THE REPORT ON BOARD OF HEALTH DELIBERATIONS AND RECOMMENDATIONS ON CHELATION THERAPY

(NOVEMBER 15, 1999)

THE REPORT IS ORGANIZED INTO TWO SECTIONS EACH OF WHICH DESCRIBES ONE OF THE TWO STAGES OF THE BOARD OF HEALTH'S REVIEW OF THE CHELATION ISSUE.. THE FIRST STAGE OF THE REVIEW PROCESS IS THE REVIEW OF THE 407 COMMITTEE OF THE BOARD. THE SECOND STAGE IS THE REVIEW OF THE FULL BOARD OF HEALTH.

1) **SUMMARY OF 407 COMMITTEE DELIBERATIONS AND ADVICE TO THE BOARD ON THE RECOMMENDATION OF THE CHELATION THERAPY TECHNICAL REVIEW COMMITTEE (FROM THE NOVEMBER 9, 1999 MEETING OF THE 407 COMMITTEE)**

THE TECHNICAL COMMITTEE RECOMMENDATION WAS AS FOLLOWS:

> **AFTER AN EXTENSIVE REVIEW OF AVAILABLE RESEARCH, LITERATURE, AND EXPERT TESTIMONY, THE CHELATION THERAPY TECHNICAL REVIEW COMMITTEE HAS FOUND THAT CHELATION THERAPY IS PROBABLY SAFE IF STANDARD PROTOCOLS (THE AMERICAN COLLEGE FOR THE ADVANCEMENT OF MEDICINE, FOR EXAMPLE) ARE USED IN THE INFUSION OF ETHYLENEDIAMINETETRAACETIC ACID ("EDTA"). THE TECHNICAL COMMITTEE CANNOT DETERMINE AT THIS TIME WHETHER OR NOT CHELATION IS AN EFFECTIVE THERAPY FOR ANYTHING OTHER THAN THE REMOVAL OF HEAVY METALS, AND CONSEQUENTLY, RECOMMENDS THAT THERE BE NO NEW LEGISLATION ENACTED WITH REGARD TO THIS ISSUE.**

COMMENTS BY THE CHAIRPERSON OF THE CHELATION THERAPY TECHNICAL COMMITTEE

JANEL FOOTE, R.P., THE CHAIRPERSON OF THE TECHNICAL COMMITTEE, COMMENTED ON THE WORK OF THE COMMITTEE, AND INFORMED THE 407 COMMITTEE MEMBERS THAT THE FOCUS OF HER COMMITTEE'S WORK WAS ON "EDTA" RATHER THAN ON ANY OTHER CHELATING AGENTS. CHAIRPERSON FOOTE ADDED THAT THE PRINCIPAL QUESTION DEALT WITH DURING THE REVIEW WAS WHETHER OR NOT "EDTA" CHELATION CAN BE USED TO EFFECTIVELY TREAT CORONARY-ARTERY DISEASE.

CHAIRPERSON FOOTE INFORMED THE 407 COMMITTEE MEMBERS THAT HER COMMITTEE HAD VERY LITTLE RESEARCH DATA TO WORK WITH, AND THAT MOST OF THE INFORMATION AVAILABLE WAS IN ONE WAY OR ANOTHER ANECDOTAL IN NATURE. THIS IS BECAUSE NO TRULY SCIENTIFIC STUDIES ON CHELATION HAVE EVER BEEN DONE.

CHAIRPERSON FOOTE STATED THAT HER COMMITTEE INVITED DAVID BOUDA, M.D., A MEDICAL ONCOLOGIST FROM U.N.M.C. TO GIVE THEM A PRESENTATION ON CHELATION THERAPY. DR. BOUDA HAS DEVELOPED AN EXPERTISE IN THE AREA OF ALTERNATIVE MEDICINE IN GENERAL INCLUDING CHELATION THERAPY. CHAIRPERSON FOOTE WENT ON TO STATED THAT DR. BOUDA INFORMED THE TECHNICAL COMMITTEE MEMBERS THAT A SCIENTIFIC STUDY ON

THE EFFECTIVENESS OF CHELATION THERAPY WILL PROBABLY NEVER OCCUR DUE TO THE HIGH COST OF SUCH STUDIES.

