hospital, November 1972 (Immunity and Cancer.)
3. Santa Ana Hospital, Symposium on Cancer, December 1972 (Immune Aspects of Neoplasia.)
4. Tumor Forum, St. Joseph Hospital, December 1972 (The Stauffer Syndrome, Reversible Hepatopathy with Hypernephroma.)
5. Orange County Hospital Center Auditorium, January 1973 (The Thymus in Neoplasia.)
6. Santa Ana Community Hospital, May 1973, ("Recent Advances in Immunotherapy.")
7. University of California, Irvine Campus, May 1973 (Immune Aspects of Cancer.)
8. Tumor Forum, St. Joseph Hospital, June 1973, Chairman ("Hairy-Cell Leukemia.")

LECTURES (Continued)

9. Orange County Medical Center, August 1973 (Dysproteinemias).
10. Santa Ana Community Hospital, September 1973 (Bleeding Problems in Multiple Myeloma, Symposium "Multiple Myeloma.")
11. University of California, Irvine Campus, October 1973, (Immunoglobulins Relationship to Disease.)
12. American Cancer Society, University of California, Irvine Campus, Oct. 20, 1973, (Chemotherapy of Cancer, Symposium "Conquest of Cancer.")
13. Surgical Departmental Meeting, St. Joseph Hospital, November 5, 1973, (Why is the Patient Bleeding?)
14. Town Hall For Health, Marymount College Auditorium, Orange, California, May 1974, (Chemotherapy of Cancer.)
15. Staff Meeting, Santa Ana Community Hospital, Santa Ana, July 1974, (The Clinical Approach to Anemias.)
16. Tumor Forum, St. Joseph Hospital, November 1974, (Skin Manifestations of Malignancy.)