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CARDIOVASCULAR DISEASE: IS THE GOVERNMENT DOING MORE HARM THAN GOOD? EDTA CHELATION THERAPY

HEARING

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED SIXTH CONGRESS

FIRST SESSION

MARCH 10, 1999

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CARDIOVASCULAR DISEASE: IS THE GOVERNMENT DOING MORE HARM THAN GOOD? EDTA CHELATION THERAPY

WEDNESDAY, MARCH 10, 1999

HOUSE OF REPRESENTATIVES,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The committee met, pursuant to notice, at 11:22 a.m., in room 2154, Rayburn House Office Building, Hon. Dan Burton (chairman of the committee) presiding.

Present: Representatives Burton, Morella, Horn, Ose, Waxman, Norton, and Kucinich.

Staff present: Kevin Binger, staff director; Dan Moll, deputy staff director; Beth Clay, professional staff member; Mark Corallo, director of communications; John Williams, deputy director of communications; Carla Martin, chief clerk; Lisa Arafune, deputy chief clerk; Maria Tamburri, staff assistant; Phil Schiliro, minority staff director; Phil Barnett, minority chief counsel; Kristin Amerling, Sarah Depres, and Michael Yang, minority counsels; David McMillen, minority professional staff member; Ellen Rayner, minority chief clerk; and Earley Green, minority staff assistant.

Mr. BURTON. The committee will come to order.

I apologize for us being just a little bit tardy. We had a vote on the floor. But I do appreciate your patience.

I ask unanimous consent that all Members' and witnesses' written and opening statements be included in the record. And without objection, so ordered.

Today we continue our inquiry into Americans access to complementary and alternative medicine. We began this year's hearings with a look at the level of integration of complementary and alternative medicine into government-funded healthcare. During that hearing, we heard testimony from Dr. Dean Ornish about the importance of other options to treat cardiovascular disease. We are continuing to work with the Department of Health and Human Services on increasing access to alternative therapies that have received positive results.

Today's hearing expands our inquiry into alternative treatments for the leading cause of death in America, cardiovascular disease. One alternative treatment that is widely used for cardiovascular disease is EDTA chelation therapy. Chelation therapy is the intravenous injection into the bloodstream of a substance which bonds with heavy metals and then is expelled from the body. It is a man-

made amino acid. EDTA chelation is used by some physicians to treat circulatory problems as well.

Off-label use means that a drug is used for purposes other than those for which the FDA originally approved it, and for which the indications are provided on the label. This off-label use of an FDA-approved drug has been shown to be safe and, according to some, effective.

The off-label use of chelation therapy is an excellent example of an alternative therapy with tremendous bias against it within the medical establishment and within the government.

The National Heart, Lung, and Blood Institute has never funded any research into chelation therapy. The National Library of Medicine has refused to index the Journal for the Advancement of Medicine in MEDLINE. The Federal Trade Commission has launched an attack on the free flow of information from a non-profit professional medical association. The Federal Trade Commission has been working with the Federation of State Medical Boards and individual State medical boards to identify physicians who offer EDTA chelation for off-label use and to remove their licenses. They want to drive them out of business.

Dr. Joseph Jacobs, former Director of the Office of Alternative Medicine at the National Institutes of Health, stated, "I came to the conclusion that EDTA chelation merited study because of the possible truth of the claims made in favor of the therapy, and because of the exceedingly large numbers of Americans who seek out and submit to this therapy."

In 1978, a U.S. District Court rejected the actions of the Food and Drug Administration when they sought an injunction against a physician that administered chelation. The court characterized the FDA's actions as, "an attempt to compel physicians to practice according to State-sanctioned protocols."

Furthermore, the court determined that the weight of the evidence submitted to it supports the practice of chelation.

We will hear testimony today from the National Heart, Lung, and Blood Institute. Last year, this institute had a total budget of over $1.5 billion. They spent only $5.6 million on alternative medical research. That is not even one-half of 1 percent. The National Heart, Lung, and Blood Institute has never funded any research in the off-label use of chelation therapy and vascular disease.

The committee has learned that researchers from several leading U.S. medical schools have approached the Institute with the desire to conduct studies in this area, but they were discouraged from doing so.

And I want to know why.

While the new National Center for Complementary and Alternative Medicine now has the ability to conduct research without clearing it through the various institutes and centers of the National Institutes of Health, the center leadership has stated that they will continue to utilize the expertise of these Institutes.

If there continues to be a bias, will it stand in the way of research? For a rigorous, scientific study, such as a large, multi-site clinical trial to be conducted on EDTA chelation, and for the results to be acceptable to the medical and regulatory communities, the

National Heart, Lung, and Blood Institute will have to be a major player.

We will also hear from the National Library of Medicine. MEDLINE is the most well-known of the library's data bases. It allows anyone to query the library's computerized store of journal article references on specific topics. Several of the broader, "alternative journals" have been indexed for MEDLINE; however, several of the specialty journals have not.

The committee has concerns that doctors and the public, who refer to MEDLINE for access for medical information, are not gaining access to novel treatments that have not been accepted in mainstream publications. It is widely known that there is a publication bias against alternative medicine in conventional journals.

And I would like to know why that is the case as well.

One special issue of the Journal of the American Medical Association does not cure that. I guess there was one special issue on this subject, and that doesn't cure the problem.

Therefore, specialty journals play an important role in providing information about treatments that do not get published in mainstream journals. Also, the bibliographic data base of alternative medicine research clinical trials at the NIH is drawn from MEDLINE.

The Federal Trade Commission enforces a variety of Federal antitrust and consumer-protection laws. With respect to regulatory activities, this hearing will seek to determine whether the Federal Trade Commission exceeded its statutory authority by opening an investigation of and extracting a settlement agreement from the American College for Advancement in Medicine [ACAM], a nonprofit medical society.

The committee is concerned that Federal agency actions like this can adversely affect patient access to complementary and alternative medical therapies. This association entered into a consent agreement in December with the Federal Trade Commission because they were afraid to challenge a government bureaucracy.

And that fear is something we want to see end.

With the permission of the author, I have attached one patient letter submitted to the Commission during the comment period for this action. This retired Navy captain did his own research when facing open-heart surgery and opted for chelation as a first choice. Within 6 months, his Navy doctor told him he no longer needed open-heart surgery.

This is pretty astounding. They told him he had to have open-heart surgery. He went ahead and had chelation therapy; went back to his Navy doctor 6 months later, and he said you don't need open-heart surgery anymore, but whatever you are doing, keep on doing it.

An additional concern with the Commission is the actions in determining the scientific validity of medical therapies. Is this an appropriate action for the Commission to undertake?

The Commission claims that there is not enough evidence to show that chelation therapy was an effective treatment for cardiovascular disease. Apparently, the standard of evidence that the medical society relied upon in making their statements did not meet the standard of evidence the Commission expected.

However, it has not been made clear in the consent order or in conversations with the Commission what the level of evidence would need to be. Chelation has remained one of the most controversial topics in alternative medicine. It is important to remove longstanding bias from our government agencies, to conduct research in areas where there is a need, and to preserve the free flow of information in this country, including that of differing medical opinions.

We will hear today from four conventionally trained doctors who, in order to better care for their patients, began including alternative therapies for their patients, including EDTA chelation.

We look forward to hearing from today's witnesses. There has been a great desire by many patients, healthcare providers, associations, and researchers to speak to the committee about this topic. We were not able to bring them all in today, but we will hold the record open until March 25th to allow for written submissions to be included in the hearing record.

I now recognize my colleague from California, Mr. Waxman.

[The prepared statement of Hon. Dan Burton follows:]

OPENING STATEMENT

CHAIRMAN DAN BURTON
COMMITTEE ON GOVERNMENT REFORM

"Cardiovascular Disease: Is the Federal Government Doing More Harm Than Good?

EDTA Chelation"

Wednesday, March 10, 1998

11:00 AM

Room 2154, Rayburn House Office Building
Washington, D.C.

Good morning. Today we continue our inquiry into American's access to Complementary and Alternative Medicine. We began this year's hearings with a look at the level of integration of complementary and alternative medicine in Government-funded health care. During that hearing we heard testimony from Dr. Dean Ornish about the importance to other options to treat cardiovascular disease. We are continuing to work with the Department of Health and Human Services on increasing access to alternative therapies that have gotten results.

Today's hearing expands our inquiry into alternative treatments for the leading cause of death in America – cardiovascular disease. One alternative treatment that is widely used for cardiovascular disease is EDTA Chelation Therapy. Chelation Therapy is the intravenous injection into the bloodstream of a substance which bonds with heavy metals and then is expelled from the body. It is a man-made amino acid. EDTA Chelation is used by some physicians to treat circulatory problems. Off-label use means that a drug is used for purposes other than those for which the FDA originally approved it, and for which the indications are provided on the label. This off-label use of an FDA-approved drug has been shown to be safe, and according to some, effective. The off-label use of Chelation Therapy is an excellent example of an alternative therapy with tremendous bias against it within the medical establishment and the Government.

The National Heart, Lung, and Blood Institute has never funded any research in Chelation Therapy. The National Library of Medicine has refused to index the *Journal for the Advancement of Medicine* in MEDLINE. The Federal Trade Commission has launched an attack on the free flow of information from a non-profit professional medical association. The Federal Trade Commission has been working with the Federation of State Medical Boards and individual State Medical Boards to identify physicians who offer EDTA Chelation for off-label use and to remove their licenses.

Dr. Joseph Jacobs, former director of the Office of Alternative Medicine at the National Institutes of Health stated, "I came to the conclusion that EDTA Chelation merited study because of the possible truth of the claims made in favor of the therapy and because of the exceedingly large numbers of Americans who seek out and submit to this therapy"[1]

In 1978, a U.S. District Court rejected the actions of the Food and Drug Administration when they sought an injunction against a physician that administered Chelation. The Court characterized the FDA's actions as "an attempt to compel physicians to practice according to state-sanctioned protocols." Furthermore, the Court determined that the weight of the evidence submitted to it supports the practice of Chelation.[2]

We will hear testimony today from the National Heart, Lung, and Blood Institute. Last year this institute had a total budget of over $1.5 billion. They spent only $5.6 million on alternative medicine research. That is not even one-half of one percent. The National Heart,

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[1] Dr. Joseph Jacobs, Foreword to A Critical Review of EDTA Chelation Therapy in the Treatment of Occlusive Atherosclerotic Vascular Disease, ISBN-0-9668200-0-2, pg i.
[2] A Critical Review of EDTA Chelation Therapy in the Treatment of Occlusive Atherosclerotic Vascular Disease, ISBN-0-9668200-0-2, pg 105.

Lung, and Blood Institute has never funded any research in the off-label use of Chelation Therapy in vascular disease. The Committee has learned that researchers from several leading U.S. medical schools have approached the institute with a desire to conduct studies in this area, but were discouraged from doing so. While the new National Center for Complementary and Alternative Medicine now has the ability to conduct research without clearing it through the various Institutes and Centers of the National Institutes of Health, the Center leadership has stated that they will continue to utilize the expertise of these Institutes. If there continues to be a bias, will it stand in the way of research? For a rigorous scientific study such as a large multi-site clinical trial to be conducted on EDTA Chelation, and for the results to be acceptable to the medical and regulatory communities, the National Heart, Lung, and Blood Institute will have to be a major player.

We will also hear from the National Library of Medicine. MEDLINE is the most well known of the Library's databases. It allows anyone to query the Library's computerized store of journal article references on specific topics. Several of the broader "alternative" journals have been indexed for MEDLINE. However, several of the specialty journals have not. The Committee has concerns that doctors and the public who refer to MEDLINE for access to medical information are not gaining access to novel treatments that have not been accepted in mainstream publications. It is widely known that there is a publication bias, against alternative medicine in conventional journals. One special issue of *the Journal of the American Medical Association* does not cure that. Therefore, specialty journals play an important role in providing information about treatments that do not get published in mainstream journals. Also, the bibliographic database of alternative medicine research clinical trials at the NIH is drawn from MEDLINE.

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An additional concern with the Commission is the actions in determining the scientific validity of medical therapies. Is this an appropriate action for the Commission to undertake? The Commission claims that there is not enough evidence to show that chelation therapy was an effective treatment for cardiovascular disease. Apparently, the standard of evidence that the medical society relied upon in making their statements did not meet the standard of evidence the

Commission expected. However, it has not been made clear in the consent order or in conversations with the Commission what the level of evidence would need to be.

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Attachment

Robert & McKenzie Leopold

1620 Dearborn Drive
Virginia Beach
VA 23451-5946
(757) 425-6778

February 9, 1999

Age: 65
Captain, U.S.N. (Ret.)
Master Mariner

Federal Trade Commission
Office of the Secretary
Room 159
600 Pennsylvania Ave., N.W.
Washington, DC 20580

RE: American College for Advancement in Medicine, File No. 962-3147.

Dear Mr. Secretary:

I understand that your office is currently investigating allegations about statements made in an educational brochure the American College for Advancement in Medicine (ACAM) has sent to individual "consumers" and sold to ACAM's members for use in their medical practices. Since I am currently a patient of an ACAM physician and have been for the past several months. I feel that it is appropriate to share my experience with you.

In August of 1998 while living in Louisiana I was told that I needed heart surgery to correct arterial blockages and replace a valve. Needless to say I was frightened – the long term odds for success of the bypass operation are abysmally poor. Friends from all over the country urged us to explore EDTA chelation before consenting to any surgery. I cancelled the operation and set out to learn what I could about chelation. My first provider of information was an 85 year old friend who five years ago was told she needed heart surgery but was too old for it and was just going to die. She took chelation for a few months and believes that it saved her life. When we talked with this woman she looked the picture of health and vitality, and her daughter told us the the chelation had given her her life back. We contacted her chelating doctor, who heard my story and told me that chelation had helped others in my circumstances. At no time did he ever give me any assurances that the chelation would correct all of my heart problems. The physician's facilities were convenient and immaculate. His staff was pleasant and obviously well trained. I began chelating almost immediately. Being able to avoid having my chest split open was an incredible anxiety reliever. For me, the decision was a no–brainer.

I believe I have seen the ACAM brochure in question. As you know, the brochure gives basic information about and history of the treatment while carefully avoiding any predictions of success, and pointing out the controversial nature of the procedure.

In September 1998, we decided to move to Virginia Beach, VA. My three children and five grandchildren are here, and we figured that the heart needs hugs just as much as medical treatment. Within three days of our arrival in Virginia Beach, I was seen by a cardiologist at Portsmouth Naval Hospital. After reviewing the Louisiana data he agreed that the surgery was needed, and fairly soon; but before the surgery, he first wanted to do his own echo–cardiogram, which we did a day or two later. The Navy doctor read it and told me that the heart appeared stronger than it had at the time of the Louisiana readings. Before making any decisions, he wanted to have the cardiology staff review the test results with him.

Meanwhile I found a local chelation physician who told me that it had helped others with conditions similar to mine. As with the Louisiana physician there was no "hard sell", nor any claims that chelation would inevitably solve all of my heart problems. I started chelating with him and his professional office personnel.

The Navy doctor met with me two weeks later. The Cardiology department had reviewed the test results,and they didn't see any need for an operation now or in the immediate future. He said he couldn't explain it, but I should keep doing whatever I was doing and come back for another echo–cardiogram in six months. He prescribed a cardiac rehab program.

Mr. Secretary, the only thing that had changed between the echo–cardiogram in August and the one he had done in November was chelation and lots of hugs.
The exercise program in conjunction with the chelation has increased my physical endurance several–fold, and I can do things physically that I could not sustain back in July/August of the past year. I continue to be monitored by my Navy doctor. Obviously I am thrilled at the restoration of my former capabilities without having to undergo the trauma of the surgeon's saw and knife.

I need to reassure you, Mr. Secretary, that at no time during my discussions of chelation therapy with my Louisiana and Virginia Beach providers were any representations made to me that the therapy was an effective treatment for atherosclerosis or other diseases or conditions of the human circulatory system. That notwithstanding, it is impossible not to be excited by the documented improvement in my heart capacity after just a few months of EDTA chelation.

I must admit to being surprised and dismayed at the FTC involvement in this case. ACAM is not trying to market a "pig-in-a-poke". They merely wish to educate physicians, to advance and support scientific research, and to encourage and develop public awareness of complementary, alternative and preventative medical practices. Why should this require the commitment of FTC assets (people and $$$) to investigate and regulate? This appears to be yet another intrusion of our "Big Brother" government in an area where normal market, consumer and educational forces can seek their own level.

I do not believe that there is a provision in the FTC Charter for the regulation of medicine. And yet It seems that "Medicine" (AMA) is trying to regulate the FTC. As a taxpayer, I resent the FTC bowing to the demands of medicine's big-guns. What they don't like, they shoot down; and they don't like chelation.

I know that there is a sub rosa alliance between organized medicine and the insurance companies.

As I was making the tough choices between heart surgery and chelation the insurance company told me that they would approve and reimburse the dangerous and invasive heart surgery (up to $100,000,00 or more) but would not approve the non-invasive and obviously effective chelation ($3,000–6,000). They justified not reimbursing chelation by saying that it was "experimental." That is patently absurd as well as being incorrect. The military did numerous chelations as far back as the 1940's for soldiers with toxic metal poisoning. The chelations were successful. This information is available; however, I understand that medical computer archiving goes back only as far as the 1960's.

It is not surprising that organized medicine would attack chelation; successful chelations could obviate the need for surgery for some patients, impacting the income of heart surgeons and consultants. Determinations such as the one in my case by insurance companies are in my mind pure fraud against the medical consumer (patient) and is the equivalent to medical malpractice.

I believe that by trying to discredit chelation, the Medical and Insurance powers-that-be are guilty of defrauding the medical consumer They do this in many ways. One is by not educating medical doctors about the truth of chelation. To say that the procedure is unproven, experimental or "bunk" is fraud in the truest sense of the word. Doctors have few excuses for such statements. If they believe that what they are saying is true then they have been seriously misinformed / uneducated. And that, I believe, is a criminal error of omission on the part of Medical universities. If the doctors know that what they are saying is a lie, isn't that fraud? If their greed does not allow them to tell the patient that there is an effective procedure called chelation, isn't that withholding pertinent information, and isn't *that* a form of medical-malpractice.

I resent valid, alternative choices being taken away from me, and I believe the Medical and Insurance honchos are trying to do just that, in any way they can. In this case they are having you do some of their dirty work by having you carry out an investigation that will drain ACAM's financial and human resources, thereby limiting this non-profit organization's ability to perform their activities which are directed toward scientific, educational and health purposes, and which includes disseminating *truthful information about chelation.*

Please have your minions lay off of ACAM and permit them to educate and supervise this procedure which has given me and others our lives back.

Copy : ACAM
U.S.Congress,Subcommittee of Health & Environment
Congressman Owen Pickett

Sincerely,

Robert K. Leopold

PS: Mr. Secretary, if you personally do not know he true facts and history about chelation, I recommend that you educate yourself. It may someday save your life or the life of a loved one. It is imperative to your ability to make a valid judgment/decision concerning this investigation.

Permission to distribute to GRC by prior 3/1

Mr. WAXMAN. Thank you, Mr. Chairman. At the outset, I would like to express my concern with the title of this hearing, "Cardiovascular Disease: Is the Federal Government Doing More Harm Than Good?" The answer is obvious. The Federal Government has, in fact, made huge investments into medical research, preventive health, epidemiology, and primary care to combat cardiovascular disease.

There can be no doubt that the work of the public health service and the Federal health programs has dramatically improved the quality of life and survival of Americans suffering from cardiovascular disease.

I also want to point out the role that the FTC, one of today's witnesses, has played in the fight against heart disease. The FTC ensures that the public has access to accurate information by monitoring claims made by advertisers.

One recent example of FTC's work involves cigarettes, a major risk factor of heart disease. Earlier this month, R.J. Reynolds agreed to settle FTC charges that ads for Winston cigarettes, which claim that those cigarettes are additive free, make an implied claim that they are somehow safer.

But as we all know, there is no such thing as a safe cigarette. Under the agreement, Reynolds has to make a disclosure on future Winston ads that reads, "No additive in our tobacco, does not mean a safer cigarette."

This is a fine example of how the FTC has contributed to the fight against cardiovascular disease.

I understand that today we are focusing on EDTA chelation therapy as a way to treat heart and blood-vessel disease. Clearly there are a diversity of views on whether such views of chelation therapy is safe and effective. Hearings such as these give us a good opportunity to learn about new therapies. It is important to keep an open mind about new, safe, and effective treatments for diseases that can be so crippling and affect so many people.

However, as we keep an open mind, we should also be humble enough to know that no member of this committee, at least as far as I know, is a medical scientist. And if we hear competing claims on medical issues, we have to recognize the fact that we are not in a position to adjudicate these claims, that there are proper agencies to do that within the Food and Drug Administration, if it is a matter before them, within the American Medical Association and within the medical societies generally, through the scientific method, to adjudicate whether claims and hypotheses really are effective.

Having said that, we must take into consideration the reservations about chelation therapy raised by many doctors who have devoted their lives to treating heart disease. The American Medical Association, the American College of Cardiology, and the American Heart Association have all found that the evidence of chelation therapy's efficacy in treating heart disease is inconclusive at best.

At this point, Mr. Chairman, I ask that the formal positions of these groups be entered into the hearing record.

Mr. BURTON. Without objection.

[The information referred to follows:]

POSITION OF THE AMERICAN MEDICAL ASSOCIATION

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 investigation, and to disseminate study results in the usually accepted channels. (Sub. Res. 66, I-84; Reaffirmed by CLRPD Rep. 3 - I-94)

POSITION OF THE AMERICAN COLLEGE OF CARDIOLOGY

American College of Cardiology Position Statement

Chelation Therapy

[The following ACC position statement was adopted by the ACC Executive Committee March 9, 1985 and reapproved in 1990. Reprints are available from: Educational Products Sales and Marketing; 9111 Old Georgetown Road; Bethesda, MD 20814; 800/257-4740.]

There is insufficient scientific evidence to justify the application of chelation therapy for atherosclerosis on a clinical basis. At the present time, therefore, chelation therapy for atherosclerosis should be applied only under an investigation protocol.

Furthermore, the American College of Cardiology endorses the following position of the American Medical Association (December 4, 1984) on this therapy:

RESOLVED, That the American Medical Association (AMA) lauds scientific advancements which have been made in the treatment of atherosclerotic vascular disease, which is the leading cause of death in the United States, and be it further

RESOLVED, That AMA studies show that there is no scientific documentation that the use of chelation therapy is effective in the treatment of cardiovascular disease, atherosclerosis, rheumatoid arthritis, and cancer, and be it further

RESOLVED, That if chelation therapy is a useful medical treatment, it is the responsibility of its proponents to (a) conduct properly controlled scientific studies, (b) adhere to Food and Drug Administration guidelines for the investigation of drugs, and (c) disseminate results of scientific studies in the usually accepted channels.

Adopted by the AMA House of Delegates on December 4, 1984.

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POSITION OF THE AMERICAN HEART ASSOCIATION

American Heart Association.
Fighting Heart Disease and Stroke

CHELATION THERAPY

AHA Recommendation

The American Heart Association has reviewed the available literature on the use of chelation (E.D.T.A., ethylenediamine tetraacetic acid) in treating arteriosclerotic heart disease. They found no scientific evidence to demonstrate any benefit from this form of therapy.

Chelation therapy is a recognized treatment for heavy metal (such as lead) poisoning. E.D.T.A., injected into the blood, will bind the metals and allow them to be removed from the body in the urine.

There have been no adequate, controlled, published scientific studies using currently approved scientific methodology to support this therapy. The United States Food and Drug Administration (FDA), the National Institutes of Health (NIH) and the American College of Cardiology all agree with the AHA on this point.

Furthermore, using this form of unproven treatment may deprive patients of the well-established benefits from the many other valuable methods of treating these diseases.

A recent study of chelation therapy, using currently approved scientific methodology, determined that EDTA chelation therapy was no more effective than a placebo (sugar pill) in treating men and women with peripheral vascular disease of the legs (intermittent claudication). Thus, there still is no scientific evidence that demonstrates any benefit from this form of therapy.

For more information about chelation therapy, visit the Mayo Clinic's Web site .

See also in this A-Z Guide:

- Atherosclerosis
- Drug Approvals
- Peripheral Vascular Disease

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The information contained in this American Heart Association (AHA) Web site is not a substitute for medical advice or treatment, and the AHA recommends consultation with your doctor or health care professional.

Mr. WAXMAN. I also want to point out that we want to be sure that the National Library of Medicine and other institutions that are funded by the taxpayers of this country are operating on good science and that they are not operating from a position of bias. That's a question that is a legitimate one. As I understand the National Library of Medicine has a periodic consultation with experts from different fields to evaluate the library's collection of periodicals in that field. The board of the National Library of Medicine will use the experts' recommendations when reviewing journals in that field.

In fall of 1997, the board asked 14 organizations involved with complementary and alternative medicine to advise it on the NLM's collection, these experts review 695 titles, 79 percent of which the NLM already held, the reviewers determined that 6 titles not held should be added to the collection and recommended that 7 titles be added to MEDLINE. And these titles have been added to MEDLINE.

I would be disturbed if the National Library of Medicine were open to consulting with those in this area of alternative medicine, but it appears that they have tried to sort out those issues for which various titles would be appropriate to be added to MEDLINE.

I welcome our witnesses. I look forward to their testimony. I thank the chairman for holding this hearing, and I yield back the balance of my time.

Mr. Chairman, we have a unanimous consent request that some of our members want to insert opening statements. I presume that your unanimous consent request was all Members have that opportunity.

Mr. BURTON. That is correct. Do any of the Members have a brief opening statement they would like to make? Mrs. Morella.

Mrs. MORELLA. I simply want to tell you that I look forward to this hearing. I think we are going to learn a great deal, and I want to thank the panelists for being here. I particularly wanted to extend my appreciation and give recognition to the Director of the National Heart, Lung, and Blood Institute, Dr. Lenfant, since the National Institutes of Health is in my district, as well as Dr. Donald Lindberg, the Director of the National Library of Medicine, since the National Library of Medicine is also in my district.

Bethesda is well-named for the healing powers of the pool of Bethesda in the Bible.

Thank you, Mr. Chairman.

Mr. BURTON. Thank you, Mrs. Morella. Mr. Kucinich.

Mr. KUCINICH. Thank you very much, Mr. Chairman. I want to thank the chair for holding these hearings. I have a statement, which I would like included in the record.

And at the outset, I would like to say that I think these hearings on alternative and complementary medicine are important because, as much respect as we all have for allopathic practice in this country, which is second to none in the world, it is important that we keep our minds open with the new frontiers because the allopathic practice, which we recognize today as being the best, was advanced through many years of having to push the barriers and create de-

bates over their practice. And things that were years ago considered at the fringe are now at the heart of allopathic practice.

So we have to consider that our understanding of human health and the ways in which we treat disease keep changing. And it keeps changing because we learn of newer and sometimes alternatively effective ways of doing things.

So I appreciate the spirit in which Mr. Burton has proceeded on this. I am very grateful for the leadership which you have shown. And I look forward to the testimony.

[The prepared statement of Hon. Dennis J. Kucinich follows:]

Opening Statement For
Dennis J. Kucinich
Government Reform Committee
3-10-99

Mr. Chairman, fellow committee members, and members of the panel, I am glad to see the Committee continuing its inquiry into Complimentary and Alternative Medicine. As I stated in the previous hearing I support the Committees efforts to expand the treatment options that are available to physicians. Treatment options that are safe and scientifically founded must be made available to doctors and patients alike.

A recent report from the Centers for Disease Control stated that Cardiovascular disease is the Nations' leading killer, accounting for over 960 thousand deaths a year. The study also reveals cardiovascular disease as one of the five most costly chronic diseases in the United State, together totaling 1/3 of all yearly health care costs. With these statistics in mind, I believe we must do everything within our power to advance therapies that provide safe and effective treatments to this devastating disease. If medical methods considered Complimentary and Alternative are able to provide safe and proven treatments for cardiovascular disease, they must be explored.

To facilitate modern medicine and encourage acceptance of Complimentary and Alternative medical theories, we must conquer the earth is flat psychology. If a bias against new ways of treating disease exists lets overcome it with research and education. Sound scientific research alleviates fears and allows physicians to prescribe the best treatment options for there patients without questioning their efficacy or safety.

The most useful research does no good without a vehicle to distribute the information, we must provide for efficient and peer reviewed dissemination of medical research.

Mr Chairman I look forward to expanding our understanding of Alternative forms of medicine and providing a forum to facilitate its research and dissemination. We have the opportunity and the responsibility to make this a healthier world and I believe we can do it if we keep an open mind.

Mr. BURTON. Thank you, Mr. Kucinich. Any further discussion? Mr. Horn.

Mr. HORN. I would just like to concur in Mr. Kucinich's and Mrs. Morella's remarks that we commend you, Mr. Chairman, for holding these hearings. I am going to have to move in and out with a few commitments, but I shall return.

Mr. BURTON. Thank you, thank you.

We are pleased to open our hearing today with four physicians who use chelation therapy. Dr. Terry Chappell of Ohio is the immediate past president of the American College for the Advancement of Medicine.

You know, those who don't agree with us, I wish they would stick around to hear some of the testimony.

Mr. KUCINICH. If I may, my leaving——

Mr. BURTON. It kind of bothers me that, you know, no disrespect to Mr. Waxman, but he reads the information that comes in from the agencies, i.e., the National Heart, Lung, and Blood Institute, and makes a statement about that, and then leaves before we even have a chance to have the chelation experts testify. That is disappointing. But we are pleased——

Mr. KUCINICH. Mr. Chairman, if I may, on behalf of Mr. Waxman. He presents a point of view, which is challenging to us to keep advancing our point of view, but he did have a conflict which he had to sadly fulfill.

Mr. BURTON. Since you are on his side of the aisle, Mr. Kucinich, I hope that you will convey to him all the relevant facts that we get from this hearing.

Mr. KUCINICH. I will do that, Mr. Chairman. Thank you.

[The prepared statement of Hon. Danny K. Davis follows:]

Danny K. Davis

Statement of Danny K. Davis
Committee on Government Reform and Oversight
"Cardiovascular Disease: Is the Federal
Government Doing More Harm than Good?"
March 10, 1999

Thank you very much for allotting me some time to speak on today's hearing. Although the hearing is specifically on the use of EDTA Chelation Therapy. EDTA Chelation Therapy is an alternative method used by some physicians to treat arteriosclerosis, claudication, and various other circulatory problems.