CHAIRPERSON FOOTE THEN COMMENTED ON THE PUBLIC HEARING OF HER COMMITTEE HELD ON OCTOBER 21, 1999. CHAIRPERSON FOOTE NOTED THAT ALL TESTIMONY WAS PROPONENT TESTIMONY, AND THAT SOME OF THE TESTIFIERS CRITICIZED THE REVIEW PROCESS FOR A THE LACK OF SCIENTIFIC EVIDENCE UPON WHICH TO BASE ITS RECOMMENDATIONS. CHAIRPERSON FOOTE STATED THAT MOST OF THE TESTIMONY WAS ANECDOTAL IN NATURE, AND EACH TESTIFIER TOLD THE COMMITTEE ABOUT THE BENEFITS THAT CHELATION THERAPY HAD BROUGHT TO THEIR LIFE AND HEALTH.

CHAIRPERSON FOOTE COMMENTED ON HER COMMITTEE'S RECOMMENDATIONS BY STATING THAT THE TECHNICAL COMMITTEE MEMBERS RECOMMENDED THAT THERE BE NO CHANGE IN PUBLIC POLICY PERTINENT TO CHELATION THERAPY BECAUSE THEY HAD RECEIVED NO STRONG EVIDENCE TO INDICATE EITHER THAT EDTA CHELATION WAS OR WAS NOT EFFECTIVE IN DEALING WITH CORONARY-ARTERY DISEASE.. CHAIRPERSON FOOTE WENT ON TO STATE THAT THE COMMITTEE MEMBERS RECEIVED REASONABLE ASSURANCE FROM TWO MEMBERS OF THEIR COMMITTEE WHO WERE THEMSELVES PHYSICIANS THAT EDTA CHELATION CAN BE ADMINISTERED SAFELY AND EFFECTIVELY IF STANDARD PROTOCOLS AND APPROPRIATE STANDARDS OF CARE ARE FOLLOWED.

CHAIRPERSON FOOTE COMMENTED THAT THE TECHNICAL COMMITTEE MEMBERS DID NOT WANT TO SINGLE OUT EDTA CHELATION FOR RESTRICTIONS GIVEN THAT THERE ARE MANY OTHER THERAPIES USED BY PHYSICIANS THAT HAVE NO MORE SCIENCE BEHIND THEM THAN DOES CHELATION.

CHAIRPERSON FOOTE EXPRESSED SUPPORT FOR THE RECOMMENDATION OF HER COMMITTEE BUT DID EXPRESS RESERVATIONS ABOUT THE FACT THAT THE COMMITTEE DIDN'T RECOMMEND PLACING RESTRICTIONS ON CHELATION SUCH AS BANNING ITS USE IN THE TREATMENT OF CANCER, FOR EXAMPLE. HOWEVER, CHAIRPERSON FOOTE STATED THAT THE PROVISION ON STANDARD PROTOCOLS CONTAINED IN THE RECOMMENDATION GOES A LONG WAY IN ADDRESSING CONCERNS.

<u>407 COMMITTEE MEMBER DISCUSSION</u>

407 COMMITTEE CHAIRPERSON JERRY VAUGHAN, O.D., ASKED WHETHER OR NOT THE BOARD OF MEDICAL EXAMINERS WOULD INTERPRET ANY USE OF EDTA OTHER THAN FOR HEAVY METAL POISONING AS UNPROFESSIONAL CONDUCT. RON KLUTMAN, M.D., MEMBER OF THE TECHNICAL COMMITTEE. RESPONDED THAT THE BOARD OF MEDICAL EXAMINERS IS CONCERNED THAT THOSE WHO USE EDTA DO SO IN A MANNER CONSISTENT WITH STANDARD PROTOCOLS AND APPROPRIATE STANDARDS OF CARE, AND THAT THE BOARD IS UNLIKELY TO TAKE ACTION AGAINST A PRACTITIONER SIMPLY BECAUSE THEY ARE USING EDTA CHELATION TO TREAT CORONARY-ARTERY DISEASE.

