

VICTORIA HOSPITAL - LONDON, ONTARIO

301 SOUTH STREET NOA 4G5

(519) 432-5241

A. R. Thorfinnson, Executive Director

Department of Medicine July 9, 1976

Dr. W. Sherwood Lawrence Medical Officer California State Department of Health Food and Drug Section 714 P Street Sacramento, California 95814

Dear Doctor Lawrence:

In reply to your letter of July 6, 1976, concerning my opinion regarding chelation therapy, I will make a brief statement in this letter. I will say that I would be available to testify to my opinion if required.

In addition to the qualifications to which you refer, (i.e., that I am a member of the Ad Hoc Committee on Chelation Therapy of the Advisory Panel on Internal Medicine of the California Medical Association, and was present at the hearing in Los Angeles, and that I was a member of a federal investigating team which visited a hospital in Louisiana in 1975, to determine whether the routine use of EDTA constituted a danger to the health and safety of the patients of that hospital), I recently qualified in Federal District Court, the Eastern District of Louisiana, and testified as an expert witness for the FDA, on the subject of chelation therapy and atherosclerosis, on June 30, 1976.

The subject of my investigation, which has until now been confidential, is a matter of public record as a result of the hearing in New Orleans on June 30 of 1976. I am, therefore, at liberty to make public statements regarding that investigation, and I believe that the results of the investigation constitute atrong evidence of the (danger of the treating use of chelation therapy by infusion of sodium EDTA, for the prevention of the complications of the complications.

In my opinion, such routine use of EDTA infusion resulted in thirteen deaths at Meadowbrook Hospital, Belle Chasse, Louisiana, in a period of some two years which were covered by the medical records which I examined. The causes of death included hypoglycemia, from the enhancement of insulin action by EDTA; congestive heart failure because in the manner in which EDTA is used, it constitutes a 2% saline infusion, and is frequently given to elderly patients with heart disease; and deaths were also attributable to renal failure, which, in a number of cases, was not present before the administration of EDTA. These complic-

ations of EDTA infusion are documented in the literature, but it has been the argument of the American Academy of Medical Preventics, as presented at the hearing of the Ad Hoc Committee on Chelation Therapy in Los Angeles on March 26th, that the doses which are now in use in the practice of chelation therapy are much lower than those which were required to produce the complications cited in the literature. On the contrary, the manner in which chelation therapy was used at Meadowbrook Hospital in Louisiana, was the manner in which chelation therapy is used by a member of the American Academy of Medical Preventics, who has on his office wall, a certificate of merit from the American Academy of Medical Preventics.

EDTA is not suitable for clinical practice in the treatment of paripheral vascular disease and coronary vascular disease. There is no cyidence as to the efficacy of this treatment, other than a series of anecdotal accounts. The rationale for the use of chelation therapy bears no relationship to the current understanding of the pathogenesis of atherosclerosis. The older theory regarding the role of calcium in maintaining atherosclerotic plaques, which would be washed away if the calcium were dissolved out of the plaques, (sometimes referred to as the roto-rooter theory), has been replaced by a more sophisticated theory based on the notion that toxic trace metals may accumulate in the arteries of clderly nations and may therefore, interfere with enzyme function in arterial walls and result in the lesions of atherosclerosis. This is a theory which is not supported by any of the known facts regarding atherosclerosis.

In regard to your question of whether I am aware of any physician conducting therapeutic trials on a sound scientific basis, I can say the following:

At the hearing of the Ad Hoc Committee on Chelation Therapy in Los Angeles, I was given the opportunity to scudy a computer printout of a study which was conducted in Sacramento at the center for prevention of aging, which showed the results of the study of some five hundred patients. The patients were assessed on the basis of clinical examination and symptoms, plethysmography, and thermography. While this trial is not a properly designed study, it is the only one of which I am aware which compared the results of patients treated with EDTA chelation therapy, with patients who were not treated. Although the computer did not tabulate the results for patients who were not treated, I was able to go through the printout and tabulate the results by hand. My study showed that while the results claimed for patients treated with EDTA based on the criteria used, were excellent or fair in seventy-six percent of the cases, the results for patients who were not treated with EDTA ware excellent or fair in eighty-nine percent of the sener. Thus, the best evidence available, indicates that patients not treated with EDTA did better than those who received treatment.

This chemical laboratory agent is clearly unsuitable for general therapeutic application on an unrestricted basis. The use of this agent in studies of therapy for atherosclerosis is probably not even warranted on an experimental basis, because there is no reason to think that it would work, from current understanding of the pathogenesis of atherosclerosis. However, if some people were convinced enough on the basis of anecdotal experience to think that it ought to be given a scientific trial. then it might be justifiable to conduct a properly designed study in a limited number of patients using careful controls, and using methods which evaluate flow in arteries, as opposed to the plethysmography and thermography which have been used up until now. Plethysmography and thermography. which are highly susceptible to changes in emotions, environmental temperature, and factors other than arterial flow, are unsuitable for assessing atherosclerosis, which is a disease of arteries, and not a disease of the small resistance vessels in the skin. The administration of this laboratory agent intravenously on a wholesale basis to healthy people whose only problem is that they are over the age of fifty and, therefore, have gray hair and are suspected of having arterial disease, can only be justified on the basis that it would earn a great deal of money for the practitioners of this experiment. The infusion of FDTA intravenously in elderly patients with heart disease should be done only for proper indications, such as hypercalcemia w. ich does not respond to standard therapy, and should only be done in a setting of continual nursing care, with cardiac monitoring, and with calcium gluconate or other such antic antedote drawn up and available at the bedside. To administer the infusion of EDTA in some other manner, is to ignore the principles of intravenous therapy with agents known to cause convalsions and cardiac arrhythmias if their rate is uncontrolled. A further safeguard which should be available, is that the drug should be controlled by an infusion pump, so that the rate of infusion cannot exceed a safe rate

A further and less obvious toxicity of this therapy is that belief in its powers has attained the status almost of a religion, among the people who administer it. They have convinced themselves and, indeed, many of their patients, of the benefit of this therapy, and as I observed in Louisiana, there is firm evidence that this therapy has been used instead of standard life-saving available therapies, such as hemodialysis, and the result has been the death of the patient.

I strongly urge you to do everything in your power to protect the citizens of California and, indeed, of the United States (since this movement is so active in California, the precedent in California will have nation-wide implications) from this dangerous and unscientific practice.

I stand ready to do whatever I can to help you in this task. I name, as a reference for my credentials, Dean Tupper of the University of

California School of Medicine at Davis, California. He is the chairman of the Ad Hoc Committee on Chelation Therapy, and I am sure that he would also be available for advice regarding this problem.

Yours very truly,

J. David Spence, M.D., P.R.C.P.(C)

Assistant Professor of

Internal Medicine and Neurology

JDS/bt