I look forward to hearing from our distinguished witnesses today. The topic of today's hearing is an interesting one. I would however like to note that it is my understanding that the Federal Trade Commission was trying to protect the consumer by not allowing the American College for Advancement in Medicine (ACAM) to advertise about a treatment that had not yet been approved by the National Heart, Lung, and Blood Institute (NHLBI) on Chelation Therapy. Furthermore, according to the NHLBI, tens of thousands of grant applications have been received in the last 30 years, and only three have addressed chelation therapy. There have been only two scientific trials which met NHLBI's standard of scientific rigor and neither of these studies found any benefit to chelation therapy. Thus, I feel that these federal government agencies were trying to do their job by protecting the consumer and adhering to the high quality standards that Americans deserve.

Thank you very much.

Mr. BURTON. Thank you very much.

We are pleased to open our hearing today with four physicians who use chelation therapy. Dr. Terry Chappell of Ohio is the immediate past president of the American College for the Advancement of Medicine. He is board-certified in family practice, pain management, and geriatrics.

Dr. Ted Rozema of North Carolina is the president-elect of the American College for the Advancement of Medicine. He is board-certified in family medicine and is considered one of the world's leading experts in chelation therapy.

Dr. Norman Levin is board-certified in internal medicine and rheuminology, rheumatology, pardon me, and has a private practice just outside of Middleburg, VA.

Dr. Marcial-Vega, a friend of mine of Coral Gables, FL, is a board-certified oncologist who received his oncology training at the Johns Hopkins University Hospitals. And he has held academic appointments at the Washington University and the University of Miami.

Gentlemen, we sometimes have people sworn in because we want to make sure that the testimony is accurate and documented. So if you would rise and raise your right hands, I would like to swear you in as well as the other witnesses.

[Witnesses sworn.]

Mr. BURTON. Let the record reflect that the witnesses responded in the affirmative.

On behalf of the committee, I want to thank you for being here today. And we would like to have you give your opening statements. If your opening statement is beyond 5 minutes, if you could condense, we would appreciate it, and we will put the rest of your statement in the record.

So why don't we start with you, Dr. Chappell.

STATEMENTS OF L. TERRY CHAPPELL, M.D., IMMEDIATE PAST PRESIDENT, AMERICAN COLLEGE FOR THE ADVANCEMENT OF MEDICINE, ACCOMPANIED BY THEODORE ROZEMA, M.D., PRESIDENT-ELECT, AMERICAN COLLEGE FOR THE ADVANCEMENT OF MEDICINE; NORMAN LEVIN, M.D., BOARD CERTIFIED, INTERNAL MEDICINE AND RHEUMATOLOGY; AND VICTOR MARCIAL-VEGA, M.D., BOARD CERTIFIED ONCOLOGIST

Dr. CHAPPELL. Thank you, Mr. Chairman, members of the committee. My name is Dr. Terry Chappell, and I am from Bluffton, OH. As was stated in the introduction, I practice integrative medicine, which I would define as using the best from conventional medicine, and the safest treatments from conventional medicine, and combining that with the best and most scientific treatments from alternative medicine.

Chelation therapy is one of the treatments that I use in my practice. I have used this for about 19 years. I find that 85 to 95 percent of the patients that I treat show measurable improvement with objective tests that we do before and after the treatment. Many of the patients have been able to avoid cardiac surgery. Others have come after they have had cardiac surgery that has not worked very well for them, and still they might do quite well.

Personally, I have had coronary disease with a positive stress test and I took chelation treatments alongside my patients. Eighteen months after that I was able to run a 26-mile marathon without stopping. I take no medications and have no further cardiac symptoms.

Next month, I will have the opportunity to present at the Ohio Academy of Family Physicians Research Day two projects that I have been working on. The first was looking at the 10 leading causes of death and how alternative medicine might improve those causes of death.

When I looked at those carefully, I found that the fourth leading cause of death, which is often not listed, is prescription medications, medications prescribed by physicians. And even more shocking to me, when we added up the statistics, we found that the ninth leading cause of death is cardiac surgery.

So 2 out of the top 10 leading causes of death are actually caused by the well-meaning efforts by physicians to treat their patients. There is a significant risk in the medicine that we do practice today.

Very interestingly too, 5 out of the top 10 leading causes of death are related to vascular disease, and that is obviously the biggest challenge we face.

The second project was a survey. And I wrote to 230 of the leaders of alternative medicine that I identified mostly in this country, and I asked them what were the five alternative therapies that they found most effective in their practice and experience.

Interestingly enough, chelation therapy was the No. 1 therapy most commonly mentioned. Of the five therapies that were most commonly mentioned, four of those have had very little, if any, research funded by the U.S. Government.

So the question is: Are we doing research on the wrong therapies?

I think we are in a situation where we have the majority of deaths in this country due to vascular disease. One of the most promising therapies we have is chelation therapy, and yet those responsible for doing research in this country, and the government is included, and the medical schools, too, have refused to do research on chelation therapy.

Something is wrong. Something is drastically wrong with this situation.

And there are a number of factors that Chairman Burton mentioned in his opening statement. I'll just touch on a few.

One is publication bias. Journals for years have had bias against various alternative therapies, and research projects on those therapies. And they have not been accepted for publication. Chelation therapy is a good example of that.

The Journal for the Advancement of Medicine, which has a number of studies on chelation therapy published, has not been indexed in the Index Medicus. And the excuse given is that there hasn't been enough high-quality scientific studies submitted to the journals.

Well, those journals will not receive submissions from authors who have high-quality scientific studies if the journal isn't indexed. So it is a catch-22 situation.

Many universities have been approached to do studies on chelation therapy, including Harvard and Emory University. At Washington University, we worked for 2 years to try to get a study on chelation therapy done, and it got down to the very last day of submission of NIH of this proposal, and all a sudden the dean of the medical school withdrew the application with no explanation to anybody as to why he withdrew it.

Then we worked with the University of Missouri. For another year and a half we worked with the University of Missouri and officials at NIH and tried to get the best protocol we could. Spent a lot of our resources in doing that. It was finally submitted to NIH, and this last fall it was turned down flatly.

I have to say that, to me, the review comments that were made were—seemed to be much more political than they were scientific.

For years, governmental agencies have made negative comments about chelation therapy when asked by the public, and they have referred to editorial comments that have appeared in journals, and they have not fairly represented the research that has been done on chelation therapy.

This has been another obstacle.

I would like to say just a few words about the FTC action against ACAM. First of all, I never dreamed that the FTC would get into these issues. ACAM is a research and educational medical society. And the FTC asked for 3 years of activity—everything that ACAM had done over a 3-year period. And they found a couple of statements in two educational brochures that were meant—the purpose of those brochures were to enhance the doctor-patient communication. And the main brochure in question contained a waiver saying that other physicians have different opinions about what was expressed in the brochure.

Somehow the FTC called this advertising. I don't believe it was advertising. I believe also that all the statements did have a scientific basis, although they did not have the two double-blind studies that the FTC requires. That is what ACAM has been trying to get accomplished over the last 25 years.

ACAM did sign a consent order. They had no choice because if they tried to fight it, they would have had to submit to bankruptcy. The legal fees were astronomical to fight it.

This consent order has the potential of having a huge impact on ACAM. It was very costly, and it puts ACAM under FTC supervision for 20 years.

On the positive side, there is a major textbook on cardiovascular drug therapies, edited by Messerli, which came out with its latest edition and it devoted an entire chapter to chelation therapy. It was very positive in its effects and its descriptions.

Stephen Olmstead, who is a professor at University of Washington, published a monograph that was an exhaustive look at the research, the pharmacology, the chemistry, the history of chelation therapy. It is 140 pages, and has many, many references. This is significant because he was an independent observer. He was not in favor, he was not against chelation therapy. His conclusions in this monograph were, first of all, that more research had to be done.

But second, that the preponderance of the evidence on chelation therapy was in favor of the therapy for cardiovascular disease, for coronary-artery disease, for peripheral vascular disease.

There are many other studies that have come out recently. One of the most significant ones was by Hancke in Denmark. They took 65 people that were on the waiting list for bypass surgery and they chelated them; 58 out of those 65 were able to cancel their surgery.

Even more significant, they took 27 patients who were waiting to have their limbs amputated, and 24 out of the 27 were able to save their limbs by giving chelation therapy. They did not require surgery.

My hope is that the government will encourage research on all aspects of chelation therapy. The potential benefit is staggering, both for reducing death and improving quality of life, especially for certain conditions, such as critical limb ischemia, macular degeneration, and vascular dementia, for which there is no conventional treatment that is effective. And yet we see improvements on patients that have been chelated that have these conditions.

I think it would be greatly beneficial if this monograph could be distributed widely to every physician in the country. Right now, it has just gone to medical libraries. And, further, I would hope that the FTC could be asked to stay out of the doctor-patient relationship and the practice of medicine, areas where they do not belong.

[The prepared statement of Dr. Chappell follows:]

Testimony
of
L. Terry Chappell, M.D.
Celebration of Health Center
122 Thurman Street, Box 248
Bluffton, Ohio 45817-4627

Before
Committee on Government Reform
U.S. House of Representatives

2154 Rayburn House Office Building
Washington, D.C.

March 10, 1999

11:00 a.m.

Thank you Chairman Dan Burton and Members of the Committee for the invitation to appear before the committee to relate my experience and insights about the unfortunate activities that have obstructed the research, dialogue, and dissemination of educational materials about the use of EDTA Chelation Therapy as a treatment for vascular disease and other conditions.

My curriculum vita is attached. I am a graduate of the University of Michigan Medical School in 1969. I am Board-Certified in Family Practice, Geriatrics, Pain Management and the American Board of Chelation Therapy. I am past-President of the Great Lakes College of Clinical Medicine (GLCCM) and the American College for Advancement in Medicine (ACAM), two of the leading medical societies that teach physicians about a broad range of alternative medicine, including the safe use of EDTA Chelation Therapy. I established an Institutional Review Board for GLCCM about 10 years ago that has been approved by the FDA and continues to review research projects by physicians who work with alternatives in medicine. I have carried the faculty appointment of Assistant Clinical Professor in Family Medicine (volunteer) at Wright State School of Medicine since 1977 and have exhibited for medical students at Ohio State University for the last 3 years. I have practiced integrative medicine in Bluffton, Ohio since 1978. Integrative medicine tries to combine the best of alternative medicine with the best and safest treatments from conventional medicine.

My interest in Chelation Therapy began in 1980 after one of my patients, the President of a Corporation in Lima, urged me for almost a year to investigate the use of the therapy, because several of his employees were traveling hundreds of miles to receive chelation. I finally agreed to visit two doctors who were offering chelation. The doctors were impressive, but even more impressive were the stories of the patients and the dramatic improvements that some described to me. I could no longer in good conscience avoid learning the technique for my patients' use. Subsequently, I benefited myself, as I developed chest pain while jogging with my daughter, was found to have a positive stress test and took the chelation program along side of my patients. Eighteen months latter I completed the first of 2 marathons (26 miles). My tests are now normal. I take no medications.

Only about 20-25% of my medical practice involves chelation therapy, but I have seen measurable improvements with objective testing in 85-90% of the patients I have treated. Two patients who were on the waiting list for heart transplants were subsequently removed from the lists by their cardiologists after chelation and many patients who had poor results from surgery or who were on longer candidates for surgery have done extremely well.

Recently, I have prepared two projects that I have applied to present at the Ohio Academy of Family Physicians annual Research Day. The first project examined the 10 leading causes of death in the United States and ways that alternative medicine might lessen the risk. Surprisingly, I found that the fourth leading cause of death is complications from medications prescribed by doctors and the 9th leading cause of death is cardiac surgery. These causes were not actually listed by the Monthly Vital Statistics (1996), but were buried in the statistics. Four or five of the 10 leading causes of death are directly related to vascular disease. The full list is included below. Clearly, we need to find a better way to treat and prevent vascular disease.

• Heart disease	675,000	• Accidents	92,000
• Cancer	510,000	• Pneumonia	80,000
• Stroke	150,000	• Diabetes	58,000
• Prescription medications	120,000	• Cardiac surgery complications	40,000
• COPD	100,000	• AIDS	30,000

The second project I prepared was a survey of 220 leading alternative physicians, mostly M.D.'s and D.O.'s representing 40 different alternative medical societies and 10 medical schools. I received an excellent response rate of 60%. My primary question was what were the five most effective alternative therapies in their experience. EDTA chelation therapy was the most frequently mentioned treatment. Next were food allergies, oral nutrients, intravenous nutrients and gut dysbiosis. Incredibly, the only one of the top five most effective therapies listed that have attracted any significant government funded research is oral nutrients, and that has been scattered and unorganized. The obvious message from the survey is that the government is funding research on the wrong therapies.

Thus we have vast majority of deaths in this country related to vascular disease, and the most promising therapy noted by innovative physicians is EDTA chelation therapy, which treats vascular disease. And yet those who are responsible for prioritizing and carrying out research in this country (the National Institutes of Health and the Medical Schools) have refused to do the necessary research on chelation therapy and vascular disease. Something is drastically wrong with our system. What has gone wrong? I will try to list some of the factors that might help answer this extremely important and difficult question.

1. There has been editorial and publication bias against alternative medicine and particularly against chelation therapy in indexed medical journals for the last 30 years. Too often innuendo and false, undocumented statements have been made in print about chelation therapy.
2. Journals such as the Journal for Advancement in Medicine have been denied in their applications to be included in the Index Medicus. The reason given has been that the quality of the scientific information published was not up to the highest standards. The problem with that argument is that authors with high quality studies will only submit to indexed journals, and thus alternative journals have a great deal of difficulty being accepted. Several alternative journals have been indexed in the last few years. The quality and peer review process is no different than the Journal for Advancement in Medicine, which continues to be denied, presumably because the latter published article on chelation therapy (as well as a broad range of other topics.)
3. Many university medical schools have been approached about doing research on chelation therapy. Often they express interest initially, but then after further discussion they back out due to the controversy surrounding the topic. This was true of University of Washington, Emory University, Harvard University, and others.
4. Dr. Alan Forker head of Cardiology at the University of Missouri worked closely with Dr. Peter Frommer at NIH, and officials at the FDA to put together a protocol and NIH grant application. This fall, that application was turned down flatly without even a score with harsh reviews that seemed more political than scientific.
5. The office of Alternative Medicine under Joe Jacobs, Alan Trachtenburg and Wayne Jonas has long expressed interest and has encouraged research on chelation therapy but no funding has been forthcoming, apparently due to the negative attitude at the NIH in general.

6. Even though there is substantial preliminary research on the effectiveness and modes of action on EDTA chelation that has been published, mostly in obscure journals, the Federation of State Medical Boards and the Federal Trade Commission have met together planning actions to suppress information on and even forbid the use of chelation therapy for vascular disease. This action has not been taken against any other therapy, to my knowledge.
7. Even while research projects were taking place on chelation under an investigational new drug application issued by the FDA (the Walter Reed Study in the 1980's and early 1990's), the FDA sent extremely negative statements about chelation therapy to those who inquired about its status.
8. The American Medical Association issued a statement in the late 1970's that more research was needed on chelation therapy and that the proponents should do the research. This presented major problems. First, it might be unethical for proponents or opponents of a therapy to do double blind studies on the therapy. Investigators should be independent. Secondly, the doctors who do chelation therapy do so at a much cheaper rate than the prevailing charge by other entities who give intravenous treatments. ACAM has collected some funds for research, but most of those funds have been diverted into legal battles such as the FTC investigation. ACAM has never had nearly enough money to carry out the high quality clinical trials that are need for definitive proof on a therapy. The research must be done by highly qualified research experts with appropriate consultation from experienced chelating doctors who know how the therapy might work most effectively and safely. ACAM has proposed studies and commissioned protocols to be written but none since the Walter Reed study have been funded.
9. The FDA harassed chelation pioneer, Ray Ever, M.D., for may years. Dr. Evers eventually won in court. The Supreme Court determined that physicians can use medications for "off-label" purposes after a drug is approved by the FDA. This is still the law of the land.

I would like to comment briefly on the FTC investigation of ACAM. After an exhaustive investigation, the FTC came up with only a minor concern about a claim made on the efficacy of chelation therapy in two booklets that were intended only for educational distribution for those that expressed interest in chelation therapy. The booklet most in question clearly stated that other doctors held differing views. The FTC held that this educational material was advertising. This was not the intent of ACAM, and the statements questioned by the FTC were taken out of context. All of the statements by ACAM had a scientific basis. They did not have the definitive scientific proof that the FTC wanted, but that is what ACAM has been trying to make happen through proposed clinical trials and education since its inception 25 years ago.

ACAM is an educational and research medical society. There is considerable question whether the FTC has jurisdiction over such non-profit societies. ACAM entered into a consent order primarily because contesting the FTC action would have resulted in bankruptcy from legal bills even if ACAM had won. ACAM immediately changed the wording in the brochures to be within the newly stated FTC guidelines. In my opinion, it is illegal for government agencies to harass nonprofit educational societies like ACAM and cause them great expense when the society is trying to carry out its educational activities.

On the positive side, the standard textbook, Cardiovascular Drug Therapy, edited by Messerli contains an entire chapter about the benefits of chelation therapy. Magnesium EDTA is listed along with many other drugs that are commonly used for vascular disease that have not had definitive research done.

Technically, EDTA should not even be considered an alternative therapy, because it is included in the standard textbook.

Dr. Stephen Olmstead published a monograph on EDTA chelation therapy late in 1998. He is an independent Assistant Professor of cardiology at University of Washington, who is neither an advocate nor critic of the therapy. He thoroughly discussed the chemistry, pharmacology, mechanisms of action, history and published research on chelation therapy for vascular disease. His conclusions were that more research needs to be done but that the preponderance of the scientific evidence indicates that chelation might be effective for coronary artery and peripheral vascular disease.

I am providing copies of the book I wrote called Questions from the Heart. Included in the appendices are the meta-analyses and scientific references that I published elsewhere. The conclusions of the meta-analyses were that there was a high correlation between the treatment with EDTA chelation therapy and documented improvement in vascular disease by objective testing on 24,000 patients. One of the most striking series in the primary meta-analysis was submitted by Hancke and Flytlie of Denmark. They chelated 65 patients who were on the waiting list for bypass surgery and 59 were able to cancel their surgery. Similarly 24 out of 27 patients who were waiting for amputation and were chelated were able to save their limbs.

My sincere hope is that the various agencies of the government will encourage definitive research on chelation therapy and vascular disease. The potential benefit is staggering. Not only might we lower the major causes of death and improve the quality of life for millions of patients, but we might also define an effective therapy for such problems as macular degeneration, critical limb ischemia and vascular related dementia, all of which have no treatment from conventional medicine that is effective.

An excellent first step would be to facilitate the distribution of Olmstead's monograph to every physician in the country.

Thank you for your consideration.

Mr. BURTON. Dr. Chappell, we let you go on a little bit longer than normal because——

Dr. CHAPPELL. I am sorry.

Mr. BURTON. No. That is OK because I think the information that you are giving us is very important. In fact, a lot of the studies and results that you have just cited there, I would like to have those.

Dr. CHAPPELL. I would be happy to provide them.

Mr. BURTON. And if you could give that information to Beth, she is our righthand person on this issue, I really would appreciate it because what we are going to do is we are going to make sure the Food and Drug Administration, Health and Human Services are given this statistical information so that they can't say they don't have it.

We want to make sure it is stuck right on their desk so they can look at it. Then we will ask them why we are not responding on that issue.

[NOTE.—The monograph prepared by Stephen F. Olmstead, M.D., is held in the committee files.]

[The information referred to follows:]

Cardiovascular Drug Therapy

Second Edition

Franz H. Messerli, M.D.
Ochsner Clinic and Alton Ochsner Medical Foundation
New Orleans, Louisiana

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CHAPTER 175

Magnesium EDTA Chelation

Martin Rubin, Ph.D.

The complex pathophysiologic cascade of the development of atherosclerosis, with its major stages of lipid oxidation initiating vascular wall damage, ensuing coagulation, and underlying cell death with calcification, poses a therapeutic challenge. That these individual processes exist simultaneously at varied sites limits the applicability of therapeutic agents targeted to one or another component of the disease progression. In this respect, EDTA chelation therapy has an implicit advantage in that it can favorably influence

all facets of the disease development. Thus, it can also provide an alternative to the combination of drugs administered to attain a multiplicity of therapeutic effects.

The term "chelation" stems from the Greek *chele*, meaning "a claw." It represents the linkage of a polyvalent metal and an organic molecule in a ring chelate structure. Such compounds, exemplified in biologic systems by the chelation of iron in the heme portion of hemoglobin, are characteristic of the binding of polyvalent cations *in vivo*. The chelating compound ethylenediaminetetraacetic acid, EDTA, was invented in Germany in the mid-1930s. It was developed as a substitute for citric acid to maintain the solubility of Ca^{2+} and Mg^{2+} in the alkaline solutions used in the textile and photographic industries.

A continued, sustained expansion in industrial, agricultural, and pharmaceutical applications of EDTA chelation followed the 1952 publication of *The Chemistry of Metal Chelate Compounds*.[1] By 1989, EDTA production reached an international annual level of 40 tons.[2]

CHEMISTRY

At pH 7.4, Na_2EDTA in solution has its dibasic structure. In the presence of metal ions such as Mg^{2+}, the characteristic chelate ring forms rapidly (Fig. 175–1). The log value binding constants of polyvalent cations range from 8.7 for Mg^{2+}, 10.6 for Ca^{2+}, 16.5 for Zn^{2+}, 18.0 for Pb^{2+}, and 18.8 for Cu^{2+} to 25.0 for Fe^{3+}. Thus, for example, the EDTA chelation of Ca^{2+} is about 100 times greater than that for Mg^{2+} and $10^{14.4}$ times greater for iron than for calcium. In mixtures of polyvalent metal ions, the extent of their individual EDTA chelation depends not only on their relative binding constants but also on their concentrations.

EDTA metal binding in biologic systems will be influenced by its concentration, metabolism, and excretion, as well as the presence of other metal binding ligands, including amino acids, peptides, and proteins. All these factors can vary individually during the progression of pathologic processes.

METABOLISM, PHARMACOLOGY, AND TOXICITY

The initial clinical utilization of the intravenous infusion of Na_2EDTA for therapy of atherosclerotic disease has been superseded since the 1960s by its magnesium chelate, $Na_2MgEDTA$. Although both compounds have the same spectrum of polyvalent metal binding *in vivo*, the infusion of the Mg chelate is significantly less painful. By the simultaneous release of Mg^{2+} and plasma calcium chelation with hypocalcemia, the usual pharmacologic consequences of intravenous Mg^{2+} administration are enhanced. These include hypotension and cutaneous vasodilation.[3]

The symptoms and extent of Na_2EDTA hypocalcemia are a function of its dose and rapidity of administration. Acutely toxic levels in animals result in hypocalcemic tetany and death. Repletion from the body calcium stores is rapid.[4–9] Studies in animals and observations in patients have documented renal tubular damage following large doses of Na_2EDTA.[10–13] The administration of 9.5 g in 60 minutes to patients with multiple myeloma and malignant myeloma resulted in death from renal failure in 4 days.[14] Repetitive daily doses of 5 g/day to a patient with carcinomatosis and another with vitamin D intoxication resulted in death with severe damage to the proximal convoluted tubules characterized by some epithelial loss with dilated and vacuolated cells.[15]

Since the 1960s, intravenous infusion of $Na_2MgEDTA$ to thousands of patients has essentially eliminated acute toxic responses. This has been attained by limiting the dose to a maximum of 3.0 g for patients weighing 70 kg or more with infusion periods of 1.5 to 3 hours. Two such treatments per week for 15 consecutive weeks are followed by a rest period of 4 to 6 weeks. Courses of therapy may then be repeated.

It is of interest that the hypocalcemic response to EDTA administration stimulates the hormonal output of the parathyroid gland.[16] Studies have established that "parathyroid hormone" is a mixture of polypeptides of closely related structure.[17] One of these isomers has the unique property of increasing collateral blood flow.[18] This pharmacologic response comple-

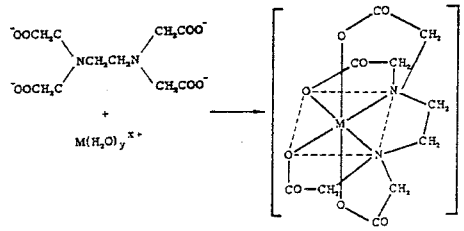

Figure 175–1. EDTA metal chelation reaction.

ments the cutaneous vasodilation associated with intravenous Mg^{2+} released by MgEDTA administration.[19]

ATHEROSCLEROSIS AND VASCULAR CALCIFICATION THERAPY

Antioxidant

Since the 1950s, EDTA has been added to foods and drugs as an inhibitor of their oxidation. *In vivo*, the formation of reactive free radicals by oxidative withdrawal of an electron from a saturated molecule is a common and essential step in the normal pathways of cell physiology. Because such free radicals are very reactive and potentially injurious, their metabolic occurrence and possible generation by low-molecular-weight iron complexes are usually controlled and restricted by a variety of endogenous systems. This capability is enhanced by the presence of ascorbic acid in aqueous compartments and vitamin E and carotene in lipid environments. When the protective mechanisms are inadequate in cells, tissues, and body fluids, the uncontrolled generation of free radicals leads to oxidized lipoproteins, their uptake by macrophages, the formation of foam cells, generation of fatty streaks, and calcification.

Although studies have delineated the complexity of atherogenesis, its initiation clearly is in the uncontrolled formation of oxidatively modified lipid-laden, low-density lipoprotein (LDL) and lipoprotein (a). This may occur in plasma or in the subendothelial space. The oxidized LDL is taken up by macrophages, which form the foam cells characteristic of the fatty streak. An extensive continuing literature documents that the oxidation of LDL depends on the presence and concentration of ferric or cupric ions in plasma and is completely inhibited by their EDTA chelation.[20–32] *In vivo*, this is followed by urinary excretion of the metal chelates. It is of interest to note that in the 1950s the intravenous administration of 3 to 4 g of $Na_2CaEDTA$ to patients with primary hemochromatosis and transfusional siderosis increased the urinary iron output by 8 to 10 times over controls. Infusion of Na_2EDTA and $Na_2MgEDTA$ yielded analogous results.[33–37]

Anticoagulant

The industrial applicability of EDTA for calcium chelation was extended to blood collection in Germany in 1942.[38] This was independently confirmed in 1951 and rapidly attained worldwide acceptance for this purpose.[39–45] When EDTA is added to whole blood as an anticoagulant, its optimal molecular ratio to blood calcium is approximately 1.1:1. *In vivo*, however, its applicability for the therapeutic inhibitory control of the multiplicity of calcium-dependent stages of the coagulation cascade is more complex. Since the mid-1980s, there has been a major expansion in the detailed knowledge of the multiplicity of factors involved in the normal and pathologic processes of the coagulation cascade. Current studies suggest that the most significant of these involve the calcium-dependent function of the platelet glycoprotein GPIIb/IIIa. While anchored within the platelet, its molecular structure extends its two calcium-binding arms beyond the cell membrane into the plasma. These provide for calcium chelation at its micromolar level and at less-specific binding sites for Ca^{2+} in the usual plasma millimolar concentration. The two extension arms of the GPIIb/IIIa glycoproteins can enter into calcium chelation with plasma proteins or with fibrinogen in pathogenic platelet clots.[46, 47] These platelet linkages are modified and disrupted at reduced yet physiologic Ca^{2+} concentrations by the presence of EDTA. This results in the dissociation of the GPIIb/IIIa into its individual GPIIb and GPIIIa monomers, which can subsequently form irreversibly aggregates.[48]

Decalcification Capability

Although calcium antagonists can inhibit the continued cellular uptake and disposition of calcium, surgical intervention has been required for its removal from calcified vascular areas. Two major calcium sources, however, provide for its plasma repletion during the hypocalcemia and urinary chelated calcium excretion characteristic of the 90-g total $Na_2MgEDTA$ infusion in a biweekly, 15-week course of therapy. Isotopic ^{45}Ca studies have established that one of these is the skeletal system and the other consists of "soft tissue" calcium. Studies in the early clinical literature of EDTA chelation provided what appeared to be significant evidence of the dissolution of tissue calcification following the hypocalcemia and therapeutic response to repetitive intravenous administration of Na_2EDTA.[49–64] Because of the current availability of radiographic ultrafast computed tomography (CT) cardiac scanning, it is possible to obtain unambiguous records of the decrement in cardiac calcification resulting from long-term repetitive infusion of $Na_2MgEDTA$ (Figs. 175–2 and 175–3). The patient was treated with a total of 48 3.0-g intravenous infusions of $Na_2MgEDTA$. It is of interest that there was a simultaneous major improvement in the patient's clinical status. Analogous results were observed in the treatment of a second patient at a different geographic location. Thirty infusions of 3.0 g of $Na_2MgEDTA$ were administered during a period of 7 months. The patient had a history of myocardial infarction and a five-vessel bypass operation 14 years prior to the present course of $Na_2MgEDTA$ chelation therapy. Ultrafast CT obtained through the coronary arteries for evaluation of calcification revealed "216 lesions for a total calcium score of 15872." The radiologic impression was "extensive multivessel coronary artery disease. This corresponds to a 91% specificity and a 74% positive predicted value based on the patient's age." The CT scan at the completion of 30 $Na_2MgEDTA$ infusions in 7 months of therapy was as follows: "There are 118 lesions and a total calcium score of 7970." The radiologic impression was "exten-

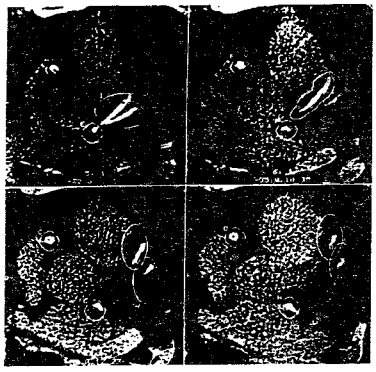

Figure 175–2. Pretreatment ultrafast CT cardiac calcification scan.

sive multivessel coronary artery disease. There has been a significant reduction in the number of lesions and in the total calcium score from the prior examination."[45]

SUMMARY

The multicomponent complexity of the pathophysiologic atherosclerotic cascade, occurring in a given individual in different stages at multiple sites, challenges the potential therapeutic efficacy of highly targeted drugs.

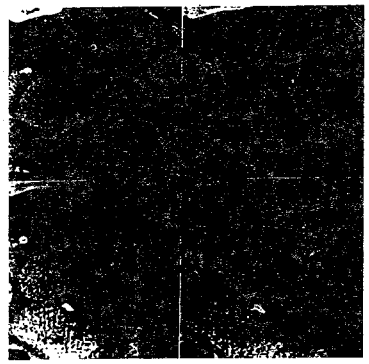

Figure 175–3. Posttreatment $Na_2MgEDTA$ ultrafast CT cardiac calcification scan.

In contrast, repetitive intravenous infusion of $Na_2MgEDTA$ promotes the restoration of the plasma and tissue balance and metabolism of essential minerals such as calcium, iron, and magnesium. This, in turn, permits the functional improvement of damaged vascular areas. A current example of this therapeutic capability is cardiac decalcification attained by the repetitive intravenous infusion of $Na_2MgEDTA$.

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Dr. CHAPPELL. Thank you.

Mr. BURTON. Dr. Rozema, you are recognized.

Dr. ROZEMA. Mr. Chairman, members of the committee, I thank you very much for the privilege of presenting information about the facts surrounding the administration of EDTA for both vascular and degenerative diseases by qualified medical practitioners.

I have been actively involved in the care of my patients using EDTA chelation therapy for the past 16 years. And over that time, I have probably treated over 2,000 patients and have administered over 80,000 infusions of EDTA.

Now, I was asked to give a brief summary about EDTA. EDTA is, as you mentioned, a manmade synthetic amino acid created in Nazi Germany back in the mid-thirties because Hitler was going to war and needed a substitute for citric acid to take minerals out of water. If you don't take minerals out of water and you dye clothing, you get dye tie-dyed, you don't get evenness in the dye. So they invented EDTA. In this country, Fredrick Bersworth invented EDTA about the same time and had it patented around 1941.

EDTA is a compound when introduced into the body has very specific method of operation. It is like a Pac-man, it goes in, it grabs a mineral ion, takes it to the kidney, and you excrete it. When the scientists and chemists figured out what this molecule was doing, they began using it for lead toxicity. Of course, in those days, the lead industry knew that there was no problem with lead, and the 1923 issue of National Geographic had a wonderful advertisement in there about how lead was so good to run the water from the city pipes into your house.

We found out differently. I recently attended a meeting, the largest international meeting ever held on lead toxicity in Bangalore, India. The purpose of the meeting was specifically to get the Indian government to remove lead from gasoline. And at that meeting, they announced that as of April next year they will be doing that.

Lead is a terrible scourge. The government has spent a lot of money on research on lead with EDTA and compounds that are chelating agents as well. Doctors in the early 1950's who began using EDTA figured that it might have an effect on removing calcium from soft tissue, including arterial walls. And Dr. Norman Clark and others found that it was effective in removing calcium from arterial walls and also from aortic valves. This was all published, I believe, in the Journal of Cardiology way back when, when they were studying this.

Now, as Dr. Chappell has said, Dr. Olmstead has done a tremendous review in his monograph, but I wanted to add something else to that. And this is a list of 489 references from the medical literature dealing with chelation, some of them EDTA and vascular disease, some of them with EDTA for other purposes, as EDTA is sold by the carload for use in industry, for use in agriculture, and for use in food as a food additive.

Now, we were talking before about the Federal Trade Commission and their involvement with ACAM. I was not party to that. I am the president-elect. So a lot of things have gone on that I have not been particularly privy to, but I want to give you a personal happening.

I started doing chelation in 1983. In 1984, the North Carolina Medical Board said that if I was doing chelation therapy and accepting money for that, they were going to revoke or suspend my license to practice medicine.

Now, I have always tried understanding what I do in medicine. So when I started using EDTA, I wanted to know more about it. So it has been a 16-year study: what this compound does and how it works. Created the International Chelation Research Foundation, which was one of the two foundations responsible for the study at Walter Reed Army Hospital. That started in the late 1980's, having to do with EDTA and peripheral vascular disease.

However, for a number of reasons, primarily the unwillingness of Army vascular surgeons to refer eligible patients into the study and transfer of personnel active in the study to the Persian Gulf during Desert Storm, the trial was discontinued before useful data was obtained.

We wanted to get something going there. But because the study got going, the North Carolina Medical Board put my license on hold. There was a cloud over it. They removed the cloud a number of years later, and a month later jumped on the physicians who in North Carolina were doing chelation therapy. Again, to take their licenses.

What happened was the public got involved. The public went to their legislators, and now North Carolina is one of eight States that have legislation protecting the physician doing alternative medicine, including chelation therapy.

Now, over the years, 13 States have tried without success to eliminate or reduce the practice of chelation therapy. Now we find that the Federal Trade Commission, a Federal agency with no authority to regulate the practice of medicine, has been working with the Federation of State Medical Boards to assist the States in their failed regulatory efforts.

Who stirred up the FTC action? What is the basis for the aggressive anti-chelation action? From whom did the FTC receive complaints? Where are the unhappy customers? Where are the patients seeking redress against their chelation doctors? Where are the injured? Where are the people saying they wish they had had surgery instead of chelation?

Is this a genuine issue or a trumped-up charge by powerful special interests with a self-rewarding hidden agenda?

People are not stupid. It costs money to take these treatments. And usually it costs money out of pocket because the insurance industry has seen fit not to pay for these treatments.

I can solidly attest that people will not continue to pay for something that is not working. You wouldn't. I wouldn't. And our patients don't.

A physician doing chelation therapy would not stay in business if he weren't delivering positive results because patients talk to friends, relatives, neighbors, and as a result, referrals come from satisfied patients, not from advertising.

We have a great deal to gain from ending this ongoing controversy. Heart disease is the leading cause of death and disability in this country. So far, there has not been 1 penny for a therapy

which has been documented as life-saving for over 40 years by hundreds of thousands of patients.

The Center for Alternative Medicine should be working diligently with the NIH to free up dollars for the benefit of our citizens. Let's put tax dollars to work where they will do a great deal of good in research to establish the effectiveness of EDTA chelation therapy for both peripheral vascular and coronary disease.

And let's not wait while many patients that could be alive with this therapy will never have the opportunity to better health with it.

Thank you.

[The prepared statement of Dr. Rozema follows:]

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Testimony of Theodore Rozema, M.D.

Committee on Government Reform
United States House of Representatives

Hearing:
Cardiovascular Disease: Is the Federal Government
Doing More Harm Than Good?
EDTA Chelation

March 10, 1999

2154 Rayburn House Office Building
Washington, D.C.20515-6143

Mr. Chairman, members of the Committee, I thank you very much for the privilege of presenting information about the facts surrounding the administration of EDTA for vascular and degenerative diseases by qualified medical practitioners. I am the Founder of the International Chelation Research Foundation, a co-sponsor of the FDA approved study on EDTA chelation therapy for peripheral vascular disease at Letterman and Walter Reed Army Hospitals. I am the Founder, President and Director of the Health Research Foundation, with the mission of investigating alternatives in medicine and dissemination of that information to the public. I have co-authored the second edition of *The Scientific Basis of EDTA Chelation Therapy* with Bruce Halstead, M.D. and am the author of *The Protocol for the Safe and Effective Administration of EDTA and Other Chelating Agents for Vascular Disease, Degenerative Disease, and Metal Toxicity,* published as a special edition in the Journal of Advancement in Medicine in 1997.

I have been actively involved in the care of my patients using EDTA for the past 16 years and can attest to it's clinical effectiveness, having treated over 2000 patients, having administered over 80,000 infusions.

I was asked to give a brief overview of EDTA and it's historical significance.

EDTA was invented in Germany in the mid '30's as a substitute for citric acid, used to demineralize water prior to dyeing cloth. About the same time, EDTA was also developed in the USA, and a US patent was given to Fredrick Bersworth in the mid 40's for using a different manufacturing process. EDTA is a synthetic amino acid. It is a chemical chelator. This means that it has only one main action, it chelates or binds minerals to itself, in this case holding them tightly, then leaving the body with the mineral, primarily through the urine. Due to the structure of the molecule, it seemed appropriate to consider it a biologically active detoxifier Remember the days when the lead industry knew their product could not produce harm to humans? Long before research proved otherwise, studies demonstrated EDTA's effectiveness in the removal of lead from the body. **It is used today around the world to remove lead from children burdened with this metal.** Currently, even low level lead toxicity is suspected to be an unrecognized cause of many ailments including kidney failure.

Subsequently, researchers postulated that this compound might remove calcium from soft tissue, including arterial walls. It was originally tried for vascular disease by researchers in Detroit in the early '50's. Clinical benefits led many centers to investigate this "new" compound, and results were encouraging. Symptoms of angina and intermittent claudication were relieved, calcium in aortic valves was

reduced. Encouraged by these findings, investigators tried it for other conditions such as radioactive element poisoning, cataracts, calcified muscles, scleroderma, sarcoidosis and porphyria, with positive results. Even insulin requirements in diabetics were reduced.

We all know that lifestyle changes are necessary to improve health. You all are aware that bypass surgery may only last for 5 to 7 years before another procedure is needed, and angioplasty may restenose within 4 to 6 months. The literature on EDTA chelation therapy indicates that over 85% of people may avoid bypass and over 88% of people may avoid amputation of limbs due to vascular disease. With an approximate savings of $30,000 per patient (angioplasty or bypass) chelation therapy with EDTA (for the over 500,000 patients undergoing bypass and 600,000 patients undergoing angioplasties), would save the establishment Billions of dollars on a yearly basis. The chelation treatments usually will cost less than $6,000 each, only about 15% of the costs for the invasive alternatives and leave the patient in a far better permanent physical condition.

Dr. Stephen F. Olmstead M.D., a noted research cardiologist, recently published *A Critical Review of EDTA Chelation Therapy on the Treatment of Occlusive Atherosclerotic Vascular Disease.* He concluded in the epilogue, Page 96: "**The preponderance of clinical reports in the medical literature support a claim of efficacy for symptomatic angina pectoris, intermittent claudication, and critical leg ischemia**".

The subject of this hearing is, Cardiovascular Disease: is the Federal Government doing more harm than good?? Let me relay to you a personal story that will lead to my conclusions on this question.

In 1983, study of the subject and actual use of EDTA on select patients in my office led to a realization that this therapy was doing something more for my patients than any other therapy I had practiced. However, within a year after beginning to use EDTA, the North Carolina Medical Board charged me with prescribing the use of EDTA for patients: "you treated various patients with EDTA for the alleged treatment and alleviation of vascular ailments, including arteriosclerosis and atherosclerosis and for such prescribing and treating you were paid money. The above allegations, if proven, would constitute grounds for the suspension or revocation of the license to practice medicine issued to you by the undersigned Board".

Prior to this action by the North Carolina Board of Medical Examiners, I had created the International Chelation Research Foundation, Inc., (ICRF), expressly for the purpose of obtaining funds for research in this field of medicine. I had asked Keith Sehnert, M.D. to be the president as he had eight years experience as the medical director of Ciba, and was on the teaching staff of the University of North Carolina Medical School. He was **denied a license** to practice medicine in North Carolina **simply because he had practiced chelation therapy** in Minnesota. This led to the selection of Martin Rubin, Ph.D., Professor Emeritus, Georgetown University, as the president of the ICRF and to the subsequent study of EDTA in Peripheral Vascular disease at Letterman and Walter Reed Army Hospitals. Because of the FDA approved scientific study of EDTA, the action against me was put on hold until the study was completed.

For a number of reasons, including the unwillingness of Army vascular surgeons to refer eligible patients into the study and the transfer of personnel active in the study to the Persian Gulf during Desert Storm, the trial was discontinued before any useful data were obtained. Nevertheless, the North Carolina Board of Medical Examiners sent me a letter informing me that I was no longer under investigation. By this time, however, I had moved by complete practice to South Carolina. A month later they brought new charges against the physicians in North Carolina that were doing chelation therapy and proceeded again to remove their licenses. This resulted in **a great public outcry;** the state legislature created new regulations that **specifically** protected licenses of physicians involved in alternative medicine **and** chelation therapy.

Over the years thirteen states have tried -- without success -- to eliminate or reduce the practice of chelation therapy. Now we find that the Federal Trade Commission -- a federal agency with no authority to regulate the practice of medicine -- has been working with the Federation of State Medical Boards to assist the states in their failed regulatory efforts. Who stirred up this FTC action? The FTC hosted a meeting in Dallas, ostensibly for law enforcement officials only, where they deputized for a day a group of private citizens known as "the quackbusters" who are openly opposed to chelation therapy as well as other complementary and alternative medical treatments. Although an anti-chelation group was permitted to participate in this closed meeting of government officials, when chelation advocates requested to attend, they were turned away. This reminds me of the antitrust case brought against the American Medical Association for suppressing the practice of chiropractic medicine. Except this time a government agency is facilitating the anticompetitive behavior.

What is the basis for this aggressive anti-chelation action? From whom did the FTC receive complaints? Where are the unhappy consumers? Where are the patients seeking redress against their chelation doctors? Where are the injured? Where are people saying they wish they'd had surgery instead of chelation? **Is this a genuine issue or a trumped-up charge by powerful special interests with a self-rewarding hidden agenda?**

It has always amazed me that the negative comments and scathing diatribes leveled at practitioners who utilize this therapy traditionally come from the self-appointed "experts" who **have never used the therapy**, hiding behind the rubric of "unproved" "unscientific" and of no "statistical significance". The repeated claim by opponents that there is no science supporting EDTA chelation is **science fiction**. Physicians who have well satisfied patients **know** that this therapy is working, and the patients know their health has been improved. **The complaints about this therapy are not coming from the patients** but from the establishment nay-sayers with a built-in bias against a therapy that would **help** millions of patients and **save** billions of dollars. The skyrocketing medical costs of treating heart disease primarily with surgery and drugs can be cut dramatically by re-evaluating and changing the established methods of the present health care delivery system.

People are not stupid. It costs **money** out of pocket to take these treatments. It takes **fortitude** to continue 30 or more treatments and endure the testing and IV needles on a regular basis. I can solidly attest that people will **not** continue to pay for something that isn't working. A physician doing chelation therapy would not stay in business if he weren't delivering positive results. Patients **talk** - to friends, relatives, neighbors, and as a result, referrals come from satisfied patients.

We **all** have a great deal to gain from ending this ongoing controversy: heart disease is the leading cause of death and disability in this country. Heart attacks, stroke and related ailments take a huge toll in human suffering and medical costs, while chelation therapy is not only life-saving but an economic boon as well. So far there has been not one penny for a therapy which has been documented as life-saving for over forty years by hundreds of thousands of patients. The Center for Alternative Medicine should be working diligently with the NIH to free up dollars for the benefit of our citizens.

If the large number of supportive documents that have already been presented to the FTC are not sufficient to convince them that this therapy is everything millions

of patients and thousands of physicians have found it to be, then there is a simple solution.

Let's put tax dollars to work where they'll do a great deal of good - in research to establish the effectiveness of EDTA chelation therapy for both peripheral vascular disease and coronary angina. And let's not wait while many patients who could be alive today with this therapy will never have the opportunity to better health with it.

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Mr. BURTON. Thank you, Doctor. And as I said to Dr. Chappell, any statistical data you have regarding the people you have treated or any other information, we would sure like to have that because those documented figures that you have will be helpful in us presenting the case to the appropriate health agencies.

Dr. Levin.

Dr. LEVIN. Mr. Chairman, members, thank you. I'm Dr. Norman Levin. I am 53 years old and I have been married for 22 years. My wife and I have three children and two grandchildren. My medical training was all academic and university-based in Philadelphia and Denver, and I have been practicing clinical medicine for 21 years. I am board-certified in internal medicine and rheumatology.

Two years ago, I completed my board certification in chelation therapy, which is a 2-year process that consists of written and oral examinations as well as supervising a certain number of chelations. I am a member of the American Association of Physicians and Surgeons, the American College of Rheumatology, the American College for Advancement in Medicine, and I am on the board of directors of the Great Lake College of Clinical Medicine.

Up until today, I have never been involved in the politics of healthcare. I am one of those rare birds, actually, an increasingly endangered species, I am a private-practice physician in solo practice. My practice is in my home in the Virginia countryside, west of here, near Middleburg, in a small town called Aldie, which is a very tight little community where everybody knows everybody else.

My clinic is housed in the main part of my home. I, my wife, Kate, and our youngest child, Sarah, who are both with me here today, live upstairs.

So how did I become involved in something as controversial as chelation therapy? That's a good question.

Actually, I was recruited to do chelation therapy by a journalist and medical writer who had the ulterior motive of wanting a doctor trained in chelation near her home so that she and her husband would be able to get chelation therapy regularly.

This was something that I greatly resisted for many, many months. Why would I go out and intentionally look for trouble, especially with the current climate in healthcare and the related regulatory agencies?

However, after reading about chelation therapy, both the clinical and the basic science aspects, talking to patients who had chelation therapy, and attending conferences related to chelation therapy, I could no longer avoid proceeding with my own training because I thought of so many of my patients who might benefit greatly by chelation therapy. And that was approximately 7 years ago.

Over these years, I have supervised many thousands of chelation therapies on hundreds and hundreds of people. My experience, which is backed up detailed medical records, support two conclusions. First, chelation therapy is extremely safe when administered by properly trained physicians. We have not ever had a patient have a side effect that required any kind of remedial treatment as a result of receiving chelation. Second, the therapy is so very, very effective. And I can think of only a handful, maybe 10 at the most out of hundreds and hundreds of people doing chelation, who did not have any appreciable benefit as a result of this therapy.

The vast majority are so significantly improved that they are textbook examples of successful patient outcomes. However, as with any single approach, chelation therapy is not a panacea by itself. A successful program includes lifestyle changes, nutrients, and oftentimes emotional work. The patients who have cardiovascular problems either already have a cardiologist or are strongly advised to get one by me because balance is important. It doesn't have to be all one way, all conventional therapy or all alternative therapy. An integrative approach is often the approach that works best.

Occasionally, an individual who starts chelation therapy will deteriorate clinically and need some kind of acute intervention, such as angioplasty. This is a rare occurrence, but certainly can happen. Then, when the patient returns to complete the course of chelation therapy, we find that they don't require any further invasive therapies.

It's a sad comment on the times that most patients choose not to tell their other doctors that they are taking chelation therapy because they are afraid of the response that they will get from their other doctors.

Why do people come to me for chelation therapy? I don't advertise or market my practice in any way, nor do I give public talks to recruit patients. We don't even have a brochure to hand out or fliers or any kind of promotional material. Nevertheless, I see two to four new patients a day.

Most of the patients that I see have already been through the so-called system and have either not responded satisfactorily or have had such bad experiences one way or the other that they refuse to continue on the conventional or, "acceptable" medical path.

Most of the people who come to me are there because of word of mouth. They have come because a patient recommended the treatment based on their own experience or they know of someone who has responded well to the treatment. Or they have read about chelation and want to try a non-invasive therapy before undergoing surgery. Some may have read an article that I wrote that was published in an alternative medical journal or gotten my name from a list of doctors who are qualified and certified in chelation therapy.

I think that there has been a deliberate campaign to produce the misconception that physicians doing chelation are akin to gypsies in the business of selling driveway repair jobs to little old ladies who don't know any better. Nothing could be further from reality. Most of the chelating physicians I have met at conferences were trained at the finest medical universities in the country. Many are board-certified cardiologists. And a surprising number used to do cardiovascular surgery.

I always make it a point to talk to the new physicians coming to a conference for the first time. And one of the questions I ask is why are you here. Almost all report getting interested in chelation therapy because patients requested that they look into it. Then they become further involved for the same reason that I did, because it works.

As for the patients, many of the people being chelated in my office are professionals and very well educated. Our patients include

doctors, lawyers—and I was nervous the first time I chelated a lawyer—CEO's of very large companies, accountants, a famous national announcer, a former major league baseball player, Harvard graduates, one of whom wrote the definitive biography on George Washington, et cetera.

We also have a small number of patients who don't want it known that they are being chelated. These are airline pilots, who need to maintain drug-free optimal health to stay flight-status qualified. Because of our location, I also see many country people and farmers, who may not have advanced degrees but are very wise in the ways of the world and nature.

I don't have to sell people on chelation. Most of the people I chelate come to me for that purpose. It is my responsibility to evaluate their condition, to make sure that chelation is an appropriate treatment. Then I set up a program, and we proceed one treatment at a time, paying very close attention to the feedback that the person is getting. That is: How are they doing? Better, worse, or no change?

Most of the patients being chelated for cardiovascular disease are on pharmaceutical treatment when they come to me. They are maintained on these treatments until we start seeing evidence of improvement, and then, hopefully, medications can be slowly and carefully tapered, ideally under the supervision of a cardiologist.

I think it is important to point out that you would be hard-pressed to find a doctor who administers chelation who doesn't chelate themselves and their family. To me, that says something significant about the nature of the treatment and the physicians who are offering it to their patients.

And not uncommonly, the results are so dramatic and life-changing in people that their gratitude brings tears to your eyes because it is such a wonderfully fulfilling feeling to be treating people this way and to so consistently be getting this kind of feedback.

In the past 5 or 6 years, I have been investigated by the Virginia Board of Medicine on two occasions. The second time the investigators just showed up at the office unannounced. As I later found out, both cases were instigated by other physicians who heard about the treatments I was doing, didn't like the sounds of the treatments, and then reported me to the medical board. The, "concerned" doctors didn't call me to ask about what I was doing, nor did they consider the fact that the patients were being helped by the treatments that they reported me for.

Also, the accusers went unidentified. Both cases were investigated by the board, which can be a harrowing experience and can really distract you from your purpose. In both instances I was acquitted of the charges and no action was taken or recorded on the record by the board.

In my 21 years of practice, I have never had a complaint filed by a patient, and I have never had a suit filed against me. When people come to me in my office, I would like to be able to recommend to them what I feel will best serve them based on my academic knowledge and, most importantly, on my clinical experience. I don't want to be concerned that these therapeutic decisions will be judged by someone who might have a vested interest but most

assuredly has no practical knowledge with the therapies that he will be judging.

Thank you very much.

[The prepared statement of Dr. Levin follows:]

Testimony of

Norman W. Levin, M.D.
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Before the

Committee on Government Reform

Hearing on

"Cardiovascular Disease: Is the Federal Government
Doing More Harm Than Good?
EDTA Chelation"

Committee on Government Reform
2154 Rayburn House Office Building
Washington, D.C.
March 10, 1999
11:00 a.m.

Good morning. I'm Dr. Norman Levin. I'm 53 years old and have been married for 22 years. My wife and I have 3 children and 2 grandchildren. My medical training was all academic and university-based in Philadelphia and Denver and I have been practicing clinical medicine for 21 years. I am board certified in internal medicine and rheumatology. Two years ago I completed my board certification in chelation therapy which is a two year process consisting of written and oral testing as well as supervising a certain number of chelations.

I am a member of The American Association of Physicians and Surgeons, The American College of Rheumatology, The American College for Advancement in Medicine and am on the board of directors of The Great Lakes College of Clinical Medicine.

Up until today, I've never been involved in the politics of healthcare. I am one of those rare birds - an increasingly endangered species - a private practice physician, a clinician in solo practice. My practice is in my home in the Virginia countryside west of here near Middleburg in a small town called Aldie. Let me tell you a bit about Aldie - it's a very tight community where everyone knows everyone else. My clinic is housed in the main part of my home. I, my wife and youngest child, my daughter, who are both here with me today - live upstairs. So how did I come to be involved in something as controversial as 'chelation therapy'? Good question.

I was "recruited" to do chelation therapy by a journalist and medical writer who had the ulterior motive of wanting a doctor trained in chelation near her home so that she and her husband would be able to receive chelation therapy regularly. I resisted greatly for several months. Why would I go out and intentionally look for trouble especially with the current climate in healthcare and the related regulatory agencies? However, after reading about chelation therapy (clinical and basic science aspects), talking to patients who had chelation therapy and attending conferences related to chelation therapy, I could no longer avoid proceeding with my own training because I thought of so many of my own patients who could possibly benefit from chelation therapy. That was approximately 7 years ago.

Doing chelation therapy is just one aspect of my practice and it comprises about 15-20% of all that we do. Over these years I have supervised many thousands of chelation therapies on hundreds of people. My experience, backed up by detailed medical records, support two conclusions: First, chelation therapy is extremely safe when administered properly by trained physicians. We have not ever had a patient have a side effect that required remedial treatment as a result of receiving chelation. Second: the therapy is so very effective. I can think of only a handful of people, perhaps 10 out of hundreds who did not have any appreciable benefit as a result of chelation therapy. The vast majority are so significantly improved, they are textbook examples of successful patient outcomes.

As with any single approach, chelation is not a panacea by itself. A successful program includes lifestyle changes, nutrients and oftentimes, emotional work. The patients with cardiovascular problems either already have a cardiologist or are strongly advised to get one by me. Balance is important - it does not have to be all one way (conventional therapy) or the other way (alternative therapy),but rather an integrative approach often works best. Occasionally, an individual who starts chelation therapy, deteriorates and needs an acute intervention such as angioplasty. This is a rare occurrence. Then, when the patient returns to complete the course of chelation therapy, we find he does not require further invasive therapies. It is a sad comment on the times that most patients choose not to tell their other doctors that they are taking chelation because they are afraid of the response that they will get.

Why and how do people come to me for chelation therapy? I do not advertise or market my practice in any way, nor do I give public talks to recruit patients. We don't even have a brochure to hand out, or flyers or any promotional material. Nevertheless, I see 2-4 new patients a day. Most of the patients that I see have already been through the so-called "system" and have either not responded satisfactorily or have had such bad experiences one way or the other that they refuse to continue on the conventional or "acceptable" medical path. Most of the people who come to me are there because of word of mouth. They've come because a patient recommended the treatment based on their own experience, or they know of someone who has responded well to the treatment, or have read about chelation and want to try a non-invasive therapy before undergoing surgery.

Some may have read an article that I wrote that was published in an alternative medicine journal and in a book on fibromyalgia and chronic fatigue syndrome or have gotten my name from lists of doctors who are qualified and certified in chelation therapy.

I think that there has been a deliberate campaign to produce the misconception that physicians doing chelation are akin to gypsies in the business of selling driveway repair jobs to little old ladies who don't know any better. Nothing could be further from reality. Most of the chelating physicians I've met at conferences were trained at the finest medical universities in the country, Many are board certified cardiologists. A surprising number used to do cardiovascular surgery - bypasses and angioplasties. I always make it a point to talk to the new physicians coming to a conference for the first time- and one of the things I ask is'why are you here?' Almost all report getting interested in chelation therapy because patients requested that they look into it. Then they become further involved for the same reason that I did- because it works! As for the patients, many of the people being chelated in my office are professionals and very well educated. Our patients include doctors, lawyers (and I was very nervous the first time that I chelated a lawyer), CEO's of very large companies, accountants, a famous national announcer, a former major league baseball player, a Harvard graduate who wrote the "definitive" biography on George Washington etc. etc. We also have a small number of patients who don't want it known they're being chelated - airline pilots who need to maintain drug-free optimal health to stay flight status qualified.

Because of our location, I also see many country people and farmers who may not have advanced degrees, but are very wise in the ways of the world and nature. I don't have to sell people on chelation. Most of the people I chelate come to me for that purpose. It is my responsibility to evaluate their condition to make sure that chelation is an appropriate treatment. I then set up a program and we proceed one treatment at a time, paying very close attention to the feedback that the person is getting, i.e. how are they doing? Are they better, worse or no change? Most of the patients being chelated for cardiovascular disease are on pharmaceutical treatment when they come to me. They are maintained on these treatments until we start seeing evidence of improvement and then hopefully medications can be slowly and carefully tapered, ideally under the supervision of a cardiologist.

I think that it is important to point out that you would be hard-pressed to find a doctor who administers chelation who does not chelate themselves and their family. To me, that says something significant about the nature of the treatment and the physicians who are offering it to their patients. Not uncommonly, the results are so dramatic and life-changing in people that their gratitude brings tears to your eyes - it is such a wonderfully fulfilling feeling.

In the past 5-6 years, I have been investigated by the Virginia Board of Medicine on two occasions. The second time the investigators just showed up at the office unannounced. As I later found out, both cases were instigated by other physicians, who heard about treatments that I was doing, didn't like the sounds of the treatments and reported me to

the board. The "concerned" doctors didn't call me to ask about what I was doing, nor did they consider the fact the patients were helped by the treatments. Also the accusers went unidentified. Both cases were investigated by the board which can be a harrowing experience and can really distract you from your purpose. In both instances I was acquitted of the charges and no action was taken or recorded on my record by the board. In my 21 years of practice, I've never had a patient file a complaint. I have never had a suit filed against me.

When people come to me in my office, I would like to be able to recommend what I feel will best serve them based on my academic knowledge and most importantly on my clinical experience. I don't want to be concerned that these therapeutic decisions will be judged by someone who might have a vested interest, but most assuredly has no practical knowledge with the therapies that he will be judging.

Mr. BURTON. Thank you, Doctor. You said you treated how many patients?

Dr. LEVIN. With chelation therapy? Probably 400 or 500.

Mr. BURTON. Do you have any records that we could see?

Dr. LEVIN. With me?

Mr. BURTON. No. Not with you.

Dr. LEVIN. Yes, certainly.

Mr. BURTON. And you are welcome to black out their names. We don't want to intrude on anybody's privacy.

Dr. LEVIN. Certainly.

Mr. BURTON. But we would like to get that——

Dr. LEVIN. Actually, one of my patients has probably received more chelations than anybody else is here, who is a government retiree.

Mr. BURTON. Maybe we can talk to him after the hearing is over.

Dr. LEVIN. Sure.

Mr. BURTON. My good friend, Dr. Vega.

Dr. MARCIAL-VEGA. How are you doing? Thank you, Mr. Chairman, and one member of the committee that I see.

Mr. BURTON. Rest assured that the other Members will get the information. I promise.

Dr. MARCIAL-VEGA. I hope so. They will do great with chelation, too. [Laughter.]

Thank you for the opportunity to speak to you today, and I thank God for this opportunity and ask for illumination to better serve humanity. I am a board-certified radiation oncologist, and I trained at the Johns Hopkins Hospital. Subsequently to that, I have taught at Washington University in St. Louis and the University of Miami. And I am presently researching ways to assist individuals to reach optimal states of health and rejuvenation through the use of tools that strengthen the whole person.

And this is the essence of holistic medicine. This new type of medicine can heal any condition, and the public needs to know this. And to give you two examples that will better illustrate this, I would like to talk about two patients of mine.

One of my patients was operated on at the Mayo Clinic. And he was evaluated there. He was also evaluated at the Baptist Hospital of Miami. And both institutions recommended to him chemotherapy and radiation for his condition. He had a stage 4 non-Hodgkins lymphoma. But in addition to this, they told him that they could not cure him. So they recommended this with that prognosis.

The patient evaluated the situation and he denied any conventional treatment from both institutions, and his surgeon at the time referred him immediately to me. At that time I evaluated the patient and as part of his therapy, I recommended chelation therapy and other things that I have in a complete rejuvenation and holistic program.

He followed the program diligently and, to make the long story short, it has been 3½ years, and this patient has no evidence of cancer. He is 80 years old, and he is living a completely fulfilling and healthy life. Some of you may know this person, as I'm sure he is a very well-respected and trusted friend of yours. His name is Luis Cerna.

Mr. Cerna's son is here today representing his dad. He is right behind me. And he has been through that ordeal with his father. So he knows what those physicians were telling him throughout the ordeal: "There is nothing we can do, but do radiation, do chemotherapy." And on the other hand, what the reality of what happened was.

Another patient of mine was preparing to die. Just as simple as that, he was preparing to die. There was nothing else that could be offered to him. He had full-blown AIDS. And this patient had a cancer spread throughout his abdominal cavity. It was so spread out that he had a scar where I could put my hand into the abdomen. It could not close because the tumor was so large—just to give you an idea of what was going on with this individual.

He again was told that there was nothing else that could be done. This was 3 months ago.

In the meantime, he has done, among other things, chelation therapy. Of course, there are other things that go together. What we are talking about here today not only applies for chelation, but other things that have been not looked at or persecuted or not evaluated properly or disseminated to the public.

This patient did the treatment and, today, basically all his symptoms have gone away. I did an x ray about a week ago, and the x ray showed no cancer, totally gone from the whole abdominal cavity. This was a tumor that was about a foot in diameter, 1 foot. And the scar has closed; there is no more pain; he has gained about 20 pounds. And also 95 percent of the virus has disappeared from his blood. Today he is leading a totally normal and healthy lifestyle. This is 3 months later.

Also, I would like to tell you about my story. It is not in the testimony here because I just decided to tell you. I was very sick 4 years ago and that is one of the reasons why I went into alternative medicine. I had full-blown AIDS, which means I had 40 pounds less than what you see here today. I was very sick, with fevers, and fatigue. Sixty to 70 percent of the time I was in disability. I had partial blindness of my left eye. I was having seizures. But I was even more scared that I knew what medicine could do for this disease. And I didn't do any medicine. None.

All I did was natural, and part of that was chelation therapy also. To make the long story short, my T–4 count became normal. It has been normal for 3 years. My viral load, which means how much virus I have in my blood, is zero, has been undetectable for 3 years. In addition, if you take my blood today, it is HIV negative. And it has been HIV negative for 3 years.

So no one can tell me anything. No agency can tell me that these things work or don't work because I am living proof of what the reality of this is.

So what do these things mean? Just to give you the other side of the story. If you can remember the losses of King Hussein and Jacqueline Kennedy Onassis with all the money in the world and all the available information from the best medical—supposedly medical, but I would say conventional medical care—and they still died. And they didn't die from the cancers; they died from treatment-related complications.

Why? Why should this happen? Basically, because what we call conventional medicine, the medicine that I was trained, that I was given as a trainee, an oncologist at Johns Hopkins Hospital, that type of training does not include things that actually cause the benefits that we have heard about here today. None of the training includes that today.

And in addition to that, I recognized the fact that I needed to go outside of my medical training in order to get this information. There is no school that teaches this. We needed to learn this, most of us, in the trenches, which makes things harder.

And, not only that, but the importance of this is that Americans are dying today. It's as simple as that. Our country is dying because the information is not available. We need to inform the public.

There are three things that I propose in order to stop this ignorance. No. 1, I propose that a study is instituted that recruits physicians already achieving these similar results, like the gentlemen, people, here. And so we can discuss the outcomes and study them in a right fashion, phase one, two, three, and four studies. And those are the studies that we need to do.

Second, let new programs be designed to implement this knowledge into medical schools. This is non-existent at the present time.

Third, that we expand on the general consensus of the way disease is treated in the United States, cancer, AIDS, what have you, that does not look at the cause of why the disease is there. So that is why they don't look into ways to improve the body, ways of strengthening the individual.

Chelation therapy is an integral part of the care that I give my patients. And as an NIH-funded research researcher—I have done from NIH-funded programs—I know the importance of this to be integrated into the regular or conventional medicine at the present point. The Federal agencies have not conducted research in this field, and they have done a disservice because the information is not being disseminated to the public.

Another thing I want to say is that I have here a letter from the editor-in-chief of the New England Journal of Medicine. This is the medical journal in the world; I would consider it that. This is Dr. Kassirer. And I sent him a study of 205 patients—and I'll give you copies, of course—205 patients treated with an eye preparation.

Mr. BURTON. Doctor, could I interrupt you? We have to run and vote. And what I would like to do is come back and let you finish your testimony and read that letter. Then I would like to go into questions of the four of you. I have a number of questions.

Dr. MARCIAL-VEGA. Thank you very much. OK.

Mr. BURTON. And the other panel from the health agencies, we will get to you just as soon as we get through with this panel. But we are going to be gone about 10 minutes for the vote, and I will be back just as quickly as possible.

We stand in recess at the fall of the gavel.

[Recess.]

Mr. BURTON. If we could have our panelists back at the table, I would sure appreciate it. We will reconvene the hearing.

Dr. Vega, you were about to read a letter from one of your patients. So won't you proceed? As soon as you complete that, we will get to the questions.

Dr. MARCIAL-VEGA. Thank you. Mr. Chairman. This letter was sent to me after I sent an abstract. An abstract is a compilation of information. I had 205 patients that I treated with certain processes. And I sent the article to the New England Journal of Medicine to be considered for publication. And this is the usual process that decisions follow.

Mr. BURTON. This is on the gentleman that you were talking about that had the AIDS problem?

Dr. MARCIAL-VEGA. No. This is a letter from the editor of the New England Journal of Medicine, just to show the point of how regular doctors look at alternative medicines.

Because sometimes they make the accusations that alternative-medicine practitioners are not doing research and are not doing double-blind—that is not true. And I will show you how they deal with this.

So he sent me a letter back. This is the editor-in-chief of the most prestigious medical journal in the world, Dr. Kassirer. And he says, directed to me, "I cannot encourage you to submit the manuscript to us because I doubt it is something we would be interested in reviewing."

And to give you my conclusions, the eye preparation that I saw had helped cataracts in 80 percent of the patients within 1 month—helped means that their vision was getting clearer, that they were seeing colors better, and some of them the prescription got better. Those were my conclusions.

So if he was not interested in that, I don't know what he would be interested in. I think that this was fascinating.

So that was the rest of what I wanted to say.

[The prepared statement of Dr. Marcial-Vega follows:]

Testimony of

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Before the

Committee on Government Reform

Hearing

"Cardiovascular Disease: Is the Federal Government
Doing More Harm Than Good?"

EDTA Chelation

Committee on Government Reform
2154 Rayburn House Office Building
Washington, D.C.

11:00 a.m.

Chairman Burton and members of the Committee, thank you for the opportunity to speak to you today. I thank God and ask for illumination to better serve humanity.

My name is Victor A. Marcial-Vega and I am a board certified radiation oncologist and the medical director of Health Horizons, an alternative medicine center in Florida. I received my medical degree from the University of Puerto Rico Medical School, was trained to be an oncologist at The Johns Hopkins Hospital and have taught at Washington University and the University of Miami. I am presently researching ways to assist individuals in reaching optimal health and rejuvenation through the use of tools that strengthen the whole person. This is the essence of a holistic approach to healing. This new type of medicine can heal any condition and the public needs to know this. A few examples can better illustrate this.

One of my patients was operated at the Mayo Clinic in Jacksonville, Florida and was found to have an advanced stage Non-Hodgkin's Lymphoma three and a half years ago. He was also evaluated at Baptist Hospital of Miami and both teams of physicians recommended radiation and chemotherapy. He was told this treatment would not cure him. He refused this type of therapy because of the possible side effects. His surgeon referred him to me immediately and he started a complete program designed to detoxify and strengthen his body. As part of his program, he had intravenous chelation therapy. He followed the program in a very disciplined fashion and today he has no evidence of cancer and leads a very active life at 80 years old. Some of you may know this patient, as I am sure he is a well-respected friend. His name is Luis Cerna. Mr. Cerna's son, Juan who was with his father on his medical journey is in the audience today representing his father.

Another patient was preparing to die when he came to see me. He had cancer spread throughout the abdomen and full blown AIDS. He had one cycle of chemotherapy and almost died from it. When I saw him 3 months ago, he had a large opening in his abdomen that would not close because the tumor would not allow it to heal.

He was started on a program that included chelation and he followed it diligently. The wound closed completely, all his pain and discomfort disappeared and he gained 15 pounds. I just obtained an X-ray that showed no evidence of cancer and 95% of the AIDS virus has disappeared from his blood. With permission to use his name, Luciano DiLorenzo is completely healthy and living again.

What do these examples mean for you? What about others whose names you recognize? The world will long mourn the losses of King Hussein and Jacqueline Kennedy Onassis. Despite having the best medical care money can buy, they died of complications to their treatment, not from the actual cancers. Why? Because the conventional medicine that I and every other oncologist in America was taught does not include the knowledge of other healing treatments, those therapies that are outside the mainstream. We as oncologists have not been properly equipped to help our patients to the extent we should be. I went outside my medical training and found answers that actually help people. Patients need to receive this information in order to save their lives. Ignorance is killing Americans today. We have the tools to heal any condition. We need to inform the public of these tools.

There are three things that I propose in order to help stop the ignorance and needless dying. I propose:

1. That a study is instituted that recruits physicians already achieving results similar to these that I have discussed and that the outcomes of these physicians are tracked so that data that is more than anecdotal is obtained.

2. That new programs be designed in all medical schools to teach holistic and alternative medical philosophies and techniques.

3. That we expand on the general consensus of the way disease is treated. Instead of attacking the problem, be it cancer, AIDS, high blood pressure, diabetes, impotence and others, that we as health care professionals, also educate and assist the individual in eradicating his or her own disease.

Chelation is an integral part of the care I provide my patients. It has a beneficial effect on their health outcomes. I say this not only as a physician, but also as someone who is trained in research. I have conducted NIH-funded research, and have a good understanding science as well as medicine. The Federal agencies that have not conducted research in this field have done a disservice to the American public. An agency prevents a professional medical association from sharing information with its members and the public about the potential benefits of this or any medical treatment has begun to take away that which we as America treasure so much -- freedom. Freedom of access to information and freedom to make our own health care choices.

Thank you very much for the opportunity to address the Committee.

Mr. BURTON. Well, thank you Dr. Vega.

Let me start off by asking Dr. Chappell—you mentioned that 58 out of 65 patients avoided surgery. Now these were patients that had closed arteries into the heart?

Dr. CHAPPELL. These were patients in Denmark. And with socialized medicine, they have a waiting list for surgery. And all of them——

Mr. BURTON. Excuse me, just 1 second.

OK, I am sorry, go ahead.

Dr. CHAPPELL. All of them had documented coronary artery disease, and were actually on the waiting list to have bypass surgery. There is a waiting list of 6 to 8 months.

Mr. BURTON. And this was in Denmark?

Dr. CHAPPELL. Yes.

Mr. BURTON. And it showed that 58 out of the 65 avoided surgery?

Dr. CHAPPELL. Yes.

Mr. BURTON. Does it go into detail in that study as to how occluded their arteries were? I mean, did they completely clear up? What does it say?

Dr. CHAPPELL. The printed study did not go into detail on that. But I could ask for further details from the author if you would like.

Mr. BURTON. I would like to have as much information as possible.

Dr. CHAPPELL. OK.

[The information referred to follows:]

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Guest Editorial: Critique of Danish Chelation Study (1,2)

This Was Not a Blinded Study

The surgeons conducting this study broke the blind prior to the final assessment. It is well known that many surgeons are biased against EDTA chelation therapy. When follow-up exercise testing was done and results measured, surgeons doing that testing knew who received placebo and who received EDTA.

Sixty-four percent of the patients were told which group they were in prior to follow-up assessments. This is another source of bias in the final results. The study was published and widely represented as being performed double blind, which it was not. In fact, it suffered from the same flaw that critics use to discredit the many studies that prove benefit from EDTA.

Serious Methodological Errors

Study subjects underwent only one qualifying exercise test to determine baseline walking distance. No effort was made to establish reproducibility. It is well known and published (3–5) that some individuals with claudication can exhibit wide variations in walking distance on repeat testing, even under identical conditions. Scientifically accepted and published procedures for exactly this type of study require that subjects with widely variable walking distance on repeat testing be excluded from the study (5). Otherwise, changes in walking distance could be caused by the training effect of repeat testing or by the inherent variability of that particular subject, and not related to treatment that is being studied. The two groups were very different in that respect.

The baseline absolute claudication distance (ACD) for the EDTA group was 119+/−38 meters. The baseline ACD for the placebo group was 157+/−266m. The EDTA group therefore suffered more severe disease at baseline than the placebo group (25% difference)

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and the placebo group exhibited a much wider variability (+/−266 m. compared with +/− 38 m., a 700% difference between groups). The two study groups were therefore not properly matched at baseline. Randomization failed to produce comparable study groups and the EDTA group obviously started out with more severe symptoms.

The study protocol required that all subjects, both placebo and EDTA, develop symptoms of claudication between 50 and 200 m. for entry into the study. A standard deviation of 266 m. in the placebo group indicates that many of these subjects must have continued to walk for hundreds more meters, before stopping with pain. This indicated much less severe claudication, on the average, than in the EDTA treatment group. This was contrary to protocol and made follow-up testing of the placebo group almost totally unreliable.

Confounding Variables Were Not Accounted For

Patients were counseled to stop smoking, on dietary changes, exercise programs, and lifestyle factors. No effort was reported, however, to track differences in compliance between the two groups. Differences in adherence or non-adherence to those factors could have caused significant differences in the final observations. There were insufficient numbers of patients, making the study severely under-powered in statistical terms. No meaningful conclusion could be made without enormous and unrealistic benefits in the EDTA group.

The Vascular Clinical Trialists, a group of investigators who are members of the Society for Vascular Medicine and Biology, have established and published sample size requirements for each group when studying pharmacological agents in treatment of intermittent claudication (5). In studies of exactly this type, for a statistical significance to $p<0.05$ with a 25% difference in walking distance between the treated and control groups, would require 98 patients in each group, or 196 total subjects. A key piece of information required, however, is the standard deviation of the baseline ACD. The extremely wide variation of baseline walking distances in the control group must be considered. This gave a pooled standard deviation of 191.8 m. When this figure is entered into the equation, it would require 462 patients in each study group to yield a difference of 25 m. with statistical significance to $p<0.05$ (5% probability that the difference is random chance and unrelated to the study). The number of subjects re-

quired to detect a similarly significant difference between the groups of 50 meters walking distance would be 116 subjects in each group, or a total of 232. The number of subjects in the Danish study was much too small to exclude significant benefit from EDTA in treatment of intermittent claudication.

High Rate of Dropout

Subject dropout was not accounted for in detail by the Danish investigators. The initial dropout rate during the treatment phase was 3.8%. But five EDTA subjects dropped out, compared with only one placebo subject. Between the end of infusion phase and the 6-month post-infusion evaluations, 9 more subjects dropped out. Sixteen other patients failed to return for their 6-month post infusion exercise testing. The number of dropouts acknowledged by the investigators does not account for the reduced numbers of subjects in each group at the conclusion of the trial. The EDTA group lost 36.8%, falling from 80 to 51 subjects. The placebo group lost 29.1%, falling from 79 to 56 subjects. The authors, however, accounted for only 34 of the 52 subjects who did not complete the trial. It is not known if the missing subjects received EDTA, became completely well, and did not return. That is a possibility, based on the experience of a large group of chelation physicians. We will never know because the investigators refused access to their study records. What are they attempting to hide? Why do they not open their records to audit and independent statistical analysis?

The Danish investigators said that a number of patients did not complete the post treatment exercise test for reasons other than leg pain. What reasons? If claudication was completely relieved, as is quite possible in the EDTA group, they could have simply stopped because of exhaustion, no longer limited by claudication. Why was the total walking distance of those subjects not included in the final data? Rather than include total walking distance of such patients, it is merely stated that they were censured out of the trial without further explanation. That violates accepted scientific statistical procedures.

A research study trial this severely under-powered at the outset suffers even further compromise and becomes even more impotent from dropouts. The study began with little likelihood of detecting a significant difference between the groups and became progressively inadequate to the task when subjects left the study.

Data Manipulation and Statistical Irregularities

The investigators manipulated their observations unfairly by taking the observed percentage change at the end and calculating the ratio of that percentage change in the EDTA group to the percentage change in the placebo group, relative to the pre-treatment distance. This maneuver served to minimize the observed differences between the two groups. Proper statistical procedure would require that a comparison be made between measured changes in walking distance in each group before and after and then determining whether a statistically significant change occurred.

The usual t-test is not possible in this study because of the large number of dropouts. Such a situation called for an "intention-to-treat analysis" using a non-parametric analysis of covariance. Subjects who stopped for reasons other than intermittent claudication on their follow-up exercise tests should have been assigned their total exercise distance in place of the ACD. For example, a subject could have stopped exercise for another reason because claudication was completely resolved. If such a subject were in the EDTA group, failure to include that observation would introduce bias against EDTA. Therefore, statistical analysis should have included dropout patients. It did not! Patients who died, or went on to surgery in the control group could indicate benefit in the EDTA group. Any primary statistical analysis that did not include those subjects is potentially highly biased.

Iron Neutralizes EDTA but was Given to All Patients Daily

It is scientifically proven that EDTA preferentially binds to iron (6). By giving all patients in the study daily iron supplementation, potential benefit from EDTA would be blunted.

Despite All the Weaknesses Described Above, the Data Support the Use of EDTA

At 6 months, the EDTA group had an increase in ACD of 51.3%, from 119 to 180 m. The placebo group had an increase of only 23%, from 157 to 194 m. The investigators refused to divulge data for individual test subjects, so it is not possible to analyze this difference for statisti-

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cal significance. One wonders why they keep their raw data secret? The study therefore suggests that EDTA is effective, the opposite of the published conclusion by these authors.

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Mr. BURTON. And, if you could get that for us. Also, how many patients did you say you have treated?

Dr. CHAPPELL. I have treated probably at least 2,500 to 3,000 patients with chelation therapy.

Mr. BURTON. And what kind of results have you had?

Dr. CHAPPELL. In the ones that I have kept a running account on, the results have shown measurable improvement in 85 to 90 percent. That is using objective testing before and after treatment.

Mr. BURTON. And what kind of testing did you do before and after?

Dr. CHAPPELL. Mostly Doppler ultrasound to measure the blood flow through the peripheral artery.

Mr. BURTON. And it showed the arteries did open up somewhat?

Dr. CHAPPELL. Yes. There is increased blood flow to the extremities.

Mr. BURTON. Was it pretty substantial in some cases? Or was it just moderate?

Dr. CHAPPELL. Sometimes it is very substantial; sometimes it is not. It is not a perfect treatment. It is not a cure-all. But it shows a significant improvement in the vast majority of people that are treated.

Mr. BURTON. Over time, if you continue the chelation treatments, does it continually get better or do you reach a point where it does not get any better?

Dr. CHAPPELL. With any treatment, you might see a plateau. But it is interesting with chelation that, after the basic course of treatment, there have been some studies that show even 3 months after you stop treatment there is a continued improvement 3 months later.

Mr. BURTON. I have talked to some doctors who do chelation therapy, and they have told me that the chelation that they conduct goes on for an indefinite period of time and it does show continual results, positive results, after what would be a normal period of time.

Dr. CHAPPELL. A lot of times that is the case. The other thing is, one of the effects of chelation is that it has a very positive effect on the platelets, so that the blood doesn't clot as easily. And the platelets' life span is about 3½ weeks. So to get the continued effect, many times we will give monthly treatments and maintenance.

Mr. BURTON. How long do your treatments usually last?

Dr. CHAPPELL. About 3 hours.

Mr. BURTON. But over what period of time?

Dr. CHAPPELL. The basic course is about 30 treatments. Most of my patients take them once a week, sometimes twice a week.

Mr. BURTON. OK. Do you have any cost figure on that?

Dr. CHAPPELL. The cost in our office is $101 per treatment.

Mr. BURTON. $101. So it is not extraordinarily expensive?

Dr. CHAPPELL. No. We priced that in the home health agency and the outpatient department of the hospital, and we found that the cost for just a routine IV was two or three times that much.

Mr. BURTON. Do you ever put anything, in addition to the conventional chelation fluids, into the fluid? I mean, I have heard that some doctors add vitamin C and other things into the——

Dr. CHAPPELL. Well, in the conventional bottle, there is some vitamin C, but many times we will add additional vitamin C or other minerals or other ingredients to try to improve the effects. It is all individualized based on the patient's condition.

Mr. BURTON. And what kind of side effects do you have?

Dr. CHAPPELL. From chelation therapy?

Mr. BURTON. Do you have many side effects of any problems?

Dr. CHAPPELL. Well, it is very, very important that you monitor the kidney function. And as long as you monitor that and give a dose based on the normal kidney function and don't overload the kidneys, the side effects are very minimal, very minimal.

Mr. BURTON. So you haven't had any serious problems.

Dr. CHAPPELL. I have had no serious problems with it. Once in a while we get somebody who gets washed out or tired after a treatment because you are removing some of the minerals, normal minerals. And then you have to replenish those more aggressively. But the side effects are not significant.

Mr. BURTON. But the mercury that you remove, and things like that that are causing problems in people, it is more than offset by the minerals you replace? I mean, you are able to replace the minerals that cause problems?

Dr. CHAPPELL. We can replace those just fine.

Mr. BURTON. I mean the ones that are taken out.

Dr. CHAPPELL. Yes.

Mr. BURTON. Dr. Rozema, can you tell us how many patients you have treated?

Dr. ROZEMA. Well over 2,000.

Mr. BURTON. And, have you had any problems with the side effects from those people?

Dr. ROZEMA. As Dr. Chappell mentioned, the most prevalent, not complaint, but observation we have, when we give a patient a treatment, they are a little washed out for a few hours after the treatment. Medicare Blue Cross and Blue Shield in my Carolinas area and I got into a little argument once about, well, if a patient comes into your office and he has intermittent claudication or pain on walking a short distance because of circulation problems, the insurance company will pay for the first study because that is good medicine. But they won't pay for a second study unless you have had surgery.

Well, why not?

We all know that there is no medical treatment that is going to improve this patient without surgery. So we won't pay for the second study.

Mr. BURTON. So there is a bias.

Dr. ROZEMA. I would believe so. So I sent this gentleman 12 cases, went to my records, just pulled out 12 cases, befores and afters, that demonstrated clear reversal or clear opening of the vessels, reversal of atherosclerosis, and asked him for his comments, asked him to please share this with any of his experts.

It took 5 months. I got a letter back, "Thank you for your interesting information, but you know according to Medicare regulation XYZ, we do not pay for chelation therapy or any of the testing associated with it." That is the response I had.

Mr. BURTON. When the arteries were reopened, was it a dramatic change or just marginal, or did it vary from patient to patient?

Dr. ROZEMA. No. Most of the patients had quite a marked improvement. And I can agree with the published studies done in the office of Dr. McDonough, that if you do 30 chelation treatments on a patient, say for carotid artery disease, that you have about a 30 percent reduction in the size of that plaque in 30 treatments.

Mr. BURTON. Well, how close does that come to putting him back to completely normal? What would be the normal, 100 percent?

Dr. ROZEMA. I like the 100 percent, yes. But I think if you gave enough treatments over long enough time, you could get back to that point.

Mr. BURTON. In other words, you think that beyond the 30 treatments, if you continue to have chelation, it would eliminate most of the plaque in the artery?

Dr. ROZEMA. It does continue to improve the situation, yes.

Mr. BURTON. How many patients have you treated?

Dr. LEVIN. Probably about 500.

Mr. BURTON. Have you had pretty much the same results as the other doctors have?

Dr. LEVIN. Yes. I have.

Mr. BURTON. Have the arteries that have been reopened, been reopened substantially?

Dr. LEVIN. Substantially enough to make a significant clinical difference.

Dr. LEVIN. To eliminate the need for surgery and eliminate possible heart attacks or strokes?

Dr. LEVIN. Yes.

Mr. BURTON. How about you, Dr. Vega?

Dr. MARCIAL-VEGA. I have treated about 200 patients, and I have similar results. I checked on seven patients that had particularly the problem of impotence. And 100 percent, seven of those seven patients, had marked improvement in their erections and in their sexual function. I did a study on that.

Mr. BURTON. So what you are saying is, when the arteries started opening, it started cleaning out other capillaries and other smaller blood veins as well?

Dr. MARCIAL-VEGA. Yes. And I am assuming at this point, at least in the patients I see, that most of the causes of impotence are related to a reduced blood flow to the area.

Mr. BURTON. You guys are going to put Viagra out of business. [Laughter.]

Dr. MARCIAL-VEGA. Hopefully.

Mr. BURTON. Anyhow, that was a joke, folks.

Dr. MARCIAL-VEGA. That was a joke, too.

Mr. BURTON. None of the other doctors have said anything about this, but you mentioned you dealt with an AIDS patient that had substantial tumors. That is kind of unusual. I have never heard anybody other than you talk about how chelation really helped somebody who had the AIDS virus. Can you elaborate a little bit more on that? Was it just the chelation therapy? Or was it what else that you did?

Dr. MARCIAL-VEGA. It wasn't just the chelation therapy. I also used ozone baths. It is a machine that I have designed that gives

ozone. In addition, I have used herbal therapy. In addition, massage therapy, stress-reduction techniques, meditation. It is a complete program that takes about 3 weeks to be completed.

But chelation has another effect, in addition to opening up arteries and veins. It is a very powerful anti-oxidant. And it can repair cells in the body that have been damaged. And the whole mechanism of how chelation works is not fully understood. Some of it is by increasing circulation. Some of it is by repairing free-radical damage that has been done for whatever reason: viruses or chemicals in the body.

Mr. BURTON. Do you put large infusions of various kinds of vitamins into the chelating material?

Dr. MARCIAL-VEGA. Yes, I do. Sometimes I combine it, especially in patients with cancer or immuno-suppressed states, with high doses of vitamin C. Sometimes as high as a 100,000 milligrams. Most people take 1,000 milligrams a day as a supplement. So this is 100 times that. Intravenously.

Mr. BURTON. Does that have an adverse impact on their kidneys and other vital organs?

Dr. MARCIAL-VEGA. Not if it is given properly. Again, kidney function, like the doctor here was mentioning, is very important. And as long as that is done, there are no side effects.

Mr. BURTON. OK. I have a pretty hard question, and then I will accede to my colleague here. I suspect from your testimony, and the testimony of other doctors with whom I have talked about the chelation therapy and alternative therapies, that there is not only a bias by the conventional medical system, the AMA, the IMA, Indiana Medical Association, and all the medical associations, but that there might be some kind of a—I don't like to use word "conspiracy"—but an organized opposition to these alternative therapies because it might cut into the profits that they might be making from pharmaceutical companies or other specialties. Do you have that kind of suspicion? Or is there any indication that you have seen that that is the case?

Dr. Chappell.

Dr. CHAPPELL. Well. I don't have any firsthand knowledge of any conspiracy as such. But I think that it has evolved. There certainly are some financial interests. There certainly are some people that crop up all over the place with the same type of message that has been very obstructionist. And we certainly have some suspicions that at least there is a lot of talk among people that are opposed to chelation therapy, and they seem to coordinate their efforts to a certain degree.

Mr. BURTON. Dr. Rozema.

Dr. ROZEMA. I think it is interesting, as long as I have been involved with chelation now, 16 years, to go to the meetings and listen to the stories of the doctors who have had charges brought against them for doing medicine which is outside that which is ordinarily practiced within their State. That is usually how it is worded.

They are doing something different. There is activity going on now in many States to bring legislation to allow practitioners to use what they know works.

I know that if you go to your doctor, the first thing he is going to say was, "How do you feel?" It is a marker; it is a measure.

Can you measure that? No. But do you know it? Yes.

The comment was made earlier about evidenced-based medicine. We all do that in our practice—evidenced-based. You were in this condition to begin with. This was an intervention during this other condition after the intervention. And we can measure that. Outcomes-type research.

I think there is a bias in the fact that, if you want to call it standard medicine or the establishment medicine, AMA-based medicine likes to use scientific studies, scientific research as words to hide behind. All of us in medicine practice evidence-based medicine. Only 20 percent of everything we do in medicine has been shown to stand up to double-blind, placebo-controlled studies. So 80 percent of what we do in medicine is because we have learned it in school; we have practiced on our patients; we all do this, and we use what we know works best.

I was concerned, as I mentioned in my testimony, about the FTC hosting a Dallas meeting with the States attorney generals and the Federation of State Medical Boards. And there has been some talk about getting rid of chelation therapy and using the States to do that, and the FTC to help do this.

And this concerns me because it is not the patients that are bringing this up to any authority. If you go to the States and find out who has made a complaint against a physician, it is usually another physician. It is not a patient. Patients are satisfied.

Mr. BURTON. I think I get the gist of what you are saying. We have some people from the FTC here today. We are going to talk to them about that.

Dr. LEVIN. I don't have any firsthand experience with a conspiracy type of scenario. I agree with what Drs. Chappell and Rozema were saying. There appear to be certain people, or names, that crop up a lot of times around different trials for individuals and against chelation therapy, in general.

I think to pick up on what Dr. Rozema was saying about the double-blind, placebo-controlled studies being the gold standard by which a treatment is judged, a factor that is not considered is that there are some very significant, inherent limitations in those types of studies, because there are certain factors that are extremely important that don't get thrown into the equation, at all: emotional states, dietary factors. There is a lot of basic and cutting-edge scientific information. There is a whole field of what is called psychoneuro-immunology, which basically shows, beyond any shadow of a doubt, that every thought we have, especially those with a lot of feeling behind them, has significant effects on our physiology and on our biochemistry.

When these studies are being done, that just doesn't come into the equation at all, nor does dietary factors. Is someone eating a lot of margarine which is very, very toxic, or processed oils? What is being used as the gold standard really isn't so gold.

Mr. BURTON. Dr. Vega.

Dr. MARCIAL-VEGA. In my experience there are three major reasons why there is some bias. No. 1, physicians are afraid—conventional physicians. One of the reasons is persecution from govern-

ment agencies. But most importantly, they are afraid that other physicians will stop referring patients to them, if the referring physicians find out. "Why is he giving these herbs to this patient of mine?" They may be seen as practicing medicine that is not considered "the norm." My practice is not based on referral from other physicians. So that is not a factor for me to decide what is best for my patients.

But in most physician practices, they depend on other physicians and their opinions, in terms if these physicians think they are doing something too forward. That can stop their referral. That can stop their income. That is one of the things that I have seen.

No. 2, grant money. I have been involved with grants, directly and indirectly, for most of my medical life. The two things that most of my professors taught me were, "Get a grant for as long as you can," and "Get as much money as you can." Then, "Try to do something good about it for humanity." That was No. 3.

There is a propensity toward stretching a grant, getting money for a long time, and giving the results not very quickly, but taking as long as you can to give a result. I have lived it and I know this is a fact.

No. 3 will be insurance companies. Insurance companies do not control so-called "alternative medicine," which includes herbs, massage, and other things. Because insurance companies do not control that and that is a lot of the momentum and drive of medicine in the United States, obviously, that is another bias against it.

Mr. BURTON. Well, I think I have exhausted my questions. I would just like to make a couple of real quick comments. I would like to have any statistical data you can give us, any patient records you can give us, as many as possible. Like I said, you can mark out their names or anything that would be sensitive materials, but we would like to have that so we could use that in further testimony.

Did you have any questions you would like to ask really quickly? Mr. Kucinich.

Mr. KUCINICH. Thank you, Mr. Chairman. I just have a few questions to any of the panelists.

Are there any, that you know of, health insurance policies that cover chelation therapy, Dr. Rozema?

Dr. ROZEMA. In our area, in the northern end of the western portion of South Carolina, there is a company called the Michelin Corp. Most of us, I think, ride on tires made by Michelin. They have their U.S. headquarters. I was very surprised, a short time ago, when a patient came in and brought his benefits and his covered medical services book to the office. In that book, EDTA chelation therapy was a covered service for atherosclerosis, degenerative disease, and, by the way, lead poisoning, which is one of the only accepted reasons to use EDTA.

Mr. KUCINICH. Dr. Chappell.

Dr. CHAPPELL. We did a survey of that in our chelation office about 2 years ago. We found that there were 13 or 14 insurance companies that had covered it for individual cases. It is probably most likely if you present that: This patient is scheduled for a $40,000 bypass procedure; would you be willing to spend $3,000 to see if we can avoid the procedure? Sometimes they will approve

that on a person-to-person basis. But very few have a policy of covering chelation therapy.

Dr. LEVIN. That is my experience also. If you have a policy that covers it. Although we have had patients over the years submit their bills to insurance companies and have been reimbursed to varying degrees—maybe from 30 to 80 percent of the charge, which is about $100 a treatment.

Mr. KUCINICH. So would all of you agree that, when the issue of cost-effectiveness comes up, chelation therapy has certain advantages which are then recognized by a few insurance companies?

Dr. CHAPPELL. Yes.

Mr. KUCINICH. Would you say, Dr. Chappell, is that how you pronounce your name?

Dr. CHAPPELL. Yes.

Mr. KUCINICH. Would you say that the difference in cost between the more conventional therapy for dealing with cardiovascular disease and chelation therapy is pretty consistently the ratio that you have talked about, almost 10 to 1?

Dr. CHAPPELL. Sometimes it is much more than that. I have one patient that came to me after spending 350 days in the hospital for a 3-year period. He had had one bypass, but multiple angioplasties and five heart attacks. He totaled it up. He had spent $640,000 and his insurance covered every penny of it. He had spent one-third of his life in the hospital for the previous 3 years. After chelation, for the next 3 years, he spent 1 day in the hospital for observation. It turned out to be a muscle spasm. With me he spent, maybe $5,000, and his insurance refused to pay a penny of that, even though we demonstrated that we had just saved them $600,000-and-something. It can be very dramatic at times.

Mr. KUCINICH. When you do your reports, which in effect summarize the treatment for any given patient, is it much the same kind of dictation that takes place where an allopathic practitioner might give a comprehensive medical report, if you are using chelation?

Dr. CHAPPELL. Yes.

Mr. KUCINICH. That having been said, wouldn't it be helpful, without divulging, of course, names and confidential information about individuals, to make those reports available in a way that could indicate the value of chelation therapy to a wider community?

Dr. CHAPPELL. Perhaps.

Mr. KUCINICH. So, one of the things that the chairman and I have been talking about is if the medical library that puts things online here would consider some of the publications which summarize cases which you speak of, anecdotally, but do it in a scientific way, that could help advance the public awareness of, and also the appreciation for, chelation therapy.

Mr. BURTON. If the gentleman would yield real quickly. We talked about this a little bit earlier. If we could get a compilation of cases, like all of you are talking about, and go through and put those in some kind of a report-type form, the two of us would be happy to co-sponsor a letter—and maybe get a lot of other Members to be involved, too—to these journals that publish statistical data and information for the medical community; get them to pub-

lish the report that we come up with and ask them to get that out for doctors across the country.

Dr. CHAPPELL. We could sure try that. When we have tried similar-type things in the past, it has been dismissed as anecdotal.

Mr. BURTON. Well, you are talking to some Congressmen, now. [Laughter.]

Mr. KUCINICH. You know, what's anecdotal is one thing. I can well understand the concern of the not-alternative medical community to having folklore be the basis of scientific decisions. However, in your presentations here, and you are all M.D.'s, there is a structure of communication of systematized gathering of knowledge on individual patients, which I suppose could be presented in a way that would present itself as fairly analytical—not just fairly, but strictly analytical—where you can actually see the differences. You present the differences between the physical condition that was presented at the beginning of therapy and what was presented after therapy. That, then, would seem to be to me, if you have parallel structure for the presentation of your cases, it seems to me you have a stronger argument.

The chairman has come up with a suggestion which, I think, is a great suggestion. I share his willingness to pursue to this. If we can include the entire body of testimony from these hearings and make that available in bound form—it's a publication. We issue these as publications from the House. Get that as something that would be available to the people in the science that is behind what you do, because there is a science behind it. It may not be the science that some would pick for their approach, but there is a science behind it.

Thank you, Chairman.

Mr. BURTON. Yes, let me conclude with this panel by saying that we can send copies of this kind of information to the Agency for Health Care Policy Research—Beth just told us about that—and to some of these other agencies and really try to force the issue; make them look at it and ask them to write back to us and give us their analysis of it.

Sometimes, like you said, it takes 5 or 6 months for you to get a response and then it is just some kind of a pacifying letter that really doesn't say anything. They usually respond to us with a little more detail. So, we probably could get a little better result from that. We need to have the statistical data, the case work that you have done, and the results that you have accomplished, so that we can really make a case for that. We will try to get other doctors, as well.

Let me end up by, first of all, thanking for you for being here. Second, you told me, one case that I was really interested in was a guy that ran a marathon—which one of you did that?

Dr. CHAPPELL. That was myself.

Mr. BURTON. Was it you that ran the marathon?

Dr. CHAPPELL. Yes, it was.

Mr. BURTON. It was you?

Dr. CHAPPELL. I was the patient there.

Mr. BURTON. And you had occluded arteries?

Dr. CHAPPELL. Yes.

Mr. BURTON. And you ran a marathon?

Dr. CHAPPELL. Yes.

Mr. BURTON. Well, I admire you and I think you are crazy, too. [Laughter.]

Dr. CHAPPELL. So did my wife.

Mr. BURTON. The second thing that I'd like to say is that I have had some personal experience, on another subject, with stomach problems. I incurred a very severe stomach problem in Africa. When I was senior Republican on the Africa Subcommittee, I traveled all over Africa. I went to stomach doctors all over the place. They took little samples of my stomach tissue and everything else. They told me it was nerves and all kinds of things and gave me Zantac and Prilosec and everything else.

I read an article by a fellow named Dr. Barry Marshall. He said that it was caused by a H-pylori bacteria. I went to see him down at the University of Virginia. He tested me. Within 2 weeks I was normal and haven't had a stomach problem since.

He went before a medical group gathering in Belgium and gave a speech on his theory. They laughed him off the stage. He went home and drank the bacteria, then cured himself. Now, I think he ought to get the Nobel Prize for scientific research because he is going to cure, probably, ultimately, billions of people from severe stomach problems. Even some people who had cancer of the stomach were cured.

But the point I am trying to make is that many times people like you fellows, who actually lay your reputations on the line by trying new therapies, are not unlike Louis Pasteur and Dr. Marshall, who ultimately are proven to be accurate. I admire you for doing that, because you are not only helping people, you are also paving the way for new and innovative procedures that are going to help people.

I was watching television last night, just as a coincidence, and I watched a movie called "Lorenzo's Oil." I don't know if you have ever seen that movie. I wish everybody at the Health and Human Services and FDA would watch that movie, because they had some people from the FDA that actually tried to block and obstruct people from getting Lorenzo's Oil, even though their children were getting progressively worse, to the point where they just died.

To me, when somebody is adjudged ill and there is no cure, for us or anybody—FDA, Health and Human Services, anybody—to say, "Hey, we can't do anything more for you. Go home and die," I think that is criminal. There ought to always be hope. You folks are helping to perpetuate hope in a lot of people and doing more than that. You may be curing a lot of people. I really appreciate it.

This committee, one of its primary goals is to look into every single area where Health and Human Services, the Food and Drug Administration, and the Federal Trade Commission are blocking new research. We are going to be hauling them before this committee on a regular basis—they will get sick of seeing my face before this is over—to make sure that we are not blocking something that is going to save lives.

I don't know if you fellows have to leave right away. If you would like to stick around while we talk to the people from the other

agencies, you are welcome to do so. Maybe afterwards, we can talk a little more informally about some things.

With that, thank you very much. I really appreciate your testimony.

The next panel is Dr. Lenfant, Dr. Lindberg, and Ms. Bernstein. Would you come forward, please? Would you stand so that I can swear you in, please?

[Witnesses sworn.]

Mr. BURTON. Let the record reflect that the witnesses responded in the affirmative and then we will hear your testimony.

I'll tell you, we don't have a lot of cameras here today like we sometimes do when we have hearings. The information that you are going to give to us will be widely disseminated. And my colleagues, I can assure you, will be privy to your testimony.

So, Dr. Lenfant, do you want to start?

STATEMENTS OF CLAUDE LENFANT, M.D., DIRECTOR, NATIONAL HEART, LUNG, AND BLOOD INSTITUTE; DONALD A.B. LINDBERG, M.D., DIRECTOR, NATIONAL LIBRARY OF MEDICINE; JOAN Z. BERNSTEIN, J.D., DIRECTOR, BUREAU OF CONSUMER PROTECTION, FEDERAL TRADE COMMISSION, ACCOMPANIED BY DEBORAH VALENTINE, GENERAL COUNSEL, FEDERAL TRADE COMMISSION

Dr. LENFANT. Thank you, Mr. Chairman. As you heard from the previous panel, the first observation that chelation may improve some symptoms of a disease was made in 1950. The interest for this procedure remained somewhat insignificant until the early 1980's.

But then, the interest grew markedly, I suppose because this occurred at the time that we began to recognize the potential for alternative medicine. We at the National Heart, Lung, and Blood Institute began to receive many inquiries about chelation. They came from the public and some practicing physicians as well. Our response, at that time, was that we had no evidence in support of or against chelation to treat atherosclerosis.

At the same time, we were encouraging investigators to initiate studies, but no applications were ever submitted to the Institute. In the early 1990's, two well-designed studies were completed, one from Denmark and the other one from New Zealand. Both showed no beneficial effect of chelation therapies. And these, I have to say, were the bases for the public fact sheets that we have distributed ever since.

We are well aware of the work done by Dr. Chappell and, in particular, the meta-analyses that he conducted some time back. He came out with a very provocative conclusion, but it is not and cannot be a substitute for the gold standard and that is a blinded, randomized clinical trial.

Eventually, we had some discussions with one investigator who approached the Institute about starting an application that he wanted to submit. However, as was pointed out earlier, this application was not submitted and actually was not submitted at nearly the 26th hour. The same application finally appeared last year, but under a different name, different investigators and from a different

institution. Unfortunately, it did not do well when reviewed by scientific peers.

Since, we have had many contacts with the investigator, and I personally spoke to him on the phone last week. He indicated to me two things. First, he was satisfied with the help he has received from the staff of the Institute. But then, at the same time, he had not decided yet whether he would resubmit the application. So, Mr. Chairman, I should mention to you that I am aware of a study which is now on-going in Canada at the University of Calgary. From the information that I have received, it is very well designed. If completed as it is expected in the next couple of years, I think it will bring about some very, very valuable information.

Meanwhile, our position remains the same. We would welcome receiving applications from American investigators. So far, we have not received any except the one that I just mentioned earlier, which unfortunately, did not do well during the review process.

These, Mr. Chairman, are the comments that I wanted to make before answering questions, which I will be glad to do.

[The prepared statement of Dr. Lenfant follows:]

Statement of Dr. Claude Lenfant
Director, National Heart, Lung, and Blood Institute
National Institutes of Health

Before the
Committee on Government Reform
U.S. House of Representatives

Wednesday, March 10, 1999

The National Heart, Lung, and Blood Institute (NHBLI) appreciates the opportunity to present our views on EDTA (ethylenediaminetetraacetic acid) chelation therapy in this statement for the record.

Chelation is a chemical term named from the Greek word *chele*, meaning "claw" or "claw-like." In chelation therapy, an organic chemical bonds with metals in the bloodstream and digs them out of the system. This therapy is standard treatment for heavy metal poisoning, such as lead poisoning, and the management of iron overload following repeated blood transfusions.

During the 1950s, it was observed that a patient who was receiving chelation therapy for lead poisoning coincidentally experienced relief of angina symptoms. Since that time, many patients have sought and received chelation therapy for atherosclerosis, a "hardening of the arteries" that leads to heart disease and stroke. One theory behind using chelation to treat this disease is that it may remove calcium, which is present in some atherosclerotic lesions, and therefore decrease the obstruction in the arteries. The patient receives repeated intravenous infusions of the drug EDTA that, some believe, grasps the calcium and pulls it from the area of obstruction.

However, others believe that when EDTA is administered intravenously, it encounters and binds with calcium circulating in the blood, and not with any calcium that may exist in the atherosclerotic lesions. According to this view chelation therapy not only may be ineffective in reversing atherosclerosis, but also may expose the patient to risk by depleting the body of calcium and other essential nutrients.

There is, in fact, no sound evidence that EDTA chelation therapy is effective or has clinical benefit for atherosclerosis. For nearly three decades, the NHLBI has carefully followed the scientific literature on this issue. Our thorough and critical review of the published literature on EDTA chelation, which includes numerous case studies and testimonials, identified only two scientifically rigorous clinical trials, neither of which found any benefit of the therapy.

In August 1991 and early 1992, researchers in Denmark published results from a clinical trial of 153 patients with intermittent claudication, an atherosclerosis-related condition characterized by pain and weakness in the legs that is exacerbated by walking. The patients were divided into two groups. Patients in one of the groups received intravenous EDTA, while the other group of patients – the control group – received a "dummy" or placebo therapy of intravenous saline solution. The scientists measured patient walking distances before, during, and after treatment. They found similar improvements in walking distance in both groups – those patients who had received the EDTA treatment and those who had received the placebo treatment. The scientists noted that the results reflect "the well-known phenomenon of spontaneous improvement," – commonly known as the "placebo effect" – in which patients feel or function better for no reason other than that they are being treated or observed. They concluded that EDTA chelation therapy had no beneficial effect among the patients in the trial.

In 1994, a group of New Zealand researchers published results from a similar clinical study of 32 patients with intermittent claudication. Here again, the patients were divided into two groups. Fifteen of the patients underwent EDTA chelation therapy, and 17 patients were given a placebo of saline solution. As in the Danish study, walking distance was used as the major measure of improvement. At the end of the treatment period, 60 percent of the chelation group showed an increase in walking distance. However, 59 percent of the saline or placebo group also demonstrated such an improvement. As with the Danish study, these results again provide a classic illustration of the placebo effect – that is, improvement that springs from the mere fact of being treated, rather than from the results of the specific treatment itself. The New Zealand scientists therefore concluded, like the Danish researchers, that EDTA chelation therapy has no significant beneficial effects.

Both of these high-quality studies are referenced in an NHLBI fact sheet that we developed to respond to the many inquiries we receive regarding chelation therapy. We based our comments on only these two studies because they are the only ones that meet the standard of scientific rigor needed to make recommendations affecting people's health. A 1997 literature review published in the American Heart Association's peer-reviewed journal, *Circulation*, likewise found that the Danish and New Zealand studies were the only two of "outstanding methodological rigor" on the issue of EDTA chelation therapy.

One might ask why the NHLBI does not consider case reports and testimonials in its examination of chelation therapy. The reality is that such uncontrolled observations, while suggestive, do not enable us to identify the singular value of a particular approach. In clinical trials, patients are divided into two groups – those who receive the treatment and those who do not. Assignment to the groups is random, and neither the patients nor the researchers know up front who will be getting the treatment and who will be getting the placebo. Thus, the very design of clinical trials paves the way for unbiased results that can be compared with great confidence that variables other than the intervention itself are held constant. Clinical trials also ensure that the effects being observed are, indeed, due to the treatment and not just the result of a placebo effect.

Clinical trials are an especially important standard in the issue of chelation therapy because the novel concepts and claims involved in alternative medicine naturally call for systematic and explicit review. The National Institutes of Health's (NIH) National Center for Complementary and Alternative Medicine (formerly Office of Alternative Medicine) applies research methods at least as rigorous, if not more so, than those used as the current standard in conventional medicine.

The NHLBI is not the only agency or organization that has expressed concern about the value of chelation therapy for atherosclerosis. The American Medical Association, the American Heart Association, the American College of Cardiology, and the Food and Drug Administration all hold that EDTA chelation therapy remains a scientifically unproven technique for treating atherosclerosis.

The fact that there are only two studies that meet the public health standards of scientific rigor illustrates a central problem in the EDTA chelation controversy: Neither scientists who possess the knowledge and experience to evaluate the treatment nor practitioners who offer it have looked at it carefully. In fact, although the NHLBI has received tens of thousands of research grant applications over the past 30 years, only 3 have addressed this topic, and none of them met the high standards of scientific quality that NHLBI funding demands.

The issue of EDTA chelation therapy for atherosclerosis was addressed in 1993 by the first director of the NIH Office of Alternative Medicine (OAM; now the National Center for Complementary and Alternative Medicine), who contracted with an investigator at the University of Washington to explore the topic. The following year, staff of the NHLBI and the OAM began working collaboratively with this investigator to develop a protocol for a clinical trial. Following much discussion, the investigator wrote an application which the NHLBI was eager to receive for review in June 1996. Unfortunately, in the eleventh hour his institution withdrew its endorsement of the effort and the formal application never materialized.

Subsequently, the investigator passed his protocol on to researchers at the University of Missouri, and we continued our efforts to bring the project to fruition. This endeavor resulted in a grant application that was received in June 1998 and reviewed by the NHLBI Clinical Trials Review Committee in October 1998. Unfortunately, the non-federal scientists who evaluated this application identified a number of shortcomings that would compromise the ability of the

proposed research to resolve the controversy. A member of the Institute's staff has since been in communication with the investigator to explore ways to address the criticisms raised in the review. At this time we do not know whether the investigator plans to submit a revised application, but we would be pleased to accept such an application for re-review if he chooses to do so.

Atherosclerosis is a major underlying cause of death in developed countries. It leads to coronary heart disease, the leading cause of death in this country, as well as stroke, the third leading cause of death. If EDTA chelation therapy proved to be a valid intervention for atherosclerosis, millions of people might benefit. Until such proof comes to light, however, we cannot recommend its use.

The NHLBI is ready and willing to work with qualified researchers to resolve this important public health issue. The vast majority of research at NIH is investigator-initiated – that is, the investigator proposes the research and, if his or her application is successful in competing for funding, carries out the research. If the scientific and clinical communities share our interest in resolving the issue of the effectiveness of EDTA chelation therapy in the treatment of atherosclerosis, experts with strong study protocols must step up to the plate and apply for funding.

I would be pleased to answer any questions the Committee may have.

Mr. BURTON. Thank you.

Dr. Lindberg.

Dr. LINDBERG. Mr. Chairman, I am happy to describe to you the operation of the National Library of Medicine. This collects journals, books and scientific literature from about the world. It has done so since 1836. It has produced an electronic compilation of those publications since 1969. The Index Medicus, actually, was produced in 1879. It is an institution that has committed itself to acquire, organize and disseminate the biomedical knowledge of the world for the benefit of the public health.

I have been there only since 1984. In the last testimony you heard an interesting comment about Lorenzo's Oil and the movie. There is a real person behind Lorenzo's Oil and that is the Odone family. I want to point out to you that it was at the National Library of Medicine that the Odones found the information that they then were able to apply to curing and saving the life of their child. They did not find people who were hiding information. They found medical librarians who welcomed their inquiry and helped them to get what they needed. So, we consider them to be very much a success.

Mr. BURTON. Well, I hope you will go back and watch that movie again. Although they did get that information from that source, there were some obstacles that were thrown up in front of them by people of that Institute during the course of their investigations into getting into a final position.

Dr. LINDBERG. I have been on the platform many times with Mrs. Odone and she is full of praise and gratitude.

Mr. BURTON. Well, we'll bring her up here and we'll just see, OK?

Dr. LINDBERG. That would be a good idea.

Today, just fast-forwarding, the Library of Medicine receives 22,247 periodicals. Of these, we index approximately 4,000 for MEDLINE, which is our primary data base of journal article references and abstracts. The printed version is called Index Medicus. It now runs 18 volumes and 35,000 pages. This is basically a pretty comprehensive compilation of the world's literature.

The electronic MEDLINE data base contains 11 million references. Now I should say that all journals, whether they are in the printed or the electronic form, or just collected by the Library, are available to be read at the Library as the Odone's did or to be sent on inter-library loan to readers anywhere in the United States. We are supported by a national network of libraries of medicine, which is something for the country to be proud of.

I should comment to you on the manner in which journals are selected by NLM, to be either purchased or indexed or both. In this, the Library depends upon a committee of outside experts, duly appointed through the NIH process and compliant with the Federal Advisory Committee Act. We call this the Literature Selection Technical Review Committee. The committee meets three times a year. It is composed of medical scientists, administrators, health practitioners and librarians. At each of the meetings they review 120 to 150 new titles. It is surprising to us that 300 to 400 new journals arrive every year. These journals are nominated by publishers, health professionals, and librarians. In other words, we take their advice about which to look at.

The committee looks to see that a journal's contents are predominantly core biomedical subjects. If so, then the entire journal is indexed from cover to cover. More importantly, they assess the scientific merit of a journal's contents and consider its contribution to the field and also the quality of the editorial processes. These are features like evidence of objectivity, credibility, the quality of the contents, external peer review of articles, adherence to ethical guidelines, publication of retractions, correction of errors and publication of dissenting opinions, of course.

Of the titles reviewed at such a meeting, generally, around 20 percent are recommended strongly for indexing. That is about what we can manage to get on the data base. Since I came to NLM, incidentally, we have added 1,000 journals to the MEDLINE.

Often the committee, which is a finite number—10 to 12—feel a need for advice by additional experts in special areas. They, of course, can't know everything. So I want to move on to how they acted in the area of complementary and alternative medicine.

In September 1997, Dr. Wayne Jonas, who was then head of the NIH National Center for Alternative and Complementary Medicine, was invited to speak to the NLM Board of Regents. He did and he presented a talk on the subject and his organization. After that, his center gave us a list of 695 journals that published most of the articles in his field. We took his advice and NLM then sent that to 14 organizations that specialize in complementary and alternative medicine, a number of these nominated, and in some cases funded by Dr. Jonas. I have appended a list for you.

Of those 695 journals, we found that we already owned 79 percent. We already collected them and identified them. They were organized and in the Library. Based on the review we collected, we added six more. We added a certain number to the MEDLINE electronic file, as well.

The fact that a journal is or isn't on that list is of some importance, but following that up, there are 74 journals from the list that we do index in MEDLINE that are considered by that center to be fundamental to complementary and alternative medicine. I can give you that list, also.

[NOTE.—The information referred to is retained in committee files.]

Dr. LINDBERG. I understand that the committee is specifically interested today, amongst all the complementary and alternative medicine, in modalities in chelation therapy. Let us take a look at what MEDLINE has to say about that.

The term "chelating agents" has existed in our controlled indexing vocabulary since 1966. Many specific agents are included under that. The term "chelation therapy" was introduced in 1990. If we search MEDLINE under chelation therapy we get 59,600 references. If we narrow the search in the therapeutic use of chelating agents and cardiovascular disease, there are 762 references. There is big literature out there. We do our best to choose, fairly and consistently, in the journals that we add. We are definitely in the business of providing information not only to healthcare professionals, but the public, as well. There is a MEDLINEPlus designed for the patients' families and the public.

We are completely open to all of these new areas, and include chelation therapy for cardiovascular or any other purpose. Thank you for the chance to be with you.

[The prepared statement of Dr. Lindberg follows:]

Statement of Donald A.B. Lindberg, M.D.
Director, National Library of Medicine
National Institutes of Health

Before the Committee on Government Reform
U.S. House of Representatives

Wednesday, March 10, 1999

Mr. Chairman, members of the Committee. It is a pleasure to be here this morning to tell you about how the National Library of Medicine selects material for its indexes and databases. This subject goes to the heart of what the NLM does and I am glad to have this opportunity to explain our method of operation.

The National Library of Medicine has been indexing the medical journal literature for exactly 120 years. The first *Index Medicus* was published in 1879. Dr. John Shaw Billings, who was the director at that time, used a laundry basket to take medical journals home with him to be indexed in the evening. We have pictures of him sitting contentedly in his living room marking each article with subject headings. I am happy to say that since then we have introduced a few modernizations in our indexing methods.

Today the National Library of Medicine receives 22,247 periodical publications, of which some 14,000 could be labeled "journals." Of these, we index 3,982 for MEDLINE, our primary database of journal article references and abstracts. The published version of MEDLINE, the *Index Medicus*, now runs to 18 volumes and 35,000 pages in its annual bound form. Library shelves (and budgets!) around the world are finite. The electronic MEDLINE database contains 11 million references from the sixties to today and increases by more than 400,000 entries each year. One of our goals in accepting this relatively high volume of new entries each year is to include publications that present significant differences in opinion on important topics, and to reduce the chance of missing important new discoveries. All journals, whether included in *Index Medicus* or not, are available to be read or copied by library patrons, whether on site in Bethesda or at a far away library.

The Selection Process

The users of MEDLINE and *Index Medicus* are many and varied, including researchers, health care practitioners, educators, administrators, and students, in this country and abroad. Now that MEDLINE is easily accessible via the World Wide Web, we also count the general public among our audiences. Our database, therefore, must reflect this diversity and include journals in many disciplines related to the health sciences broadly. Because much important research is done in other countries, and published in languages other than English, our scope must be worldwide.

To select the journals that NLM will index, the Library depends on a committee of outside experts, the Literature Selection Technical Review Committee. The Committee, which meets three times a year, is composed of medical scientists and administrators, health practitioners, and librarians. At each of their meetings they review about 120 new titles and others that are nominated by publishers, health professionals, and librarians.

The Committee looks to see that a journal's contents are predominantly on core biomedical subjects. Most journals are indexed cover to cover. Most important, they assess the scientific merit of a journal's contents and consider its contribution to the subject field. The reviewers look also at the quality of the editorial processes—features that give assurance as to the objectivity, credibility, and quality of the contents, for example: external peer review of articles, adherence to ethical guidelines, retractions and correction of errors, and dissenting opinions. Both print and electronic journals are considered. Of the titles reviewed at each meeting, the reviewers generally recommend about 20 percent for indexing. Sometimes the Committee feels it needs the advice of additional experts in special areas. In fact, this is what happened in the area you are especially interested in, Alternative Medicine.

Coverage of Complementary and Alternative Medicine

In September 1997, Dr. Wayne Jonas, then head of the NIH National Center for Alternative and Complementary Medicine (CAM), was invited to the NLM Board of Regents meeting to talk about the work of his organization. After that meeting the Center compiled a list of 695 journals that published most of the articles in the field. NLM then sent the list to 14 organizations specializing in complementary and alternative medicine for their recommendation. (A list of

these organizations is in Appendix A.) Of the 695, it was found that the NLM already held in its collection 79 percent of the titles. Six more titles were added to the Library's collection as a result of the review.

It should be noted here that many articles on various alternative therapies are published in traditional journals. Just last fall, for example, the *Journal of the American Medical Association* devoted most of an issue to alternative medicine. But if one considers journals that specialize in complementary and alternative medicine, there are 74 now being indexed in MEDLINE. To give this figure some meaning, there are 38 journals that specialize in ophthalmology, 21 in gastroenterology, and 26 in orthopedics. That NLM's coverage of complementary and alternative medicine is substantial may be seen in the fact that the National Center for Alternative and Complementary Medicine has a reference database called CAM Citation Index (CCI) of 180,000 articles in that field; all are from MEDLINE.

I understand that this Committee is interested specifically in chelation therapy. There is in fact much material in MEDLINE on this subject. The term CHELATING AGENTS has existed in our controlled indexing vocabulary since 1966, and many specific agents are also included. The term CHELATION THERAPY was introduced in 1990. Searching MEDLINE broadly under the several specific chelating agents results in 59,632 references being retrieved. If one narrows the search to the therapeutic use of chelating agents in CARDIOVASCULAR DISEASES, there are 762 references.

I have sought to accomplish two things in my testimony this morning. First, I wanted to shed some light on how we at the National Library of Medicine select the journals we index. Second, I hope I have demonstrated to your satisfaction that there is much material in MEDLINE relating to complementary and alternative medicine, and that we are always receptive to considering new journals. We believe that the integrity of MEDLINE demands continued emphasis on quality.

Appendix A

Complementary and Alternative Medicine Review Organizations

The Complementary Medicine Program at the University of Maryland School of Medicine

The Center for Addiction and Alternative Medicine Research (Minneapolis)

The Center for Complementary and Alternative Medicine Research in Asthma, Allergy and Immunology at the University of California, Davis

A specialist in chiropractic medicine

The Stanford Center for Research in Diseases Prevention

Projekt Muncher Model at Ludwig-Maximullism-Universitat, Munich, Germany

The Center for the Studies of Complementary and Alternative Therapies at the School of Nursing, University of Virginia

The Center for Alternative Medicine Research, Houston

The AIDS Research Center at Bastyr University, Bothell, Washington

Kessler Research, West Orange, New Jersey

The Center for Alternative Medical Research at Beth Israel Deaconess Medical Center, Boston

The Research Council for Complementary Medicine, London

The Center for CAM Research in Women's Health, Columbia University

The Institute of Information on Traditional Chinese Medicine, Beijing

Mr. BURTON. Thank you.

Dr. Bernstein.

Ms. BERNSTEIN. Thank you very much, Mr. Chairman. I am Joanie Bernstein. I am the Director of the Bureau of Consumer Protection at the FTC. With me this morning is the agency's general counsel, Deborah Valentine who, if it is appropriate, may wish to join me at the table.

Thank you for the opportunity to be with you today and to provide this information, particularly about the settlement of the American College for the Advancement of Medicine with the Commission.

First, a brief word about the Commission's mission. It really is to prevent unfair competition and protect consumers from unfair or deceptive acts or practices in commerce. As part of it, the Commission has long sought to encourage the dissemination of truthful advertising. We have approached it two ways. The first is, where it is appropriate, we have challenged private restraints on truthful advertising. And second, we have a longstanding program of challenging misleading claims in advertising. It is particularly important, the Commission believes, in healthcare advertising.

Each year, consumers spend billions of dollars on products and services in this field. Advertising plays an important, we think, often vital role in informing consumers about the availability, the cost and other features of these products and services. If the advertising is misleading or deceptive, the consequences for consumers can be especially serious, causing not only economic injury, but creating risks to consumer health and safety. For this reason, the Commission has paid close attention to deceptive advertising claims for a wide variety of healthcare-related products and services.

I want to address some of the questions you raised in your correspondence with the Commission, Mr. Chairman. First, you focus specifically on the settlement with the American College for the Advancement of Medicine. In that case, the Commission has alleged that ACAM, if we may call it by its briefer name, promoted chelation therapy directly to the public as an effective treatment for atherosclerosis, through an Internet website and through brochures that it distributed directly to consumers who contacted ACAM.

Our inquiry focused on two claims that ACAM allegedly made to consumers. The first claim, which is alleged to be false, is that scientific studies show that EDTA chelation therapy is an effective treatment for atherosclerosis. Second claim, which is alleged to be unsupported by reliable scientific evidence, is that EDTA chelation therapy is effective in treating atherosclerosis.

The staff then investigated, in order to formulate those complaints; conducted an extensive review of information concerning this therapy; reviewed information, principally from ACAM, and also from other sources. They conducted a literature search and consulted with experts in the treatment of atherosclerosis and with other Government agencies. In the settlement process which then followed, staff met with ACAM attorneys on numerous occasions and advised them that staff believed that the existing scientific evidence did not support ACAM's claims.

ACAM representatives then met with me and each of the commissioners to present their arguments against the staff's recommendations. Following these meetings, ACAM again met with staff and decided to enter into a settlement of the allegations. On December 8, 1990, the Commission accepted, subject to public, an agreement containing a consent order. This order would ensure that advertising and promotional claims relating to chelation therapy, distributed by ACAM to consumers, was both truthful and supported by competent, reliable scientific evidence. These are the same standards as would be and, indeed, are applied to all healthcare advertisers promoting products and services as treatments for serious diseases.

It is important, I think, critically important to focus on, as we have tried to do, what the order does not do. The proposed order does not restrict patient access to medical treatment. It does not restrict a physician's use of chelation therapy. It does not regulate how individual doctors use or prescribe drugs in the course of treating or advising their patients, or other choice of therapy issues. In other words, Mr. Chairman, members of the committee, each of the doctors whom you heard at the first panel could continue to practice medicine in the exact same way as they are doing now, based upon their experience in their practices and their views and opinions, based upon the administration of that therapy. The proposed order—the Commission's proposed order—only applies to representations made in advertising and promotional material by ACAM.

Consistent with that policy, the Commission's analysis to aid public comment which was issued in conjunction with the proposed settlement states, "The Commission's actions should not be construed to regulate how doctors use or prescribe drugs in the course of treating their patients or other choice of therapy issues."

Your letter also raised additional questions concerning the staff's interaction with other Federal and State agencies concerning chelation therapy. As explained in our fuller, written testimony, at various times in the proceeding Commission staff consulted with the Federation of State Medical Boards, individual State medical boards and other Federal regulatory enforcement agencies in regard to chelation therapy.

In general, the primary purpose of these contacts has been to collect information regarding the therapy. Such contacts are a routine part of the Commissions efforts to maintain an active and coordinated program in the healthcare field. The proposed order in this case, as I indicated earlier, is now on the public record. Commission received a substantial number of comments on the proposed settlement. When the comment period is closed, the staff reviews the comments, makes a recommendation to the Commission. The Commission will review all that information, including all of the comments, and decide what action to take. Thank you.

[The prepared statement of Ms. Bernstein follows:]

PREPARED STATEMENT OF

THE FEDERAL TRADE COMMISSION ON

"Agency Lockout on the Off-Label Use of EDTA Chelation Therapy"

Before the

COMMITTEE ON GOVERNMENT REFORM

UNITED STATES HOUSE OF REPRESENTATIVES

Washington, D.C.

March 10, 1999

Mr. Chairman and members of the Committee, I am Jodie Bernstein, Director of the Bureau of Consumer Protection, Federal Trade Commission ("FTC" or "Commission"). I am pleased to have this opportunity to provide information concerning the Commission's investigation and settlement with the American College for the Advancement of Medicine.[1]

At the outset, I would like to note that the Commission's testimony concerns a pending law enforcement matter. Therefore, much of the information relating to this matter is protected from public disclosure under the Federal Trade Commission Act and the agency's rules and policies concerning the confidentiality of investigative information. The Commission's statement provides information concerning the investigation consistent with these statutory and policy constraints.

I. Introduction

The mission of the Federal Trade Commission is to prevent unfair competition, and to protect consumers from unfair or deceptive practices in the marketplace. In particular, the Commission enforces Section 5 of the Federal Trade Commission Act, which prohibits "unfair or deceptive acts and practices in or affecting commerce,"[2] and Section 12, which prohibits the false advertisement of "food, drugs, devices, services, or cosmetics."[3] To advance its mission, the Commission has long sought to prevent the dissemination of false and misleading advertising. The Commission recognizes that

[1] The written statement presents the views of the Federal Trade Commission. Responses to questions reflect my views and do not necessarily reflect the views of the Commission or any Commissioner.

[2] 15 U.S.C. § 45.

[3] 15 U.S.C. § 52.

advertising provides many important benefits to consumers and to competition. For example, the Commission has opposed bans on advertising by doctors and other professionals as anticompetitive restraints of trade. *American Medical Association*, 94 F.T.C. 701, 987 (1979), *aff'd*, 638 F.2d 443 (2d Cir. 1980), *aff'd by an equally divided Court*, 455 U.S. 676 (1982). But, these benefits from advertising may be thwarted when the information disseminated is false or misleading.

Accurate information about health care choices is vital to consumers. Each year, consumers spend hundreds of billions of dollars on health care products and services. Advertising plays an important role in informing consumers about the availability, cost, and other features of these products and services.

Unfortunately, in the health care field, as is true in almost all industries, some of the information provided to consumers can be false or misleading. When that happens, the consequences of deception can be especially serious, causing not only economic injury by undermining consumers' ability to make informed choices, but creating risks to consumer health and safety. For this reason, the Commission has paid close attention to deceptive advertising claims for health care products and services.[4]

II. History of the ACAM Investigation

The ACAM investigation was opened in January, 1996.[5] At the time of our investigation, the

[4] *See* Appendix for a list of some recent cases.

[5] ACAM is a non-profit corporation under the laws of California composed principally of medical doctors and osteopaths. It is exempt from federal taxation under the Internal Revenue Code, 26 U.S.C. § 501(c)(6), the exemption for "business leagues" and similar organizations that promote members' common business interests. *See* 26 C.F.R. § 1.501(c)(6) -1.

association promoted EDTA chelation therapy[6] (herein "chelation therapy") as an effective treatment for atherosclerosis. The Commission has alleged that ACAM promoted this therapy directly to the public through an Internet Website and through brochures it distributed to consumers who contacted ACAM. The Commission's action challenges only ACAM's promotional activities.

In its investigation, Commission staff sought and received from ACAM materials it uses to promote chelation therapy, as well as material that the association has relied upon to support its claims relating to the efficacy of EDTA chelation therapy. For example, ACAM promotional materials stated that *"Chelation therapy is a safe, effective and relatively inexpensive treatment to restore blood flow in victims of atherosclerosis,"* and *"Chelation therapy is used to reverse symptoms of hardening of the arteries, also known as atherosclerosis or arteriosclerosis."* Staff also conducted an independent literature search and contacted third party resources to collect materials on chelation therapy. Staff reviewed all of this material and submitted key papers and studies to experts familiar with research methodologies or the etiology and treatment of atherosclerosis.[7] In addition, staff consulted with other government agencies and health organizations to ascertain their views.

Attorneys for ACAM met numerous times with Commission staff and provided their views relating to this case. Based on its investigation, staff was concerned that ACAM's supporting evidence

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[6] Chelation therapy consists of the intravenous injection into the body of a substance which, after bonding with heavy metals in the bloodstream, is expelled through the body's excretory functions. The bonding substance recommended by ACAM, and used generally by practicing chelationists is a man-made amino acid called *ethylene diamine tetraacetic acid* (EDTA).

[7] The Commission has provided a list of experts in response to Chairman Burton's request. The list includes highly credentialed scientists and medical professionals in a number of disciplines.

was inadequate to support ACAM's claim that EDTA chelation therapy is effective in the treatment of atherosclerosis and ACAM's implied claim that scientific studies proved that the treatment was effective was false. Thereafter, consistent with normal Commission practice, ACAM representatives met with me, and each of the Commissioners to present their arguments against Commission action. Following these meetings, ACAM decided to enter into a settlement of the allegations against it.

On December 8, 1998, the Commission accepted, subject to public comment, an Agreement containing a Consent Order executed by ACAM. ACAM, while not admitting the Commission's allegations, waived its right to contest the issues in a trial on the merits. The Commission's complaint accompanying the consent agreement alleges that ACAM made: (1) unsubstantiated claims that EDTA chelation therapy is effective in treating atherosclerosis (blocked arteries); and (2) false claims that scientific studies prove that EDTA chelation therapy is an effective treatment for atherosclerosis.[8] The proposed consent order would prohibit ACAM in the future from making unsubstantiated claims concerning the effectiveness of chelation therapy in the treatment of circulatory diseases, and would prohibit ACAM from misrepresenting scientific evidence in connection with its advertising for chelation therapy.

It is important to understand what the proposed order does <u>not</u> do. It does not restrict any

[8] Organizations that, at one time or another, have concluded that use of EDTA chelation for the treatment of coronary artery disease is unproven, unsafe, or both include: The National Institutes of Health, The National Research Council, the California Medical Society, the American Medical Association, the Centers for Disease Control and Prevention, the American Heart Association, the American College of Physicians, the American Academy of Family Practice, the American Society of Clinical Pharmacology Therapeutics, the American College of Cardiology, the American Osteopathic Association, the U.S. Public Health Service, and the U.S. Health Care Finance Administration.

ACAM member from offering or performing chelation therapy. It does not prohibit ACAM or any chelationist from promoting or advertising chelation therapy.[9] It does not restrict communications between doctors and patients about course of treatment decisions. Rather, the order would simply require that advertising claims be truthful and substantiated.

On December 16, 1998, the Commission placed the complaint and agreement on the FTC's public record for sixty days for comment. The comment period expired on February 16, 1999. The Commission has now reopened and extended the comment period until March 31, 1999.[10]

III. Legal Principles

In considering the advertising claims by ACAM, the Commission applied the same legal principles it has developed and applied over decades of reviewing health claims for products or services. They are well established principles articulated in Commission case law and explained in our policy statements, and they are designed to ensure that consumers are given truthful and nonmisleading information so that they can make decisions about their health and safety.

These principles are:

- Objective claims that a product or service is effective must be supported by a reasonable

[9] Commission staff has engaged in extensive discussions with ACAM's representatives on this point and the staff has provided ACAM with considerable guidance. Moreover, consistent with Commission practice and procedure, if the order is made final, our compliance staff will continue to work with ACAM to provide further guidance concerning compliance with the order. *See Kraft v. FTC*, 970 F.2d 311, 326 (7th Cir. 1992), *cert. denied*, 507 U.S. 909 (1993).

[10] The Commission vote to extend the public comment period was 3-1, with Commissioner Sheila Anthony dissenting. Commissioner Anthony and Commissioner Orson Swindle issued separate statements.

basis.[11]

- What constitutes a reasonable basis depends on the nature of the claims and the context in which they are presented in the ad.

- If an advertiser states or implies a level of support for a claim, the advertiser must in fact have that level of substantiation.

- If the advertiser is silent on the level of support, the level of substantiation is determined on the basis of a number of factors, such as the type of product, type of claim, benefits of a truthful claim, the cost and feasibility of developing substantiation for the claim, the consequences of a false claim, and the amount of substantiation that experts in the field believe is reasonable.[12]

- Scientific evidence is required to support claims when an advertisement states or implies that claims are supported by scientific evidence, or when unqualified claims concern the efficacy or safety of a drug.[13]

In assessing the amount of substantiation experts in a field believe is reasonable, the Commission gives great weight to the generally accepted standards in the relevant fields of research and consults with experts from a wide variety of disciplines. Where there is an existing standard for substantiation developed by a government agency or other authoritative body, the FTC accords substantial deference to that standard.[14]

The FTC's standard for evaluating substantiation is sufficiently flexible to ensure that consumers have access to information about emerging areas of science. At the same time, it is sufficiently rigorous

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[11] *See, e.g., Thompson Medical Corp. Inc. v. FTC*, 791 F.2d 189, 193 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987); *Firestone*, 81 F.T.C. 398, 451-52 (1972), *aff'd*, 481 F.2d 246 (6th Cir.), *cert. denied*, 414 U.S. 1112 (1973).

[12] *Thompson Medical Corp.*, 104 F.T.C. at 821.

[13] *Id.* 104 F.T.C. at 822; "FTC Policy Statement Regarding Advertising Substantiation," appended to *Thompson Medical Corp.*, 104 F.T.C. at 839.

[14] *See Thompson Medical Corp.*, 104 F.T.C. at 825.

to ensure that consumers can have confidence in the accuracy of information presented in advertising.

In past cases, the Commission has often required well-controlled clinical studies to substantiate drug and medical device efficacy claims.[15] When considering whether a claim is substantiated, all available evidence is evaluated, including contrary evidence. Commission staff evaluated the evidence relating to the effectiveness of EDTA chelation therapy in a manner consistent with these principles.

IV. Access to Medical Treatment

I have been asked to comment on whether the Commission's action restricts patient access to medical treatment. It does not. The proposed order does not pertain to a physician's use of chelation therapy. Also, as mentioned above, the proposed order does not apply to doctors acting in their individual capacities giving advice to their patients and it does not regulate how individual doctors use or prescribe drugs in the course of treating or advising their patients or other choice of therapy issues. The proposed order applies only to representations made in advertising and promotional material by ACAM, a trade association, *i.e.*, commercial speech, disseminated to consumers.

The Commission is mindful of the development of alternative modes of treatment and, as an agency charged with enforcing competition laws, is sensitive to the competitive impact of its enforcement actions. Indeed, the FTC has a lengthy history of taking actions that prevent

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[15] *Removatron Int'l* Corp., 111 F.T.C. 206 (1988), *aff'd*, 884 F.2d 1489 (1st Cir. 1998)(requiring "adequate and well-controlled clinical testing" to substantiate claims for hair removal product); *Thompson Medical Corp.*, 104 F.T.C. at 826 (two well-controlled clinical tests required to substantiate arthritis pain relief claim); *See also*, *Porter & Dietsch, Inc.*, 90 F.T.C. 770, 885 (1977), *aff'd*, 605 F.2d 294 (7th Cir. 1979), *cert. denied*, 445 U.S. 950 (1980) (claims that any food, drug, or device can help a user achieve any result, such as weight loss, must be substantiated by "competent scientific or medical tests or studies").

anticompetitive conduct in health care and other industries.[16] The Commission believes that careful, consistent enforcement of the standard for advertising claims, *i.e.*, that claims in advertising not be misleading and be adequately substantiated, will enable consumers to receive useful information about their options in the health care marketplace.

Consistent with this policy, the Commission's Analysis for Public Comment issued in conjunction with the consent agreement in this case states that the "Commission's action should not be construed to regulate how doctors use or prescribe drugs in the course of treating their patients or other choice of therapy issues." This message is clearly stated in the letter ACAM would be required to send to doctors under the consent agreement. *See* Attachment A to the Consent Agreement.

V. Coordination with other Regulatory Agencies.

The Commission has been asked to discuss the FTC's interactions with the Federation of State Medical Boards, individual state medical boards, and other Federal regulatory or enforcement agencies in regard to physicians who incorporate the use of EDTA chelation into their practice of medicine. Commission staff has attended meetings of the Federation of State Medical Boards, as well as the Board's Ad Hoc Committee on Health Fraud. The Federation also jointly sponsored with the Federal Trade Commission and the National Association of Attorneys General a law enforcement conference on June 26-27, 1997 in Dallas, Texas in which EDTA chelation therapy was discussed by some participants. Generally, these meetings involved the informal exchange of information, including the

[16] For example, the Commission has challenged private conspiracies to obstruct nurse midwives and podiatrists from obtaining hospital privileges. *Medical Staff of Memorial Med. Center*, 110 F.T.C. 541 (1988) (consent order); *North Carolina Orthopaedic Ass'n*, 108 F.T.C. (1986) (consent order).

identification of current areas of interest; discussions of how to coordinate law enforcement activity, *e.g.*, identifying appropriate contacts in other agencies on particular matters; presentations by experts on various types of products or services; and descriptions of each participating agency's law enforcement authority, priorities, and procedures. FTC staff also has contacted staff of the California State Medical Board and other boards in order to collect information concerning chelation therapy. In addition, in at least one instance, our staff was contacted by a state medical board concerning physician advertising for chelation therapy.

FTC staff has contacted staff at other federal agencies as well, including the Public Health Service, National Institute of Health's Heart, Blood and Lung Institute, the Food and Drug Administration, and the National Center for Complementary and Alternative Medicine concerning either specific scientific questions or to obtain information concerning the agency's position, if any, on the effectiveness of EDTA chelation therapy. Commission staff regularly consults with other regulatory agencies on advertising issues. Through these contacts, Commission staff has developed a good working relationship with state and federal regulatory agencies and keeps them advised of Commission actions in related areas.

VII. Conclusion

The Commission has received a substantial number of comments on the proposed settlement with ACAM. When the comment period is closed, staff will review the comments and make its recommendation to the Commission. The Commission will then consider whether to adopt the order as final or direct such further action as it may consider appropriate.

Appendix

Pacific Medical Clinics Management, Inc., No. CV-901277 GT (CM) (S.D. Cal. filed Sept. 17, 1990) (misrepresentation of safety and efficacy of treatment for obesity).

Reproductive Genetics In Vitro, P.C., 114 F.T.C. 802 (1991) (false and unsubstantiated success rate claims for IVF infertility treatment).

Dr. Scott M. Ross, 115 F.T.C. 54 (1992) (misrepresentation of safety, recovery period, discomfort of liposuction).

NME Hospitals, Inc., 115 F.T.C. 798 (1992) (false claims success rate and superiority of Bowel-Disorder surgery).

Belage Plastic Surgery Center, 115 F.T.C. 871 (1992) (misrepresentation of safety, lack of risks, recovery period, painlessness of breast implants).

Medical Marketing Services, Inc., 116 F.T.C. 35 (1993) (misrepresentation of risks, pain, recovery period and results of chemical face-peels).

David Green, M.D., 119 F.T.C. 930 (1995) (misrepresentation of pain, permanence and success rate of non-surgical vein treatment).

Stillman Dyslexia Center and Transformational Training Center, Inc., No. CV-95-0685-ER (Shx) (C.D. Cal. filed Feb. 2, 1995) (false and unsubstantiated efficacy claims for dyslexia treatment device).

Genetus Alexandria, Inc., 121 F.T.C. 62 (1996) (false safety and efficacy claims for impotence treatment).

Cancer Treatment Centers of America, 121 F.T.C. 692 (1996) (false and unsubstantiated efficacy claims; unsubstantiated survivorship rate).

American Urological Corporation, No. 1:98-CV-2199 (JOF) (N.D. GA filed Aug. 3, 1998) (false efficacy claims for impotence treatment products).

Mr. BURTON. Dr. Bernstein.

Ms. BERNSTEIN. Yes.

Mr. BURTON. Does this order that you entered into with them, does that prohibit a doctor from talking to their patients about alternative therapies such as chelation therapy?

Ms. BERNSTEIN. No, it does not.

Mr. BURTON. It is only advertising?

Ms. BERNSTEIN. Only advertising.

Mr. BURTON. As I understand it, you said that you had public comment about this before a decision was reached?

Ms. BERNSTEIN. What I said was that once the Commission provisionally accepted, that is conditionally accepted, the settlement—which is a routine way in the Commission operates—it is placed on the public record and a request for public comment is made. We are in that comment period now, which ends the end of March. We are receiving comments from the public at this time.

Mr. BURTON. I have here, I think, all the comments that you have received so far?

Ms. BERNSTEIN. Yes.

Mr. BURTON. And as I understand it from my staff, it is about 97 percent positive that chelation therapy has been beneficial. Are you aware of that?

Ms. BERNSTEIN. We have not completed our review of the comments. My information is that there are almost 800 comments. Many comments are positive about, particularly, alternative medicine in general. They are in support for alternative medicine, some specifically to chelation therapy. But you are quite correct that a large majority appear to be in support of chelation therapy.

Mr. BURTON. As I understand it, the reason that the ACAM settled was because they were concerned about the long-term, high legal costs that they would incur if they had to fight this thing. They thought discretion was the better part of valor because they didn't have the money. Are you aware of that?

Ms. BERNSTEIN. I think that is frequently a concern of any organization that makes a decision about whether to litigate a matter such as this.

Mr. BURTON. So the Government comes with a sledge hammer and makes an accusation and the organization either has to acquiesce or go bankrupt.

Ms. BERNSTEIN. Well, it often doesn't cost that much.

Mr. BURTON. That is not what ACAM told us. They just simply didn't have the resources so they had to acquiesce. I think that is kind of unfortunate, especially if they have a valid argument they want to make. It really is.

Ms. BERNSTEIN. I believe they had every opportunity to make all of their arguments to the Commission that were heard. I would not like to think that we proceed in this organization, or any other, with a sledge hammer. I don't believe we have in this instance. I don't believe it is the intention of the Commission to have us proceed in that fashion.

Mr. BURTON. This folder I have here has all the responses you received. Well over 90 percent support the theory that chelation therapy has helped these people—over 90 percent—and yet they had to pay a penalty. Doctors around the country are in jeopardy

of losing their medical license if they don't stop, cease and desist using chelation therapy.

Ms. BERNSTEIN. I think that is not correct, Mr. Chairman.

Mr. BURTON. We don't have doctors being threatened in individual States with losing their medical licenses?

Ms. BERNSTEIN. Not by the Federal Trade Commission.

Mr. BURTON. No, I understand. But you are working with those States, I believe, aren't you?

Ms. BERNSTEIN. We are not working with the States in regard to licensing. We have worked with the States, as we do with States' Attorneys General and other organizations where there is a law enforcement matter, where we coordinate or share information.

Mr. BURTON. Dr. Lenfant, you get $1.5 billion in your budget, is that correct?

Dr. LENFANT. Yes.

Mr. BURTON. How much of that do you spend on alternative therapies, such as chelation?

Dr. LENFANT. On chelation, nothing. Well, chelation for atherosclerosis, nothing. We do support a great deal of work for other chelation therapies, such as for Cooley's Anemia, for example. But that is no longer considered alternative medicine.

To answer your question, we support approximately $5 or $6 million in alternative medicine. I should say, so that you understand the context within which we provide that amount of support, we have solicited applications in alternative medicine and we receive very few—very, very few.

Mr. BURTON. For chelation therapy?

Dr. LENFANT. No, not on chelation. Just alternative medicine.

Mr. BURTON. I wonder why that is? There are a lot of people interested in Chelation therapy.

Dr. LENFANT. Well, yes. Yes, from what I understand here from the previous presentations made to you, it would appear that chelation therapy and alternative medicine are in the practice of the private physician, rather than the academic setting. Of course, all the National Institutes of Health is primarily researchers from academic institutions.

As I am sure you know, Mr. Chairman, the previously named Office of Alternative Medicine, has become a stand-alone at the National Institutes of Health. I think that is going to increase the visibility of that program tremendously. We are beginning to receive some applications from academic institutions.

Mr. BURTON. So it should be directed to them first?

Dr. LENFANT. Many programs at NIH are shared between various centers of the Institute. My belief is that, for example, would an application come on chelation therapy for the treatment of atherosclerosis, it would be dually assigned to the Center for Alternative Medicine and to the Institute. The one application that I mentioned earlier, the one from the University of Missouri, was exclusively and solely assigned to the National Heart, Lung, and Blood Institute. I want to say it one more time. We would have supported that application if it had passed peer review.

Mr. BURTON. What would you say if we had the doctors who are here assembled today, if they sent in a couple of thousand cases where there had been positive results from the chelation therapy?

We put that in a binder with a report and sent it to you. Would you review that? Or is that not the way you do things over there?

Dr. LENFANT. Well, if we would get this data, most likely I think it would probably go to the Agency for Health Care Policy and Research. Should that come to us, we would certainly look at it and hand out an opinion on it. That is not quite the same thing as submitting a proposal to undertake a research project. I was discussing with one of your previous witnesses this issue during the recess and said to him, "Why don't you send an application?" The fact, Mr. Chairman, is that we do not receive applications.

It is true that today our budget is, in fact, $1.8 billion for 1999. During the last 20 or 25 years we have received over 50,000 applications for research grants.

Mr. BURTON. Excuse me for interrupting. I didn't want to lose this thought. My staff said that several leading medical research institutes contacted your office and were discouraged from submitting applications. Is that not correct?

Dr. LENFANT. Mr. Chairman, I heard you say that when you introduced this hearing. All I can say is that I don't know about it. I am the Director of the Institute, none of these interested investigators came to me to mention that to me. If they had done it, I would have acted upon it.

Mr. BURTON. Well, why don't we do this in order to eliminate any misunderstanding. Why don't we contact those institutes and have them submit their applications through us. We will give them to you directly. We will take them right to your office and lay them on your desk.

Dr. LENFANT. That would be fine to me. They will be reviewed and fairly reviewed. And then we will see what peer review comes up with.

Mr. BURTON. We will get to work on that right away.

Dr. LENFANT. Again, Mr. Chairman, I really would like to say that we support approximately 25 percent of the applications that we receive. The 75 percent that are not supported always say that the system is flawed. I cannot blame them for it. I guess if I would be in that position, I would do that as well. But the fact of the matter is if an investigator feels that he or she has not been treated appropriately by the Institute, again, they should come to the Director of the Institute and say what is going on there. I can tell you in my case, I would have addressed that.

Mr. BURTON. All I can tell you is that we will contact those institutions. We will get their submissions, which they have already sent to you and haven't received any response. Or they have been discouraged, I guess. And we will be sure to put those right in your hand. In fact, I will be happy to come over and give them to you, personally. How is that?

Dr. LENFANT. I'll come down and get them.

Mr. BURTON. Well that's good. We'll have lunch. [Laughter.]

Mr. WAXMAN. Mr. Chairman, I have a conflict.

Mr. BURTON. Well, you know, Mr. Waxman, you have been gone all day. We have been sitting here hearing testimony. We had doctors, prominent, eminent doctors here, testify about the efficacy of chelation therapy. You weren't here to hear their testimony, which

was disconcerting. If you need to have 5 minutes now, we will give you 5 minutes.

Mr. WAXMAN. Mr. Chairman, I don't need a lecture from you on how to do my job. I have conflicts in my schedule. I am sorry that I was not here to listen to all the witnesses. I would have regretted not being here and not listening to other people in other meetings that I have at the same time. But I am entitled under the rules to be able to ask questions, and the Chair went 5 minutes beyond when his time had expired. After I leave, He can continue on in another round. Those are the rules; so let's follow the rules. Under the rules, I want to ask some questions.

Dr. Lenfant, when you get a request for a grant proposal do you have uniform standards by which you evaluate proposed grants?

Dr. LENFANT. That is correct. At the first place, it is not reviewed by the Institute. In fact, for a very simple reason: in order to eliminate biases for or against the application. It is reviewed by an independent unit of the National Institutes of Health.

Mr. WAXMAN. You don't have a different standard for proposals regarding complementary and alternative treatment than you do for any other proposal?

Dr. LENFANT. Not me.

Mr. WAXMAN. Not you or your Institute?

Dr. LENFANT. Not me or my Institute. I must admit that I am very troubled by what was said by the chairman that some people or investigators came and said they were told not to submit an application, because that should not have been done. There is only one person in our Institute who has the authority to say that. And that person does it, always, when that needs to be done, after checking with me.

Mr. WAXMAN. I believe that you testified that, of the tens of thousands of grant proposals the NHLBI has received in the past 30 years, only three have addressed chelation therapy as a treatment for heart disease?

Dr. LENFANT. That is correct. Only one was on clinical studies, and the two other ones were some more basic aspects of it.

Mr. WAXMAN. Were these proposals evaluated with the same criteria that other proposals are evaluated?

Dr. LENFANT. My answer to that would be "yes."

Mr. WAXMAN. Dr. Bernstein, if an association of doctors ran advertisements making unsubstantiated efficacy claims regarding coronary artery bypass surgery, would the FTC take action against the association?

Ms. BERNSTEIN. Yes, we would if we had evidence that they were not substantiated or were false.

Mr. WAXMAN. Are such claims being made now?

Ms. BERNSTEIN. Not to our knowledge, Mr. Waxman.

Mr. WAXMAN. How has the advertising community reacted to the FTC's policy of requiring that advertisers substantiate their substantive ad claims?

Ms. BERNSTEIN. Extremely well. After the Commission adopted its substantiation for certain kinds of claims in the 1970's, in the 1980's in order to review that policy—that is, requiring substantiation for objective claims, particularly for drugs and medical devices—it was put out for public comment and the overwhelming re-

sponse of the advertising community was that it had served a very valuable purpose for the credibility of advertising which, of course, advertisers are critically concerned about as well as the general public.

Mr. WAXMAN. I know the FTC has a policy prohibiting you from talking too much about the specifics of your investigation into ACAM's claims. However, I have a few general questions about how you determined that the evidence ACAM offered was not enough to substantiate the claims they were making.

When the FTC evaluated the evidence provided by ACAM to substantiate its claims about chelation therapy, did the FTC use objective criteria to determine if the evidence was sufficient to substantiate the claims?

Ms. BERNSTEIN. Yes, we did. Yes, we did.

Mr. WAXMAN. Were these criteria the same criteria used to evaluate all medical claims?

Ms. BERNSTEIN. Correct. Absolutely, correct.

Mr. WAXMAN. Are claims regarding alternative medicine or treatments held to higher standards for substantiation than other medical claims?

Ms. BERNSTEIN. No, they are not. Indeed, Mr. Waxman, we recently published a guideline for substantiation for nutritional supplements—dietary supplements—that has been very well received by the industry, as well as by consumer groups, to provide guidance. That same kind of guidance is available for any group that would like to consult with us.

Mr. WAXMAN. The FTC's actions against ACAM does not prohibit ACAM from making substantiated claims about chelation therapy, is that right?

Ms. BERNSTEIN. That is correct.

Mr. WAXMAN. And ACAM is being held to the same standard of substantiation that anyone who makes a medical claim is held to, is that right?

Ms. BERNSTEIN. Correct.

Mr. WAXMAN. I think that is important, because people feel like maybe they are being treated differently. We want everybody to be treated the same. We want them all held to the same standard. I don't care how many letters you get in your file from people who say one thing as opposed to another. It should not be based on the number of letters you get, or comments you get. Things should be based on the substance, the arguments that are made. They ought to be all held to the same standard, whether they engineer a bunch of letters or whatever the comments. The comments ought to be taken on their merits, not on their numbers. Dr. Lindberg are there objective criteria for selecting journals for inclusion in medicine?

Dr. LINDBERG. Well, I think we try to make them objective. We certainly have printed rules and guides to evaluation, which are very similar really, to the same process that is used to evaluate applications for research grants.

Mr. WAXMAN. And are journals regarding complementary and alternative medicine treatment held to the same standards as other journals?

Dr. LINDBERG. Oh, absolutely.

Mr. WAXMAN. Can you explain the importance of holding journals you are going to include on medicine to such exacting standards?

Dr. LINDBERG. I think the whole essence of the Library is that it has to be open to ideas and it has to be open to users. We are both. A particular case is of these computer data bases. Since they can't literally contain everything in the world worth knowing, they have to be selected based on our best judgment of high-quality scientific information—high-quality scientific judgments and processes in writing the journals. And that we try to do, to the best of our ability, using all the help we can get.

Mr. WAXMAN. I said "medicine," but I meant "MEDLINE." You understood what I meant?

Dr. LINDBERG. Yes.

Mr. WAXMAN. Now, if I must just conclude in another minute or two—let me apologize to these witnesses and other witnesses, but I did have your testimony. I have had a chance to review some of the testimony. Some I am going to read over more carefully. I have an open mind on this issue. It is sometimes better not to be here all the time and still have an open mind than to be here all the time and to keep your mind closed. So I appreciate the testimony all the witnesses have given.

I also appreciate the courtesy of the chairman by allowing me to question this panel, under the rules, to which I am entitled. I yield back my time.

Mr. BURTON. Ms. Bernstein, if a physician uses a pamphlet about a medical treatment as part of his or her consultation with a patient, not to solicit patients, is that advertising?

Ms. BERNSTEIN. Probably not. It would, of course, depend on the context of it. Generally we would not consider information provided directly to a patient by a physician to be advertising, providing that patient with the appropriate advice that he has sought from the doctor.

Mr. BURTON. Well, it is my understanding that doctors are being prevented from printing a pamphlet to give to a patient who is being treated with chelation therapy.

Ms. BERNSTEIN. That is certainly not because of the Commission's provisional order. They are not prevented from printing brochures to provide to patients.

Mr. BURTON. Well, my staff says that part of the order says that if they provide this kind of a pamphlet to a patient, they can be prosecuted.

Ms. BERNSTEIN. I don't believe that that is the case.

Mr. BURTON. Well, it is in the order. You have your attorney there. Can she look that up?

Ms. BERNSTEIN. Yes, that would be fine.

Mr. BURTON. Evidently, ACAM sent a letter to all of their members to that effect; warning them that if they had pamphlets and they gave it, even to a patient that was getting chelation therapy, they could be prosecuted.

Ms. BERNSTEIN. ACAM sent the letter?

Mr. BURTON. Yes, but it was based upon your decision.

Ms. BERNSTEIN. You are asking about the letter that ACAM sent to its members?

Mr. BURTON. We are asking about your decision.

Ms. BERNSTEIN. Well, our decision, the order simply requires that a claim that ACAM would make or the advertising.

Mr. BURTON. As I understand it, while you are looking that up, ACAM was told that, as part of the order, that they should tell their members that if they even gave a pamphlet to a patient who was getting, or who might want to take, chelation, that would be a violation of the agreement and they would be prosecuted.

Ms. BERNSTEIN. That is not in the order. I believe that that's a misinterpretation of what the order provides. The order is strictly limited to advertising claims that would be made by ACAM. It does not prohibit them from any advertising claim, but requires well-controlled clinical trials. If they make a claim, that it is supported by such studies. They also must have substantiation or support for any claim they make, if they make a truthful claim. Indeed, we even gave them examples of claims that they could continue to make in the course of our discussions with them. If they wanted to say that it is a therapy that should be considered by a patient, that would be perfectly all right. The order only goes to making claims, as they did in the past, that it was scientifically proven that this was an efficacious claim. And for which they say themselves, I believe today, that they did not have such proof because the studies had not been conducted.

Mr. BURTON. Could you send me a detailed letter outlining the limitations that have been put on ACAM so that we can make absolutely sure that is clear to them, what they can and cannot do? We would like to have it in our records here in the Congress.

Ms. BERNSTEIN. I would be happy to do that. We have it with us. It is a very short order provision which really goes to substantiating a claim that is made along the lines that I just described. We would be happy to do that.

Mr. BURTON. We would like to have that.

[The information referred to follows:]

OFFICE OF
CONGRESSIONAL RELATIONS
(202) 326-2195

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

June 22, 1999

The Honorable Dan Burton
Chairman
Committee on Government Reform
2157 Rayburn House Office Building
Washington, DC 20515-6143

Re: American College for Advancement in Medicine, File No. 962-3147

Dear Chairman Burton:

Because of your interest in this matter, I wanted to inform you that the Commission has voted to issue a final order in the above-referenced matter. Enclosed is a copy of the Decision and Order of the Commission along with a copy of the Complaint.

Yours very truly,

Lorraine Miller
Director
Office of Congressional Relations

Enclosures

9623147
B257887

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

COMMISSIONERS:

Robert Pitofsky, Chairman
Sheila F. Anthony
Mozelle W. Thompson
Orson Swindle

In the Matter of	)	
	)	
AMERICAN COLLEGE FOR ADVANCEMENT IN MEDICINE, a corporation.	)	DOCKET NO. C-3882

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondents named in the caption hereof, and the respondents having been furnished thereafter with a copy of a draft of complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondents with violation of the Federal Trade Commission Act; and

The respondents and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondents of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondents that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondents have violated the said Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent

agreement and placed such agreement on the public record for a period of sixty (60) days, and having duly considered the comments filed thereafter by interested persons pursuant to § 3.25 (f) of its Rules, now in further conformity with the procedure prescribed in § 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent American College for Advancement in Medicine is a California corporation with its principal office or place of business at 23121 Verdugo Drive, Suite 204, Laguna Hills, California 92653.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondents, and the proceeding is in the public interest.

ORDER

DEFINITIONS

For the purposes of this Order:

1. Unless otherwise specified, "respondent" shall mean American College for Advancement in Medicine, its agents, representatives and employees.

2. "EDTA" shall mean the drug, *ethylene diamine tetraacetic acid.*

3. "Chelation therapy" shall mean the introduction into the human body of any agent for the purpose of bonding with and removing any compound or chemical element from the body. "EDTA chelation therapy" means that EDTA is the bonding agent used.

4. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

5.. "In or affecting commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C.§ 44.

I.

IT IS ORDERED that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the advertising, promotion, offering for sale, sale, or distribution, in or affecting commerce, of chelation therapy, shall not make any representation, in any manner, expressly or by implication:

A. That EDTA chelation therapy is an effective treatment for atherosclerosis, or

B. About the effectiveness or comparative effectiveness of chelation therapy for treating or preventing any disease or condition related to the human circulatory system,

unless, at the time the representation is made, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the advertising, promotion, offering for sale, sale, or distribution, in or affecting commerce, of chelation therapy, shall not misrepresent, in any manner, expressly or by implication, the existence, contents, validity, results, conclusions or interpretations of any test, study, or research.

III.

Nothing in this order shall prohibit respondent from making any representation for any drug that is specifically permitted in labeling for such drug under any tentative final or final standard promulgated by the U. S. Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration.

IV.

IT IS FURTHER ORDERED that respondent and its successors and assigns, shall mail, or otherwise deliver, a copy of this order and an exact copy of the letter attached hereto as Attachment A to each member of respondent within thirty (30) days after the date of service of this order.

V.

IT IS FURTHER ORDERED that respondent and its successors and assigns shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

A. All advertisements and promotional materials containing the representation;

B. All materials that were relied upon in disseminating the representation; and

C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

VI.

IT IS FURTHER ORDERED that respondent and its successors and assigns, shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondent shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

VII.

IT IS FURTHER ORDERED that respondent and its successors and assigns shall notify the Commission at least thirty (30) days prior to any change in the corporation(s) that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. Provided, however, that, with respect to any proposed change in the corporation about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580.

VIII.

IT IS FURTHER ORDERED that respondent and its successors and assigns shall, within sixty (60) days after the date of service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which it has complied with this order.

IX.

This order will terminate on June 22, 2019, or twenty (20) years from the date of its issuance, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

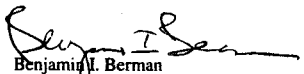
A. Any Part in this order that terminates in less than twenty (20) years;

B. This order's application to any respondent that is not named as a defendant in such complaint; and

C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.



Benjamin I. Berman
Acting Secretary

SEAL

ISSUED: June 22, 1999

Mr. BURTON. Now, if a bona fide non-profit medical society maintains a library of information for the benefit of its physician members and the public, and if the society sells to interested members of the public, from its list of publications, booklets on a medical treatment, is that advertising?

Ms. BERNSTEIN. No, it's not.

Mr. BURTON. Is that spelled out in your order, as well?

Ms. BERNSTEIN. No, it isn't. But we would be glad to provide an interpretation to that effect.

Mr. BURTON. I would like to have that in writing, too, if we could have that. That way, there would be some clarification so doctors would know what they are doing.

[The information referred to follows:]

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Bureau of Consumer Protection

April 7, 1999

The Honorable Dan Burton
Chairman
Committee on Government Reform
2157 Rayburn House Office Building
Washington, DC 20515-6143

Re: American College for Advancement in Medicine, File No. 962-3147

Dear Mr. Chairman:

At the March 10, 1999 chelation therapy hearing, you asked for additional information concerning the ACAM settlement. This letter responds to your request.[1] First, you asked me to provide a detailed analysis of what the ACAM proposed consent order covers. Second, you asked whether the proposed order prohibits ACAM from maintaining a library and making it available to doctors. Third, you asked whether the proposed order prohibits a doctor from distributing a brochure on chelation therapy to his or her patient. The information is provided below.

1. What does the proposed consent order cover?

The proposed consent order prohibits ACAM from representing in connection with the "advertising, promotion, offering for sale, sale, or distribution . . . of chelation therapy" (herein referred to collectively as "advertising") that EDTA chelation therapy is effective to treat atherosclerosis unless the representation is supported by competent and reliable scientific evidence. Thus, ACAM may not advertise chelation therapy as an effective treatment for atherosclerosis until ACAM has the necessary scientific support for that claim. In addition, the proposed order requires that ACAM have competent and reliable scientific evidence to support any advertising claims about the effectiveness or comparative effectiveness of chelation therapy for treating or preventing any disease or condition related to the human circulatory system. It also prohibits ACAM from misrepresenting in any future advertising for chelation therapy, the existence, contents, validity, conclusions or interpretations of any test, study, or research. These provisions apply to the American College for Advancement in Medicine, its agents,

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[1] The views expressed in this letter are my own, and do not necessarily reflect the views of the Commission or any individual Commissioner.

representatives and employees,[2] whether acting directly or through any corporation, subsidiary, division, or other device. The proposed order does not, however, apply to the individual members of ACAM, when acting in their individual capacities.[3]

The proposed order covers the advertising or promotion of chelation therapy. What constitutes advertising, and is therefore subject to the proposed order, requires a case-by-case analysis. Relevant considerations include (1) whether it contains a message promoting the demand for a product or service; (2) whether it refers to a specific product or service (though not necessarily by brand); (3) whether it contains information about attributes of a product or service offered for sale, such as type, price, or quality, including health benefits; (4) whether it is disseminated by means often used for commercial speech; and (5) the speaker's economic or commercial interests.[4]

Although I cannot anticipate every situation in which ACAM might distribute information, I can offer some guidance on what would constitute advertising. In the instant case, ACAM's distribution of Exhibit B (attached to the complaint) to consumers who contacted ACAM would constitute advertising within the meaning of the proposed order. Likewise, making the information in Exhibit A available through an Internet Web Page would constitute advertising. Both instances can be viewed as an attempt to influence the public about the benefits of chelation therapy. The proposed order, however, does not prohibit a doctor from distributing a brochure to his or her patient. Moreover, as noted in the Commission's statement, if ACAM has any questions about whether a particular publication is advertising, our compliance staff is always available for consultation.[5]

Finally, I would emphasize that the proposed order does not prohibit advertising. Rather, it requires only that the advertising be truthful and that covered claims be substantiated.

2. Does the proposed order prohibit ACAM from maintaining a library and making it available to doctors?

The proposed order does not prohibit ACAM from maintaining a library and making it available to doctors. As noted above, the proposed order applies to "the advertising, promotion, offering for sale, sale, or distribution . . . of chelation therapy." In my view, maintaining a *bona fide* medical library and making it available to doctors does not constitute advertising, promotion, offering for sale, sale or distribution of chelation therapy.

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[2] *See* Proposed Order Definition 1.

[3] *See* Proposed Order Attachment A.

[4] *See R.J. Reynolds Tobacco Company*, 111 F.T.C. 539, 544-46 (1988)(Interlocutory Order). *See also, Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 66-67 (1983).

[5] *See Kraft v. FTC*, 970 F.2d 311, 326 (7th Cir. 1992), *cert. denied*, 507 U.S. 909 (1993).

3. Would the proposed order prohibit a doctor from distributing a brochure on chelation therapy to his or her patient.

The proposed order does not prohibit a doctor from distributing a brochure to his or her patient. As noted in the Commission's statement in this matter, the proposed order "does not restrict communications between doctors and patients about course of treatment decisions." The prohibitions in the proposed order apply to "respondent, directly or through any corporation, subsidiary, division, or other device," and "respondent" is defined as the "American College for Advancement in Medicine, its agents, representatives and employees."

As the cases cited in the Commission's statement demonstrate, Sections 5 and 12 of the Federal Trade Commission Act do cover false and misleading advertising by a physician. Nevertheless, it is not the policy of this agency to regulate, or to attempt to regulate, the practice of medicine. This policy is clearly articulated in Attachment A to the proposed order and bears repeating here: "The Commission's action should not be construed to regulate how doctors use or prescribe drugs in the course of treating their patients or other choice of therapy issues." Accordingly, the Commission does not restrict communications between doctors and patients about course of treatment decisions, and I would not pursue an investigation where the alleged advertising merely consisted of the distribution of a brochure from a physician to his or her patient.

Finally, I believe it is worth noting that our dealings with ACAM and its counsel during the course of the investigation and subsequent settlement negotiations were entirely professional and ultimately very productive. The proposed settlement was, I believe, prompted by a recognition of the practical benefits of bringing this matter to a close, which include the desire for some degree of certainty about how ACAM may carry out its business in the future. Moreover, as in any settlement of a law enforcement matter, compromise on both sides, *i.e.*, giving up what may be less important to achieve what is more important, was an essential part of the process. As always, both parties benefitted by reaching agreement.

Thank you for the opportunity to respond in writing to your questions.

Sincerely,

Jodie Bernstein

Jodie Bernstein
Director

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Congress of the United States

House of Representatives

COMMITTEE ON GOVERNMENT REFORM

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May 27, 1999

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BERNARD SANDERS, VERMONT
INDEPENDENT

The Honorable Joan Z. Bernstein
Director, Bureau of Consumer Protection
Federal Trade Commission
Washington, D.C. 20580

Dear Ms. Bernstein:

During the Government Reform Committee's March 10 hearing on chelation therapy I asked you to submit written clarification of your responses to certain questions. I asked about the FTC's proposed order against the American College for Advancement in Medicine (ACAM). Since I have not yet received your response, I thought I would take this opportunity to further describe the follow-up information I would like to have from the FTC. I believe clarification of these points is particularly important because your hearing testimony appears to be inconsistent with certain materials in the ACAM investigative file and with statements made by one of the other witnesses during the hearing.

I am very concerned about the scope of the FTC's proposed order against ACAM. At the hearing you described the order as being quite limited in scope. You said it was intended to ensure that advertising and promotional claims relating to chelation therapy, distributed by ACAM to consumers, are both truthful and supported by competent, reliable scientific evidence." You went on to provide assurances that, "each of the doctors . . could continue to practice medicine in the exact same way as they are doing now, based upon their experience in their practices and their views and opinions . . .The proposed order . . . only applies to representations made in advertising and promotional material by ACAM."

Following your prepared testimony, I asked you to further explain the scope of the order by answering specific questions as follows:

- If a physician uses a pamphlet about a medical treatment as part of his or her consultation with a patient, not to solicit patients, is that advertising?

You replied, " Probably not. It would, of course, depend on the context of it. Generally we would not consider information provided directly to a patient by a physician to be advertising, providing that patient with the appropriate advice that he has sought from the doctor...The order is strictly limited to advertising claims that would be made by ACAM.

- What you are saying is that the brochure from doctor to patient did not constitute advertising or violating the agreement?

You replied, "That is correct."

A number of materials in the FTC's investigative file define the scope of this enforcement action very differently. They indicate that the FTC intends to encompass within the order against ACAM, a much broader range of communications than you described at the hearing – for example, publications used by ACAM's member physicians in their practices to educate their patients.

One of the most telling documents in the file is the staff's first information request to ACAM. By letter dated January 4, 1996, your staff requested from ACAM certain documents to be reviewed – as advertising – for possible law enforcement action. The letter requested all documents that ACAM "distributes or disseminates to ACAM members for use in their respective practices." For purposes of ACAM's response, the letter defined "advertising and promotion" as including "professional and educational publications or journals.". It requested copies of all documents falling within that definition that are used by ACAM's members: "in informing prospective patients or others about chelation therapy," and "to provide information to persons receiving or considering the use of chelation therapy."

In a follow-up letter dated March 8, 1996, your staff asked eight questions about certain publications ACAM had voluntarily submitted to the FTC. Four of those questions dealt with distribution of the publications to physicians, not consumers. ACAM was asked to describe "in detail" the procedures it used to distribute the publications to member and non-member physicians and to provide the total number of each publication it distributed each year to member and non-member physicians.

In addition, Paragraph 2 of the complaint that accompanies the provisionally-accepted order against ACAM states not only that ACAM "disseminated to the public brochures and other written materials that constitute advertising;" it also states that ACAM "distributes its brochures and other written materials to its members who disseminate the materials to consumers." If the order is not intended to cover the use of the materials by ACAM's member-physicans in their practices, in consultation with their patients, why does the second statement appear in the complaint? And if, as you testified, information used by doctors with their patients is not advertising, why does the order require ACAM to send each of its members a letter, warning them that they could be prosecuted by the FTC if they "disseminate advertising or promotional materials" – presumably as those terms are defined in the FTC's earlier correspondence with ACAM?

At the hearing, I asked Dr. Chappell to give me his understanding of the order language, based on his involvement with the FTC's investigation of ACAM. He stated, "We were definitely told by FTC staff in some of our deliberations that even communication between a patient and a doctor would be subject to FTC jurisdiction, if there were brochures handed back and forth.

There is no doubt that having an FTC order against ACAM has a direct impact on what doctors can and cannot say in their patient consultations, because the pamphlet challenged by the Commission was used, principally, by ACAM's member physicians in that context. It was not used as advertising. It was just used as patient education."

I am also concerned about the FTC's approach in this matter because the original complaint you forwarded to the Commission for issuance against ACAM included, as an allegedly misleading advertisement, an educational booklet that ACAM distributed to the public only through sales from its reading list. It appears from the investigative file that the staff dropped this alleged advertisement from the complaint only after ACAM had met with all of the Commission members to explain its views. The definition of advertising set out in the above-quoted January 4, 1996 letter to ACAM confirms that you and your staff considered such materials to be within the scope of the Commission's authority and within the scope of its law enforcement action. However, at the hearing, I asked you about this issue and you responded as follows:

- If a bona fide non-profit medical society maintains a library of information for the benefit of its physician members and the public, and if the society sells to interested members of the public, from its list of publications, booklets on a medical treatment, is that advertising?

You responded, "No, it's not."

- Is that spelled out in your order, as well?

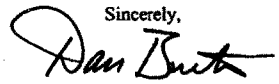
You responded, "No, it isn't. But we would be glad to provide an interpretation to that effect."

- I would like to have that in writing, too. That way, there would be some clarification so doctors would know what they are doing.

It is very important to clarify whether or not the FTC's scope of regulatory authority extends into practice of medicine generally.

Please provide by close of business June 9, written clarification to the issues described herein, including the written interpretation you offered at the hearing in response to my question about booklets sold from a publication list. If you have any questions, please contact Professional Staff Member, S. Elizabeth Clay at 202-225-5074.

Sincerely,



Dan Burton
Chairman

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Office of the Director
of Consumer Protection

June 25, 1999

The Honorable Dan Burton
Chairman
Committee on Government Reform
2157 Rayburn House Office Building
Washington, DC 20515-6143

Re: American College for Advancement in Medicine, File No. 962-3147

Dear Mr. Chairman:

This is in response to your letter of May 27, 1999. It is my understanding that as of the date of your letter, your staff had not received my earlier letter dated April 7. It is my further understanding, however, that the letter was hand-delivered and sent via fax to the Committee's office on April 7. In any event, your staff has conveyed your request for further clarification on two points addressed in my April 7 letter and my earlier testimony before your Committee. This letter amplifies my responses on those points.

First, you seek clarification as to whether physicians can distribute to their patients an ACAM-produced brochure on chelation therapy as part of their consultation with them. As I stated in my letter, the proposed order does not prohibit a doctor from distributing a brochure on chelation therapy to his or her patients during communications about course of treatment decisions. This would include brochures prepared by ACAM and procured from ACAM for distribution to that doctor's patients.

Next, I understand that you have requested clarification on the type or level of evidence or studies that would be necessary for ACAM to substantiate efficacy claims for chelation therapy. As I stated in my testimony before the Committee, objective claims that a product or service is effective must be supported by a reasonable basis.[1] The Commission's standard for

[1] *Thompson Medical Corp. Inc. v. FTC*, 791 F.2d 189, 193 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987); *Firestone*, 81 F.T.C. 398, 451-52 (1972), *aff'd*, 481 F.2d 246 (6th Cir.), *cert.*

what constitutes a "reasonable basis" is a flexible one. Thus the evidence required in a particular case depends on what claims are being made and how they are presented in the context of the entire ad. An advertiser must have at least the level of substantiation stated or implied in an advertisement. If an advertisement is silent on the level of support for a particular claim, a number of factors determine the appropriate amount and type of substantiation, including the type of product, type of claim, benefits of a truthful claim, the cost and feasibility of developing substantiation for the claim, the consequences of a false claim, and the amount of substantiation that experts in the field believe is reasonable.[2]

When an advertisement itself states or implies that the claims are supported by scientific evidence, or makes claims about the efficacy or safety of a drug, competent and reliable scientific evidence is required to support the claim.[3] In past cases, the Commission has often required well-controlled clinical studies to substantiate unqualified drug and medical device efficacy claims.[4] Experts FTC staff has consulted, as well as others who have published their views on the subject,[5] believe that such evidence is necessary to establish the efficacy of EDTA chelation

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denied, 414 U.S. 1112 (1973); *Removatron Int'l* Corp., 111 F.T.C. 206 (1988), *aff'd*, 884 F.2d 1489 (1st Cir. 1998).

[2] *Thompson Medical Corp.*, 104 F.T.C. *at* 821.

[3] *Thompson Medical Corp.*, 104 F.T.C. *at* 822; "FTC Policy Statement Regarding Advertising Substantiation," appended to *Thompson Medical Corp.*, 104 F.T.C. *at* 839.

[4] *Removatron Int'l* Corp., 111 F.T.C. 206 (1988), *aff'd*, 884 F.2d 1489 (1st Cir. 1998)(requiring "adequate and well-controlled clinical testing" to substantiate claims for hair removal product); *Thompson Medical Corp.*, 104 F.T.C. *at* 826 (two well-controlled clinical tests required to substantiate arthritis pain relief claim); *See also*, *Porter & Dietsch, Inc.*, 90 F.T.C. 770, 885 (1977), *aff'd*, 605 F.2d 294 (7th Cir. 1979), *cert. denied*, 445 U.S. 950 (1980) (claims that any food, drug, or device can help a user achieve any result, such as weight loss, must be substantiated by "competent scientific or medical tests or studies").

[5] For example, since your hearing, we have obtained a copy of a treatise entitled *A Critical Review of EDTA Chelation Therapy in the Treatment of Occlusive Atherosclerotic Vascular Disease* (Merle West Center for Clinical Research (1998))by Stephen Olmstead, M.D., an expert whom ACAM has referred to in the past. Research for this review was partially underwritten by a grant from ACAM. In that publication, Dr. Olmstead states:

> In closing, I would like to answer the question I am most frequently asked by colleagues and patients. "After all the research [I] have done on EDTA chelation, do [I] prescribe it as a therapy for atherosclerosis?" My answer is "No." . . . I realize that a large number of sincere physicians have administered this therapy to patients and that both physicians and

therapy for treating atherosclerosis.[6] Accordingly, if ACAM were to make an unqualified claim, expressly or by implication, that chelation therapy is effective for the treatment of atherosclerosis, we would expect ACAM to have well-controlled, double-blind, randomized clinical testing that substantiates the claim. In contrast, during the course of our negotiations with ACAM's counsel, staff provided ACAM with guidance on the type of representations that would be appropriate given the state of the science.

Thank you for this opportunity to provide additional clarification.

Sincerely,

Jodie Bernstein

Jodie Bernstein
Director

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many of their patients have experienced success. In addition, the preponderance of the clinical reports in the medical literature support a claim of efficacy for symptomatic angina pectoris, intermittent claudication, and critical leg ischemia. The problem with embracing this anecdotal experience is that the natural history of atherosclerotic vascular disease is variable. The absence of controlled observations makes it impossible to know whether any perceived benefit attributed to EDTA chelation is truly a consequence of the therapy. Only carefully planned, rigorously conducted, objective clinical trials will determine whether the generally favorable anecdotal experience with EDTA chelation is a true pharmacologic effect, a coincidence or a placebo response. (At p. 96) (Emphasis added)

[6] See, for example, the testimony of Claude Lenfant, M.D., Director, National Heart, Lung, and Blood Institute, NIH, before your Committee's March 10 hearing.

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BERNARD SANDERS, VERMONT,
INDEPENDENT

July 19, 1999

FAX: 202-326-2799

The Honorable Joan Z. Bernstein
Director, Bureau of Consumer Protection
Federal Trade Commission
Washington, D.C. 20580

Dear Ms. Bernstein:

I am writing to reiterate my request for answers from the Federal Trade Commission (FTC) to the questions set forth in my letter of May 27, 1999. Your June 25 response provides extensive commentary on one subject I did not mention at all (the type and level of evidence needed to substantiate claims) and misstates my inquiry about the use of educational brochures by the physician-members of the American College for Advancement in Medicine (ACAM). Because your letter failed to answer the questions I asked you to address, I am restating them below in numbered paragraphs.

The pending issues, as you know, stem from the Government Reform Committee's March 10 hearing on chelation therapy. They include, among other matters, discrepancies between the testimony of witnesses at the hearing and information in the ACAM investigative file. I am deeply concerned that the FTC voted to issue its order in final form against ACAM before responding to these important questions about the reach of the Commission's authority in general and the ACAM order in particular.

I was dismayed to learn that the Commission voted to issue the ACAM order without any accompanying analysis of the extensive number of comments it received from the public, hundreds of which were personal letters from individual patients. I personally reviewed many of these prior to the March 10 hearing. While the FTC staff may have found these letters unpersuasive, I must seriously question a decision by the members of the Commission to blatantly ignore this outpouring of public concern for its action against ACAM. I have added to the pending list of questions a request for an explanation.

Please provide complete, specific responses to each of the following questions. Each answer should refer to the number of the question to which it responds:

1. If, as you have stated, the order against ACAM does not and is not intended to cover the use of the materials mentioned in the order by ACAM's physician-members in their medical practices, why does Paragraph 2 of the complaint create a link between the materials and their use by ACAM's members by stating that ACAM "distributes its brochures and other written materials to its members who disseminate the materials to consumers?"

2. (A) If, as you have stated, the only brochure challenged in the ACAM matter is not advertising when used by doctors in their medical practices, why does the order require ACAM to send each of its members a letter, warning them that they could be prosecuted by the FTC if they "disseminate advertising or promotional material?"

   (B) Does the Commission consider "advertising" or "promotional material" to encompass all the documents described in the staff's January 4, 1996 letter to ACAM (quoted at page 2 of my May 27 letter)?

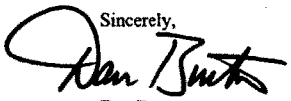
   (C) If not, which documents are/are not advertising or promotional materials?

3. Please provide the written interpretation I requested at the hearing and in my May 27 letter on the extent to which booklets on medical treatments constitute advertising when they are sold by a bona fide non-profit medical society from a list of publications it maintains for the benefit of its physician-members and the public. (Your April 7 letter is not responsive since it addresses the "availability" of a "library" to "doctors.")

4. In its notice extending the time for public comments in the ACAM matter, the FTC acknowledged receiving, at that time, more than 750 letters; and it observed that this large volume of comments demonstrated "significant public interest" in its action. Given the fact that ultimately more than 1000 comments were filed – including hundreds of personal letters from individual patients – why did the Commission decide not to include any written analysis or response when it publicly announced its final decision to issue the order on July 14?

Since the FTC's order is now binding against ACAM, I am requesting that you provide your complete response to this inquiry no later than close of business, Friday July 30. If necessary, a member of my staff will pick the letter up to insure its prompt delivery. If you have any questions, please contact Professional Staff Member, S. Elizabeth Clay at 202-225-5074.

Sincerely,



Dan Burton
Chairman

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Bureau of Consumer Protection

July 30, 1999

The Honorable Dan Burton
Chairman
Committee on Government Reform
2157 Rayburn House Office Building
Washington, DC 20515-6143

Re: American College for Advancement in Medicine, File No. 962-3147

Dear Mr. Chairman:

This is in response to your letter of July 21, 1999, seeking further responses on questions that you raised at your Committee's March 10 hearing on chelation therapy and in subsequent correspondence. Your most recent questions and my answers are set forth below.

Question 1: If, as you have stated, the order against ACAM does not and is not intended to cover the use of the materials mentioned in the order by ACAM's physician-members in their medical practices, why does Paragraph 2 of the complaint create a link between the materials and their use by ACAM's members by stating that ACAM "distributes its brochures and other written materials to its members who disseminate the materials to consumers?"

As your question indicates, the proposed order does not prohibit a doctor from distributing an ACAM-produced brochure to his or her patient in the context of a consultation with a patient. The complaint language you cite refers to the general distribution of such materials to "consumers." I understand this language to address instances in which the materials prepared by ACAM were used as advertising or promotional material to solicit prospective patients, including dissemination of the brochure to the general public.

The complaint does not allege that ACAM member-doctors had violated the law. The complaint was accompanied by a clear statement that the Commission's action should not be construed to regulate how doctors use or prescribe drugs in treating their patients. Thus, this provision is consistent with our view that the proper role of the Commission in these instances is to prevent deceptive advertising and promotion, but not to intrude on the doctor-patient relationship.

Question 2(A): If, as you have stated, the only brochure challenged in the ACAM matter is not advertising when used by doctors in their medical practices, why does the

order require ACAM to send each of its members a letter, warning them that they could be prosecuted by the FTC if they "disseminate advertising or promotional material?"

The letter to which you refer (Attachment A to the Order) notifies ACAM members of the FTC's action against ACAM. It also states that "[i]ndividual members of ACAM, when acting in their individual capacities, are not parties to the settlement," and advises ACAM members that "if you disseminate *advertising or promotional materials* that contain unsubstantiated claims for the efficacy of chelation therapy in treating diseases of the human circulatory system, or that make misrepresentations about any tests or studies, you could be subject to investigation and possible enforcement action by the FTC." (Emphasis added.) This is an accurate statement of the law.

I believe that the notice provided in Attachment A is consistent with my representations concerning the scope of the order. Our Analysis to Aid Public Comment in this matter states, "[t]he Commission's action should not be construed to regulate how doctors use or prescribe drugs in the course of treating their patients or other choice of therapy issues," and Attachment A states that the "order does not apply to member doctors acting in their individual capacities."

The FTC has long championed the right of physicians to advertise. Physicians, however, are subject to the same legal requirements as apply to other marketers that advertising claims be truthful and substantiated. The notification letter in Attachment A expressly covers only advertising and promotional material. It does not include information communicated by a physician to a patient as part of the doctor-patient relationship.

Question 2(B): Does the Commission consider "advertising" or "promotional material" to encompass all the documents described in the staff's January 4, 1996 letter to ACAM (quoted at page 2 of my May 27 letter)?

Staff's January 4, 1996 letter is an investigational letter seeking documents relevant to its investigation. The letter requests documents that might be used for advertising and promotional purposes, as well as documents relating to the Commission's jurisdiction over ACAM and its practices.

After examining all of the items submitted in response to staff's request, only three were identified as advertising or promotional. After further discussions with ACAM's counsel, only two of those were included in the final decision and order issued by the Commission.

Question 2(C): If not, which documents are/are not advertising or promotional material?

Whether particular material constitutes advertising depends on an evaluation of certain well established factors, including:

> (1) whether it contains a message promoting the demand for a product or service; (2) whether it refers to a specific product or service (though not necessarily by brand); (3) whether it contains information about attributes of a product or service offered for sale, such as type, price or quality, including health benefits; (4) whether it is disseminated by means often used for commercial speech; and (5) the speaker's economic or commercial interests.[1]

In sum, whether any particular document constitutes advertising depends on the content of the document and how it is used. In applying this standard, staff identified three documents as advertising or promotional, although only two were included in the Commission's final decision and order. The remaining documents produced by ACAM were not considered advertising or promotional.

Question 3: Please provide the written interpretation I requested at the hearing and in my May 27 letter on the extent to which booklets on medical treatments constitute advertising when they are sold by a bona fide non-profit medical society from a list of publications it maintains for the benefit of its physician-members and the public.

In my view, the sale of booklets on medical treatments by a bona fide non-profit medical society to its physician members for their use in their medical practice is unlikely to constitute advertising. With regard to the question of whether selling a brochure on medical treatment to the public would constitute advertising, the answer depends on whether the brochure is purely informational or promotional in nature. If it is purely informational, the sale of the brochure is unlikely to constitute advertising. If, however, it is promotional, and by that I mean that it is used by a seller, or organization acting on the seller's behalf, as a marketing tool to promote particular products or services, then it could be considered advertising.[2] *See Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 66-67 (1983). The factors used to make this determination have been set forth above in response to Question 2(C).

Question 4: In its notice extending the time for public comments in the ACAM matter, the FTC acknowledged receiving, at that time, more than 750 letters; and it observed that this large volume of comments demonstrated "significant public interest" in its action. Given the fact that ultimately more than 1000 comments were filed -- including

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[1] *See Reynolds Tobacco Company*, 111 F.T.C. 539, 544-46 (1988)(Interlocutory Order). *See also Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 66-67 (1983).

[2] Whether the advertising practices of a bona fide non-profit medical society would come under the jurisdiction of the FTC would depend on whether the organization carries on activities that proximately advance the economic interests of its members." *See California Dental Ass'n v. F.T.C.*, No. 97-1625, slip op. at 8-9 (U.S. May 24, 1999).

hundreds of personal letters from individual patients -- why did the Commission decide not to include any written analysis or response when it publicly announced its final decision to issue the order on July 14?

In this matter, the Commission followed the procedures it follows for all consent orders, except that in this instance, the Commission took the unusual step of extending the comment period an additional forty-three days. Staff carefully reviewed the comments and prepared a recommendation for the Commission, which was reviewed by each Commissioner. Neither the Commission's Rules of Practice (16 C.F.R. § 2.34) nor the Commission's Operating Manual (Section 6.15) require the publication of an analysis of the comments filed during the comment period. Letters are being sent to each commenter acknowledging receipt of their comment and informing the commenter of the Commission's decision.

It should be noted that many of the comments, particularly those from individual consumers, expressed concern that the Commission's order would restrict consumers' access to chelation therapy. This is not the case, however, as the order contains no prohibition or restriction on the use of chelation as a therapeutic remedy.

Thank you for this opportunity to provide additional clarification on these issues.

Sincerely,

Jodie Bernstein
Director

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Bureau of Consumer Protection

September 28, 1999

The Honorable Dan Burton
Chairman
Committee on Government Reform
2157 Rayburn House Office Building
Washington, DC 20515-6143

Re: American College for Advancement in Medicine, C-3882

Dear Mr. Chairman:

This is in further response to your letter dated September 16, 1999, which we received by fax on September 22, seeking further clarification of the kinds of information that physicians may circulate regarding chelation therapy and requesting an analysis of the public record comments on the consent order with the American College for Advancement in Medicine (ACAM). Before responding to your specific questions, however, I would like to clarify two points. First, as discussed in my letter of July 30th, the ACAM order does not bind physicians acting in their individual capacities. Accordingly, individual physicians could not be prosecuted for violating the ACAM agreement. Second, under both our order and under Section 5 of the Federal Trade Commission Act, both ACAM and physicians are free to distribute any information about chelation therapy that is truthful and substantiated.

Your most recent questions and my answers are set forth below.

Question 1: My staff was told that a physician could provide any information to a patient about EDTA chelation therapy during the physician/patient consult, including the documents mentioned in the complaint. Is this an accurate statement?

Yes. As indicated above, the ACAM order does not apply to individual physicians. Under Section 5 of the Federal Trade Commission Act, the Commission has traditionally refrained from actions involving communications between doctors and their patients about course of treatment decisions. Thus, we would not pursue an investigation where the alleged claims consisted of the distribution of a brochure from a physician to his or her patient during a course of treatment. Allegations of deceptive, misleading, or unsubstantiated claims made to patients in the course of treatment are properly handled by state licensing authorities.

Question 2: Staff was also told that physicians could not use these two documents at health fairs as a means of recruiting patients. Is this an accurate statement? Are there other documents that the FTC would forbid to be distributed at health fairs?

A physician's distribution of Exhibits A and B to the ACAM complaint at a health fair attended by members of the public for the purpose of recruiting new patients could subject the physician to an action under Section 5 of the Federal Trade Commission Act. Physicians, however, could distribute truthful and non-misleading information about chelation therapy at such an event. Only advertising and promotional material containing false, deceptive, or unsubstantiated objective claims for the efficacy of chelation therapy would be prohibited under the FTC Act.

Question 3: Are doctors forbidden from discussing the potential circulatory benefits of chelation therapy in seminars and conferences?

No. Seminars and conferences comprised of medical professionals are not considered consumer directed advertising venues. As a result, we would not recommend any action against a physician based on discussing the potential circulatory benefits of chelation therapy in such seminars and conferences. However, seminars or conferences that are directed at members of the lay public and/or consumers seeking information about treatments for diseases and disorders should avoid communicating information about chelation therapy that is misleading or unsubstantiated.

Question 4: Can information about chelation therapy be available in waiting rooms and other areas of physicians' offices?

Yes. Brochures that are truthful and not misleading can always be made available to the public. Because we believe the vast majority of visitors to a physician's waiting room are likely to be existing patients of the physician, we would not pursue an investigation where the alleged advertising was limited to the use of pamphlets and brochures about chelation therapy in waiting rooms and other areas of the physician's office.

Question 5: Is a physician allowed to provide books that have been published about chelation therapy to their clients, at health seminars, or at health fairs?

Yes. A physician could provide a book about chelation therapy as part of the communications between doctors and patients about course of treatment decisions. As indicated above, we would not take action where the alleged advertising consisted of the distribution of such material from a physician to his or her patient. Books distributed to consumers or prospective patients at health fairs or seminars would be subject to FTC scrutiny only if they are used as part of a scheme to market other products or services.

Question 6: Can a doctor list in a yellow pages ad in a local telephone book specific therapies that his or her practice offers, including chelation therapy?

Yes. The FTC Act prohibits only false, misleading or unsubstantiated statements. A listing in the yellow pages of a local telephone book indicating that a doctor performs a specific procedure, such as chelation therapy, would not violate the FTC Act.

Question 7: Can a doctor mention EDTA Chelation Therapy as part of a seminar announcement?

Yes. The mention of chelation therapy as a part of a seminar announcement would not violate the FTC Act.

Question 8: Can a doctor publish a paid advertisement that explains the potential cardiovascular benefits of EDTA Chelation Therapy?

Yes. A doctor can publish a paid advertisement concerning EDTA chelation therapy provided that the advertisement is truthful and substantiated. As part of our negotiations with ACAM, we provided it with examples of claims that could be made.

Question 9: If a physician or medical practice has a web site, can EDTA Chelation Therapy be included in this site?

Yes. A physician or medical practice with a web site could include information about chelation therapy on the site. Advertisements or promotional material maintained on a web site is subject to the FTC Act.

Question 10: Additionally, please provide to the committee an analysis of the documents that were submitted to the docket and the role that this docket played in the Commission's final ruling. Please include in this, the number of documents, a break out of the type of submitter, i.e., patient, physician, company, legislator, etc., and an analysis of the statements.

Approximately 1380 comments were filed. All but 11 of them opposed the proposed action against ACAM. Approximately 100 came from doctors and osteopaths, 600 from former or current chelation patients or their close relatives, 670 from proponents of chelation therapy or alternative medicine, and 6 from miscellaneous sources including one comment from a state legislator from Ohio. The letters from chelation patients, supporters of chelation therapy and physicians, criticize the Commission for its action against ACAM. Most of the letters raise concerns about perceived threats either to alternative therapies and patients' access to them, to physicians' right to dispense them, or to the free flow of information about the therapies. The letters from chelation patients also contain personal testimonials about the usefulness of chelation therapy in treating their own diseases or those of close relatives. These testimonials range from simple affirmative statements without further explanation to detailed descriptions of symptoms before and after chelation therapy -- sometimes accompanied by the patient's clinical records. Several of the letters from physicians also contain references to the doctors' own positive outcomes using chelation therapy.

The comments submitted on the record reflect a belief that the FTC's proposed action would result in denying patients access to alternative medical therapies in general and to chelation therapy in particular. Many of the comments reflect a belief that in taking this action,

the FTC is exceeding its authority by regulating the practice of medicine and is serving the interests of the drug companies, the American Medical Association, and the state medical boards. Many commenters also expressed the view that the FTC does not have jurisdiction over non-profit professional associations, and that the information ACAM provided by way of the pamphlet and the web page was not advertising. The comments frequently contain the charge that the FTC is denying ACAM its First Amendment rights and that the FTC presumes that it knows what health care options are best for consumers. Many of the letters take issue with the competent and reliable scientific evidence standard that the Commission applies in these types of cases. Finally, many of the letters express the belief that the FTC coerced ACAM into settling this matter because the cost of litigating the matter would have bankrupted ACAM. One letter indicated concern about the potential international effect of the Commission's action.

Of the eleven comments supporting the order, five were from state medical boards, one was from a physician, two from former chelation patients, one from a relative of a prospective chelation patient, and two from persons who looked into the treatment and concluded that it was unproven. The comment from the physician supports the order without alluding to any personal experience with chelation therapy. The comments from patients reflect unsatisfactory experiences after receiving EDTA chelation therapy, and the comment from a relative indicates scepticism about the decision of a relative to undergo EDTA chelation therapy rather than conventional care. The comments from the five state medical boards that support the order vary from short summaries of their experiences in trying to regulate EDTA chelation therapy, to statements of their board's official position with respect to the use of EDTA to treat atherosclerosis.

Although the comments underscored strong concerns among members of the public about the ACAM order, some reflected a misunderstanding of the effect of the order. In addition, many of the comments reiterated points previously considered by the Commission, such as the Commission's jurisdiction over non-profit corporations. The Commission concluded that these comments did not provide new information requiring modifications of the order.

Additionally, during the comment period staff also obtained and reviewed a copy of a monograph authored by Stephen Olmstead, M.D.[1] This document had been previously orally

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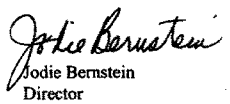
[1] *A Critical Review of EDTA Chelation Therapy in the Treatment of Occlusive Atherosclerotic Vascular Disease* (Merle West Center for Clinical Research (1998)) by Stephen Olmstead, M.D. Dr. Olmstead states:

> In closing, I would like to answer the question I am most frequently asked by colleagues and patients. "After all the research [I] have done on EDTA chelation, do [I] prescribe it as a therapy for atherosclerosis?" My answer is "No." . . . I realize that a large number of sincere physicians have administered this therapy to patients and that both physicians and many of their patients have experienced success. In addition, the preponderance of the clinical reports in the medical literature support a claim of efficacy for symptomatic angina pectoris, intermittent claudication, and critical leg ischemia. The problem with

cited to Commission staff by ACAM. The review's conclusion that the absence of controlled observations makes it impossible to know whether any perceived benefit of EDTA chelation is a consequence of therapy is consistent with the Commission's original analysis in this case and its concern about the unqualified efficacy claims contained in the ACAM materials.

Thank you for this opportunity to provide additional clarification. I hope that you will find this responsive to your questions.

Sincerely,



Jodie Bernstein
Director

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embracing this anecdotal experience is that the natural history of atherosclerotic vascular disease is variable. The absence of controlled observations makes it impossible to know whether any perceived benefit attributed to EDTA chelation is truly a consequence of the therapy. Only carefully planned, rigorously conducted, objective clinical trials will determine whether the generally favorable anecdotal experience with EDTA chelation is a true pharmacologic effect, a coincidence or a placebo response. (At p. 96)

Ms. BERNSTEIN. We have made every effort to provide ACAM with as much interpretation as they would like to have in regard to both the inquiry and the coverage of the order.

Mr. BURTON. I have a couple of questions for Dr. Lindberg. Does the Government have a physical location where the 695 journals that publish alternative medicine articles can be found, or a website where they are indexed?

Dr. LINDBERG. Sir, we have both. The physical location is at the National Library of Medicine in Bethesda. There is a Web site home page, which one can search.

Mr. BURTON. There are 695 journals, I guess, that publish these alternative medicine articles. You do stock them currently?

Dr. LINDBERG. We hold 80 percent—79 percent, I guess it is probably 80 by now—of those journals. We don't hold all the rest. Many are foreign, of course.

Mr. BURTON. Is that because you just don't have the room?

Dr. LINDBERG. We can already see the end of the storage capability, which will probably peak out in 2003. But that is not what is preventing us from getting just a few extra journals. I think, probably, the collection on alternative medicine and on chelation really has to be seen as part of the collecting responsibility that we have, overall. If I could give you just an example from, sort of, NIH's point of view of the expanding amount of knowledge and understanding and specialization and consequently the areas in which we have to draw. I have been there in the Institution only since 1984. Since that time, the following new centers and institutes have been created by the Congress and brought into effect by NIH: The National Arthritis Institute, didn't exist; the AIDS program, which is over $1 billion a year, didn't exist; Office of Women's Health, didn't exist; Office of Minority Health; the National Institute for Human Gnome Research; the National Institute for Nursing Research; the National Institute of Aging. The National Center for Complementary and Alternative Medicine is the latest.

So those all define and expand the universe in which the Library has to do its best to collect. Of course, it tries to collect the most important, the most valuable, in each of those fields. In the case of ACAM, as I indicated, we went to the then director, got his ideas, had those evaluated by 14 outside centers and ended up choosing what we thought was the very most important of that new area.

Mr. BURTON. If they requested to have some of these other journals put in that facility, you would have no objection to those, would you?

Dr. LINDBERG. It is easier to say "yes" to collecting a journal than it is to indexing it. Indexing is a costly proposition. You can't, as I said, put everything in the world worth knowing into that one computer system.

Mr. BURTON. Well, we would like to have it indexed—some of these documents. I guess we could get a list of those and possibly send them to you. Could you let us know if that would be possible?

Dr. LINDBERG. I am not certain if I understand the question, but we certainly would respond.

Mr. BURTON. If we sent a list of journals that are not currently indexed, and asked you to take a look at putting those in with the others, you would take a look at that?

Dr. LINDBERG. We would certainly take a look at them. Sure. Of course.

Mr. BURTON. All right. We will be contacting you regarding that. Dr. Lenfant, in your testimony you made specific reference to a Danish study as being high-quality research. It was found by the Danish Committee on Scientific Dishonesty that the researchers violated the blind in their trial and that they did not follow the ACAM protocol, which is the generally accepted protocol used in the United States. We often hear that conventional science does not accept many alternative medicine studies because they are not of high enough quality. Why is it that this study meets your standard of quality when they violated the blind?

Dr. LENFANT. I have to admit that I am not aware of this problem that you are mentioning. Our statements and acknowledgements that this study was of high quality was one on the design of the study, as we could see it. But more importantly, on the fact that it was published in a peer review journal of high ethical and scientific standards.

Mr. BURTON. Well, it was in the journal.

Dr. LINDBERG. It was probably after the fact.

Mr. BURTON. But the Danish Committee on Scientific Dishonesty said that the researchers violated the blind in their trial and they did not follow the ACAM protocol. So, you took a journal that had that study in it, although it had been somewhat tainted by the Danish Committee on Scientific Dishonesty, and took that as fact, I guess.

Dr. LENFANT. I understand, Mr. Chairman. The point that I am making is that the revelation of this breach in the conduct of the study was probably published—well certainly, published—after the study itself was published. So, my statement is what we are saying is on the basis of the original publication. I have to admit, I know nothing about the problem that you mention here. We will look into it. I would like to know where that has been published.

Mr. BURTON. We will get that for you.

Dr. LENFANT. I would appreciate that.

Mr. BURTON. We will get that for you and we will send you a number of these case histories of people who have been helped by chelation therapy. I hope you will take a look at those, as well.

I think that just about covers the questions. I did have one little problem that I had with Dr. Bernstein that I would like to try to clear up before you leave.

Dr. Chappell is still here and I would like to have him, if he could, come up real quickly to try to clarify the FTC order language. I guess there is still some misinterpretation. Is Dr. Chappell still here? Can you come, Dr. Chappell, take one of the microphones and maybe explain that a little bit? Can you elaborate on that?

Dr. CHAPPELL. Apparently, there was considerable confusion here. We were definitely told by FTC staff in some of our deliberations that even communication between a patient and a doctor

would be subject to FTC jurisdiction, if there were brochures handed back and forth. I am glad that this information was changed.

There is no doubt that having an FTC order against ACAM has a direct impact on what doctors can and cannot say in their patient consultations, because the pamphlet challenged by the Commission was used, principally, by ACAM's member physicians in that context. It was not used as advertising. It was just used as patient education purposes, in the first place.

Mr. BURTON. Well, here is what we are going to do to clear that up today. Dr. Bernstein has said that she would give us a letter clarifying that. Her attorney said they will give us a letter clarifying that. We will submit that to you and the ACAM Board of Directors and that can be disseminated to all of your members. That should eliminate the possibility of any prosecution as long as you comply with the decision within that framework. OK?

Dr. CHAPPELL. Sure.

Mr. BURTON. We will try to have that for you very quickly. But if there is that misunderstanding, we want to make sure it is clarified.

Dr. CHAPPELL. I appreciate that.

Mr. BURTON. And you will do that, right Doctor?

Ms. BERNSTEIN. We would be happy to do that, Mr. Chairman.

Mr. BURTON. What you are saying is that the brochure from doctor to patient did not constitute advertising or violating the agreement?

Ms. BERNSTEIN. That is correct.

Mr. BURTON. OK. Well, we will get that straightened out.

I want to thank you very much for being here today. I know that the comments from my colleague, Mr. Waxman, might be somewhat accurate in that I do have a bias. My bias is toward people who are ill or terminally ill and allowing them to have opportunity that is possible to save their lives.

The reason I feel so strongly about that, so that you will understand my position a little bit better, is my mother and father both died of cancer in October and November. My wife had breast cancer and she went into an alternative therapy treatment in Highland Park, IL. The health agencies in this country, the Food and Drug Administration and the Health and Human Services, tried to close that operation down. My wife was given a prognosis that she might live 5 years if she was lucky. There were 70-some other women in that program. The FDA did try to close it down. We were able to keep it open. My wife just passed her 5th year without cancer coming back. In large part I think that it was due to the treatment she is getting at that facility, which would not have been available had FDA been able to close it down.

So I think there is an awful lot of people who are suffering from various kinds of maladies, who are told just to go home and die when there may be other therapies that might, at least, give them some hope. I think hope is an extremely important part of science and survival. For that reason, we want to make sure that this committee does everything we can to make sure that people who do have debilitating diseases: Parkinson's Disease and cancer, and so forth, at least have an opportunity to survive, even though medical

science may say they can't take any further treatment that will do them any good.

With that, Dr. Lenfant, we will be in touch with you very soon. Dr. Lindberg, we will be in touch with you very soon. And you, as well, Dr. Bernstein. Thank you very much.

We stand adjourned.

[Whereupon, at 2:15 p.m., the committee was adjourned.]

[Additional information submitted for the hearing record follows:]

Comments Regarding Proposed Rules Governing Use Of Chelation Therapy made for the Louisiana State Board of Medical Examiners, February 24 through March 1,1999

James P. Carter, M.D., Dr.P.H.

My name is James P. Carter. I am a professor of nutrition at Tulane School of Public Health and Tropical Medicine. I am also a clinical professor of pediatrics at Tulane Medical School. I am currently on sabbatical, from July 1998 to July 1999, when I will officially retire and hopefully assume emeritus status. I will continue to teach, however, in the School of Public Health's newly established course in alternative medicine. I am also medical director of a private clinic, Complementary Medical Services, which offers Chelation therapy, as well as other alternative/complementary treatments.

I have prepared my remarks for this period of comments on the Board's proposed rules for the use of Chelation therapy, and at the same time for the preparation of the hearings on Chelation therapy which will be held by Rep Dan Burton of Indiana, who is chairman of the Government Reform and Oversight Committee. These hearings are scheduled for April 1999.

With my comments, I am submitting a copy of my curriculum vitae, (Exhibit No. 1) as well as various publications and excerpts from presentations concerning Chelation therapy, in an effort to bring the Board's files up-to-date.

The following publications in my bibliography are those where I have personally been involved in conducting research into Chelation therapy. The papers that have some bearing on the rules proposed by the board are:

1. Olszewer, E; and Carter, JP: EDTA Chelation Therapy in Chronic Degenerative Disease, Medical Hypotheses, September, 1988. Vol. 27.
2. Olszewer, E, Sabbag, FC and Carter, JP: A Pilot Double-Blind Study of the Effectiveness of EDTA in the Treatment of Peripheral Vascular Disease. Journal of the National Medical Association, Vol 82, No 3, 1990.
3 Masuta, D, Carter, JP, and Trowbridge, J: Physicians Health Habits Survey, Journal of Advancement in Medicine,Volume 2, Number 3, Fall 1989.
4. Carter, JP: If EDTA Chelation Therapy Is So Good, Why Isn't It More Widely Accepted ? Chapter in Textbook, EDTA Chelation Therapy, Edited by Elmer Cranton, M. D., Human Sciences Press, 1990.
5. Olszewer, E., Sabbag, FC., and Carter, JP: Side Effects Studies on Patients Treated with EDTA, Townsend Letter for Doctors and Patients, August/September 1996.
6. Carter, J. P.: "University Shenanigans Foil Chelation Study", Townsend Letter for Doctors and Patients, July 1997.
7. Carter, JP: Racketeering in Medicine; The Suppression of Alternatives, Published in 1992 by Hampton Roads Publishing Company

Some of these publications are now out of date. Nevertheless, some of their conclusions are relevant to the rules proposed by the Board. For example, in our retrospective study, we found that nearly 85 percent of the patients treated with coronary artery and peripheral vascular disease showed significant improvement. As will be seen later, this is exactly the same percentage of patients who responded in the recently presented Cypher study of over 19,000 patients. Our pilot double blind, politically correct, study also showed EDTA Chelation therapy to be effective in peripheral vascular disease.

The comments of one reviewer at the Lancet are interesting in regard to the pilot study. This reviewer stated that the Lancet had decided not to publish the paper, but he went out of his way to add that we should not interpret this as meaning that there was anything wrong with the way the study was conducted. They simply felt that it was not strong enough to "defeat the opposition" (Exhibit No. 2), implying that the feud and controversy surrounding this treatment at that time would require a much larger and stronger study to make a difference. It was this feud, and at least to me, the readily apparent injustice of it all, that led me to become involved in Chelation research in the first place.

Also the comments of someone who read my book on Racketeering in Medicine: The Suppression of Alternatives are also worthy of note. The book mentions Chelation therapy on many occasions. This reviewer felt that the book had made an important overall contribution. The letter was signed by Dr. Alfred Schatz who attached a post script and a one page curriculum vitae stating that he was the discoverer of streptomycin, the world's first successful antibiotic treatment of tuberculosis. (Exhibit No. 3). My publications are only listed, and I have not provided copies, because there are more important and current ones. They are available, however, if the Board would like to review them in detail. The ones that I have provided you with copies and excerpts of, are those publications and proposed studies which have come out within the past year, and some within the past few months.

This Board has played a significant role in the history of Chelation therapy, and it is hoped that this previous experience has not tainted the Board's decision with regard to the rules which are being proposed today. The Louisiana State Board of Medical Examiners has always opposed Chelation therapy. In 1974, they revoked the temporary license of Dr. Ray Evers, and denied his request for a permanent one, because he used Chelation in his private hospital in Belle Chase. It was alleged that 14 people had died because they had been treated by Dr. Evers with EDTA. Subsequent review of those cases showed that nearly all of those patients were terminal when they arrived at Dr. Ever's facility and that EDTA could not be singled out as the sole cause of death.

It is not my purpose to bring up the Evers case for further debate at this time. Only to point out that this case has no bearing on the status of EDTA today. Regardless, the Board has remained steadfast in its opposition to EDTA Chelation therapy, apparently based on its experience with Dr. