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STATEMENT TO THE ASSEMBLY HEALTH COMMITTEE OF THE CALIFORNIA LEGISLATURE

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The Statement on SB 1474 and 1475, relating to orthomolecular medicine, was to begin at a hearing scheduled for May 11, 1976. That hearing was rescheduled, and because I may not be able to attend the rescheduled hearing because of my own timetable, I am putting the statement in written form so that it may be transmitted to the committee.

My qualifications to address the subject of orthomolecular medicine and in particular the question of chelation therapy for arteriosclerosis are the following:

I graduated in medicine in 1970, and in 1974 completed a residency in Internal Medicine and Neurology. I am a qualified specialist in Internal Medicine, and since 1974 I have been enrolled at the University of California, San Francisco as a post-doctoral scholar in Clinical Pharmacology. This discipline specifically addresses itself to question of the adequacy of evidence as to efficacy of drugs, and is particularly interested in drug toxicity. My own field of specialized research is in the area of prevention of atherosclerosis by the use of drugs. I became interested in chelation therapy for arteriosclerosis as the result of a telephone call from a patient in San Francisco, who sought the advice of the University on the question of whether chelation therapy, which he had been advised to take, would be worth three hundred dollars a week to him. At that time I reviewed in detail the scientific literature purporting to bear on the issues of efficacy and toxicity of chelation therapy, and that study resulted in a letter to the San Francisc Medical Society from Dr. K.L. Melmon, the Chief of the Division of Clinical Pharmacology. The ultimate result of that letter was a resolution passed by the California Medical Association House of Delegates,

recommending that the members of the Medical Association be advised that the use of chelation therapy for arteriosclerosis was not substantiated as to efficacy, and further that the members should be advised of its potential toxicity. Following that event, I acted as a consultant to a federal survey team reporting to the Bureau of Health Insurance of the Federal Department of Health and Welfare. The survey team was charged with carrying out a full investigation of practices in a small private hospital established for the purpose of administering chelation therapy for arteriosclerosis. I thus had a unique opportunity to study in detail the procedures and the results of chelation therapy, including the entire battery of medical records in that hospital. Subsequently, I was appointed to the Ad Hoc Committee on Chelation Therapy of the Advisory Panel on Internal Medicine, of the California Medical Association. I participated in a hearing in Los Angeles on March 26, 1976, in which the American Academy of Medical Preventics (AAMP) presented arguments in favor of an appeal to the CMA, to change its position on chelation therapy. Prior to that meeting, I studied in detail some 102 pounds of "documents" which purported to bear on the issue of chelation therapy and arteriosclerosis. I was present at the hearing, and was able, therefore, in addition to reading the material submitted by the AAMP, to hear their arguments in person, and to question them regarding their rationale and practice. In addition, I received at that hearing the unique opportunity to study a computer printout entitled "Arteriosclerosis Study Detail," from the Sacramento Center for Research on Arteriosclerosis and Aging of the AAMP. I therefore submit, because of my particular exposure to the issues and literature on chelation therapy for arteriosclerosis, I am well qualified to render an opinion on the matter.

INTRODUCTION.

I am acutely aware of the perilous position that a physician puts himself in when speaking in public before a group composed largely of nonphysicians, about a new therapy which has been lauded and heralded as a possible answer to such a common ailment as arteriosclerosis. My awareness of this predicament was enhanced recently by reading an article in the "Pharos" (the AOA Medical Honor Society publication), volume 39, page 2, 1976, by John H. Dirckx, entitled "The Quack in Literature". In this article Dr. Dirckx describes the tale of the hero of Smollett's "Ferdinand Count Fathom" (1753), who on hearing a physician give a lecture at the Mineral Springs in Bristol, undertakes, for his own amusement, to contradict everything the physician says. He fabricates for the occasion an outrageous impromptu system of physics and biology, which, although totally unscientific, is totally areeable to the lay audience. Conveniently, it overturns everything which has been said by the physician. The testy doctor loses his temper, and tells the audience that "Fathom must be a person wholly ignorant of natural philosophy who could invent such a ridiculous system; furthermore, he tells the crowd that they are involved in "worse than an Egyptian fog, that they could not discern the weakness and absurdity" of Fathom's system. This introduced a dispute, which was unanimously decided by the crowd in favor of Fathom's adsurdity.

Smollett tells us that this is the usual outcome of a public debate between a physician and a charlatan. He gives three reasons why this should be so: Firstly, he cites what in modern day terms is represented by the continual friction between academia and physicians practicing on the "front line". Secondly, he points out that in arguments between people who really understand the complexities involved in a scientific problem, and those who don't, the reservations and caution demanded by

complexity will seem obscure and unintelligible, while simple theories derived from common notions and superficial observation will be more agreeable since they are more easily understood by the hearers. Thirdly, he says "the judgment of the multitude is apt to be biased by that surprise which is the effect of seeing an artist foiled at his own weapons."

It is my hope, that in weighing my statement, the committee will have regard for the absence of any possibility of my being motivated by such considerations as financial gain. My reason for coming forward is that I am appalled by the specter of such unscientific therapies being widely applied to members of the public, without adequate evidence of efficacy, and I am alarmed at the evidence of toxicity of chelation therapy for arteriosclerosis, which I saw in my capacity as consultant to the Federal survey team. On the other hand, the committee should be aware that those persons who are practicing chelation therapy for arteriosclerosis have a substantial pecuniary motive for supporting chelation therapy in statements to the committee.

FINANCIAL IMPLICATIONS:

The patient who first brought my attention to chelation therapy was being offered this treatment by a San Francisco physician who acted as the moderator for the AAMP presentations to the committee hearing of the CMA in Los Angeles on March 26, 1976. The patient stated that he was offered chelation therapy for the price of $300 a week, and that he should expect to be receiving treatments for a least three weeks. As routinely practiced by members of the AAMP, chelation therapy consists of drug infusions which take about three hours to administer. Eve assuming that the doctor only had one chelation room going at a time, he would have no trouble handling an average of three patients per day, which could at this rate earn him a thousand dollars a week, or $50,000 a year. If only 100 physicians were engaged in this practice, and even

if they only handled an average of three patients a day, they would earn $5,000,000 a year. If they were to increase their output, it would be simple to run up their revenues to tens of millions of dollars per year. It is no wonder that the AAMP has such a strong enthusiastic lobby pressing for the passage of these Senate bills. I do wonder, however, whether the California taxpayers can afford to pay the bill, although I am not sure that that is even the most important question at issue here.

LETTER FROM THE COMMITTEE FOR MEDICAL FREEDOM, MARCH 31, 1975:

This letter is attached to the statement as attachment number one. It addresses the question of Senate bills 1474 and 1475, under the heading "Mills Bills Moving Ahead." The text of this letter includes a statement to the effect that the committee for medical freedom has resisted a move from the Department of Health to delete chelation therapy for anything other than removal of heavy metals, from the bills. The letter states that Senator Mills was able to gain approval of the bills "as is" pending the outcome of a CMA Scientific Board Meeting on the subject.

It is because of this letter from the Committee for Medical Freedom, that the intentions of the chelation therapy lobby have become clear: It appears that they intend to slip a chelation therapy under the umbrella of orthomolecular medicine, under the subtle wording of Senate bill 1975, in the section which refers to "removal from the body - - - - of substances to which some patients are hypersensitive, such as toxic metals, including lead, mercury - - -". It is apparent from this letter from the Committee on Medical Freedom, that proponents of chelation therapy will gradually shift the emphasis of their efforts to promote chelation therapy for arteriosclerosis, to the notion that the removal of such toxic substances as mercury by the infusion of

the contrary, there is a vital distinction here that must be recognized. If orthomolecular medicine is restricted to the administration of nutritional supplements, and the prescription of diets in which certain dietary substances are avoided, then orthomolecular medicine, although it is unlikely to be helpful to anyone, is at least not likely to be harmful. However, the inclusion under the umbrella of orthomolecular medicine of the practice of intravenous infusions of a toxic chemical substance, (which is a fair description of chelation therapy), is entirely another matter.

TOXICITY OF CHELATION THERAPY:

From my reading of the submissions of the AAMP to the CMA Committee, from statements made by practitioners of chelation therapy during those hearings, and from my observation during the investigation of the Federal Survey Team of which I was a part in November of 1975, I am convinced that the practitioners of chelation therapy (as represented by the AAMP), have been misrepresenting chelation therapy (with infusion of EDTA) as a safe procedure. When confronted with literature reports of kidney damage due to EDTA infusion, their reply at the CMA hearing in Los Angeles was that yes, it was true that chelation therapy had been known in the past to cause kidney failure, but that in the doses in which it is now used, the treatment is innocuous. This position represents a dangerous attitude of disregard for the principles of safety which must be exercised when drugs are given directly into the blood stream. Any member of the committee who has ever had an intravenous infusion for any length of time will be aware that IV infusions have a tendency to go faster and slower according to the position of the patients arm, and a number of other factors related to the position of the needle, the setting on the valve controlling the administration

faster than that intended by the chelation therapist has a potential for causing convulsions from low blood calcium levels, serious disturbances of heart rythm, and congestive heart failure, because the infusion contains sodium corresponding to a two percent sodium chloride infusion. This therapy, therefore, should never be administered to a patient who is not constantly attended by a nurse, and should probably be administered only with mechanical devices which control the rate of administration, and with cardiac monitoring. I am not at liberty to disclose the name or location of the hospital which was the subject of the Federal Investigation in which I participated in November of 1975. Unfortunately, my report to the Bureau of Health Insurance remains an internal document of the Bureau, which has presently been subpoenaed in connection with an FDA case. However, without revealing the name and location of the hospital, I believe that it is within my right to state some of the facts of which resulted from that investigation. I examined in detail the chart of all 21 patients who had died at that hospital in the two years of its existence, and found the following: of the 21 patients who died, chelation therapy was a significant contributing factor, if not solely responsible, in my opinion, in the death of 13 of those patients. One died from hypoglycemia, (lowering of insulin requirements is a recognized effect of EDTA), four patients died from congestive heart failure, and eight patients died with renal failure. These patients were receiving chelation therapy in the manner advocated by the AAMP, under the direction of a member of the AAMP, who had on his office wall a certificate of merit from the AAMP. The manner in which chelation therapy was used in that hospital is the same as the manner in which chelation therapy was being used in California last year.

From my considerable aquaintance with verbal testimony from practitioners of chelation therapy and from literature submitted to the CMA purporting to document efficacy of chelation therapy I can state the following: the rational for chelation therapy in the treatment of atherosclerosis is unscientific, and bears no relationship to current understanding of the pathogenesis of arterial disease. The efficacy of this therapy in patients is unproven, and the "evidence" amounts to a collection of anecdotes. The most telling argument, I believe, against the efficacy of chelation therapy, comes from the study of over 500 patients by the center for retardation of human aging, in Sacramento. I was afforded the opportunity to examine in detail a computer printout reporting the results of this study, which was carried out by practitioners of chelation therapy, indeed the same practitioners who are most vocal in support of chelation therapy. Their own study show the following: Using criteria which included clinical evaluations, plethysmography, and thermography, 76 percent of patients who were treated with chelation therapy achieved results which were excellent or fair. This result was tabulated by their computer. The result which was not tabulated by the computer, but which was available by going through the printout by hand, was that 89.7 percent of the patients who did <u>not</u> receive chelation therapy achieved results which were excellent or fair. In other words, the results were better in the patients who did not receive chelation therapy, than in the patients who did receive chelation therapy.

CONCLUSION:

I believe it is abunduntly clear that chelation therapy, which is of unproven efficacy, and which is more toxic than is generally conceded by the chelation therapists, cannot be considered a standered

medical therapy. At the very best, it should be considered an experimental therapy, and should be given only to a limited number of patients, in the setting of a carefully controlled clinical study. Whatever the committee decides to recommend about orthomolecular medicine, I strongly urge the committee to make a distinction between administration of vitamins and diets, and intravenous administration of a toxic chemical to hundreds or perhaps thousands of people at a cost of millions or tens of millions of dollars annually.

The CMA Advisory Panel on Internal Medicine, through its committee on chelation therapy, has heard the evidence offered by the proponents of this exerimental practice, and they found the evidence lacking. I urge you gentlemen not to get into the risky business of overriding medical decisions about efficacy and toxicity with political decisions about who shall gain alot of money, not only at the expense of the taxpayer, but at the expense of the subjects of this uncontrolled experiment. I thank you for your attention.

J. David Spence, M.D.