DR. KLUTMAN WENT ON TO QUOTE AN AMERICAN MEDICAL ASSOCIATION LEGAL COUNSEL AS ADVOCATING THAT NO ACTION BE TAKEN AGAINST PRACTITIONERS WHO USE CHELATION THERAPY UNLESS THERE IS A VIOLATION OF PROFESSIONAL MEDICAL STANDARDS. **(The 1999 Policy Compendium of the House of Delegates of the American Medical Association clarifies the position of this association on chelation therapy as follows:**

H-175.994 Chelation Therapy:

(1) There is no scientific documentation that the use of chelation therapy is effective in the treatment of cardiovascular disease, atherosclerosis, rheumatoid arthritis, and cancer.

(2) If chelation therapy is to be considered a useful medical treatment for anything other than heavy metal poisoning, hypercalcemia or digitalis toxicity, it is the responsibility of its proponents to conduct properly controlled scientific studies, to adhere to FDA guidelines for drug investigations, and to disseminate study results in the usually accepted channels. (Sub. Res. 66, I-84; Reaffirmed by CLRPD Rep. 3-I-94)

H-175.997 Chelation Therapy:

The AMA believes that chelation therapy for atherosclerosis is an experimental process without proven efficacy. (Res. 57, A-83; Reaffirmed: CLRPD Rep. I-93-1)

DR. DVORAK COMMENTED THAT HE WOULD HAVE LIKED TO HAVE SEEN LANGUAGE IN THE REPORT THAT WOULD HAVE REQUIRED EDTA CHELATION TO BE AN "ADJUNCTIVE" THERAPY FOR CORONARY-ARTERY DISEASE SO AS TO ENSURE THAT TRADITIONAL MEDICAL MODALITIES AND PROCEDURES WOULD ALWAYS BE FOLLOWED IN THE TREATMENT OF THIS KIND OF DISEASE. JANEL FOOTE RESPONDED THAT THE PROVISION ON STANDARD PROTOCOLS IN THE TECHNICAL COMMITTEE RECOMMENDATIONS AND THE ABILITY OF THE BOARD TO ACT TO UPHOLD APPROPRIATE STANDARDS OF CARE SHOULD BE SUFFICIENT TO ADDRESS THIS CONCERN .

DR KLUTMAN COMMENTED THAT THE TECHNICAL COMMITTEE RECOMMENDATION REPRESENTS THE BEST POLICY OPTION AVAILABLE TO DEAL WITH THE ISSUE OF CHELATION BECAUSE THE RECOMMENDATION KEEPS "THE DOOR" OPEN TO A MODALITY THAT CAN BE APPLIED SAFELY BY LICENSED MEDICAL PROFESSIONALS IF DONE IN ACCORDANCE WITH WIDELY KNOWN AND ACCEPTED STANDARDS OF CARE. DR. KLUTMAN STATED THAT THE RECOMMENDATION ALSO REFRAINS FROM GIVING THE ADVOCATES OF CHELATION THERAPY A "GREEN LIGHT" TO GO BEYOND CORONARY-ARTERY DISEASE.. DR. KLUTMAN ALSO STATED THAT ANOTHER STRENGTH OF THE RECOMMENDATION IS THAT IT MAINTAINS THE BROAD AUTHORITY OF THE BOARD OF MEDICAL EXAMINERS TO DISCIPLINE A PRACTITIONER WHO USES CHELATION IN A MANNER INCONSISTENT WITH PROTOCOLS AND APPROPRIATE STANDARDS OF CARE..

407 COMMITTEE CHAIRPERSON VAUGHAN ASKED WHY THE BOARD OF MEDICAL EXAMINERS TOOK ACTION TO SPECIFICALLY PROHIBIT DR. OTIS MILLER FROM USING CHELATION THERAPY. DR. KLUTMAN RESPONDED BY STATING THAT HIS UNDERSTANDING OF THIS ACTION WAS THAT IT WAS MOTIVATED BY THE

BOARD'S CONCERN THAT DR. MILLER WAS NOT PRACTICING IN A MANNER CONSISTENT WITH APPROPRIATE STANDARDS OF CARE, NOT BY HOSTILITY TOWARDS CHELATION PER SE. DR. KLUTMAN ADDED THAT DR. MILLER HAD BEEN PROHIBITED FROM DOING OTHER THINGS AS WELL, NOT JUST CHELATION.

DR. KLUTMAN STATED THAT WHILE IT IS DOUBTFUL THAT THE BOARD WOULD TAKE ACTION AGAINST A PRACTITIONER JUST BECAUSE THEY ARE USING EDTA CHELATION, THERE IS NO DOUBT BUT THAT THEY WOULD TAKE ACTION AGAINST A PRACTITIONER WHO IS USING THIS MODALITY TO TREAT CANCER, FOR EXAMPLE.. THIS WOULD CONSTITUTE UNPROFESSIONAL CONDUCT.

FORMULATION OF RECOMMENDATIONS BY THE 407 COMMITTEE MEMBERS

THE 407 COMMITTEE MEMBERS THEN TOOK ACTION ON THE SET OF FOUR CRITERIA THAT WERE ADAPTED FROM THE SCOPE OF PRACTICE CRITERIA FOR THE PURPOSES OF THIS REVIEW. 407 COMMITTEE CHAIRPERSON VAUGHAN MOVED AND 407 COMMITTEE MEMBER KNORTZ SECONDED THAT THE TECHNICAL COMMITTEE RECOMMENDATION SATISFIES THE FIRST CRITERION WHICH STATES,

> The present situation wherein there are no statutory restrictions on the use of EDTA chelation does not create a situation of harm or danger to the health, safety, or welfare of the public, and the potential for this harm is easily recognizable and not remote or dependent upon tenuous argument.
>
> VOTING AYE WERE AKERSON, HOOVER, DVORAK, VAUGHAN, AND KNORTZ. THERE WERE NO NAY VOTES OR ABSTENTIONS.

407 COMMITTEE CHAIRPERSON VAUGHAN MOVED AND 407 COMMITTEE MEMBER KNORTZ SECONDED THAT THE TECHNICAL COMMITTEE RECOMMENDATION SATISFIES THE SECOND CRITERION WHICH STATES,

> The technical committee recommendations do not create a significant new danger to the health, safety, and welfare of the public.
>
> VOTING AYE WERE AKERSON, HOOVER, DVORAK, VAUGHAN, AND KNORTZ. THERE WERE NO NAY VOTES OR ABSTENTIONS.

407 COMMITTEE CHAIRPERSON VAUGHAN MOVED AND 407 COMMITTEE MEMBER KNORTZ SECONDED THAT THE TECHNICAL COMMITTEE RECOMMENDATION SATISFIES THE THIRD CRITERION WHICH STATES,

> The technical committee recommendations which call for continuing the current situation of no statutory restrictions on the use of EDTA chelation by the state would benefit the health, safety, or welfare of the public.
>
> VOTING AYE WERE AKERSON, HOOVER, DVORAK, VAUGHAN, AND KNORTZ. THERE WERE NO NAY VOTES OR ABSTENTIONS.

407 COMMITTEE CHAIRPERSON VAUGHAN MOVED AND 407 COMMITTEE MEMBER KNORTZ SECONDED THAT THE TECHNICAL COMMITTEE RECOMMENDATION SATISFIES THE FOURTH CRITERION WHICH STATES,

The technical committee recommendations represent the most cost-effective means of dealing with the issue of EDTA chelation.

VOTING AYE WERE AKERSON, HOOVER, DVORAK, VAUGHAN, AND KNORTZ. THERE WERE NO NAY VOTES OR ABSTENTIONS.

BY THESE ACTIONS THE 407 COMMITTEE MEMBERS RECOMMENDEDTHAT THE TECHNICAL COMMITTEE RECOMMENDATION BE ADOPTED BY THE FULL BOARD.

2) **THE FORMULATION OF RECOMMENDATIONS ON CHELATION THERAPY BY THE FULL BOARD OF HEALTH (FROM THE NOVEMBER 15, 1999 BIMONTHLY MEETING OF THE BOARD)**

407 COMMITTEE MEMBER JERRY VAUGHAN BRIEFLY SUMMARIZED THE RECOMMENDATIONS OF THE TECHNICAL REVIEW COMMITTEE AS WELL AS THE WORK OF THE 407 COMMITTEE OF THE BOARD. BOARD OF HEALTH CHAIRPERSON STEVE WOODEN THEN ASKED IF THERE WAS ANY DISCUSSION ON THE WORK OF EITHER THE TECHNICAL COMMITTEE OR THE 407 COMMITTEE. THERE BEING NO DISCUSSION, CHAIRPERSON WOODEN ASKED FOR A MOTION PERTINENT TO THE FIRST OF THE FOUR CRITERIA.

407 COMMITTEE CHAIRPERSON VAUGHAN MOVED THAT THE TECHNICAL COMMITTEE RECOMMENDATION SATISFIES THE FIRST CRITERION WHICH STATES,

The present situation wherein there are no statutory restrictions on the use of EDTA chelation does not create a situation of harm or danger to the health, safety, or welfare of the public, and the potential for this harm is easily recognizable and not remote or dependent upon tenuous argument.

VOTING AYE WERE AKERSON, HOOVER, VAUGHAN, KNORTZ , AUGUSTINE, BALTERS, BIEGANSKI, DAY, FORNEY, HIRSCHBRUNNER, IHLE, LAZURE, NELSON, SCHIEFEN, WOODEN, AND YORK. THERE WERE NO NAY VOTES OR ABSTENTIONS.

407 COMMITTEE CHAIRPERSON VAUGHAN MOVED THAT THE TECHNICAL COMMITTEE RECOMMENDATION SATISFIES THE SECOND CRITERION WHICH STATES,

The technical committee recommendations do not create a significant new danger to the health, safety, and welfare of the public.

VOTING AYE WERE AKERSON, HOOVER, VAUGHAN, KNORTZ , AUGUSTINE, BALTERS, BIEGANSKI, DAY, FORNEY, HIRSCHBRUNNER, IHLE, LAZURE, NELSON, SCHIEFEN, WOODEN, AND YORK. THERE WERE NO NAY VOTES OR ABSTENTIONS.

407 COMMITTEE CHAIRPERSON VAUGHAN MOVED THAT THE TECHNICAL COMMITTEE RECOMMENDATION SATISFIES THE THIRD CRITERION WHICH STATES,

The technical committee recommendations which call for continuing the current situation of no statutory restrictions on the use of EDTA chelation by the state would benefit the health, safety, or welfare of the public.

VOTING AYE WERE AKERSON, HOOVER, VAUGHAN, KNORTZ , AUGUSTINE, BALTERS, BIEGANSKI, DAY, FORNEY, HIRSCHBRUNNER, IHLE, LAZURE, NELSON, SCHIEFEN, WOODEN, AND YORK. THERE WERE NO NAY VOTES OR ABSTENTIONS.

407 COMMITTEE CHAIRPERSON VAUGHAN MOVED THAT THE TECHNICAL COMMITTEE RECOMMENDATION SATISFIES THE FOURTH CRITERION WHICH STATES,

The technical committee recommendations represent the most cost-effective means of dealing with the issue of EDTA chelation.

VOTING AYE WERE AKERSON, HOOVER, VAUGHAN, KNORTZ , AUGUSTINE, BALTERS, BIEGANSKI, DAY, FORNEY, HIRSCHBRUNNER, IHLE, LAZURE, NELSON, SCHIEFEN, WOODEN, AND YORK. THERE WERE NO NAY VOTES OR ABSTENTIONS.

BY THESE ACTIONS THE MEMBERS OF THE FULL BOARD OF HEALTH RECOMMENDED APPROVAL OF THE RECOMMENDATION OF THE TECHNICAL REVIEW COMMITTEE ON CHELATION THERAPY WHICH IS TO MAKE NO CHANGES IN CURRENT POLICY PERTINENT TO EDTA CHELATION.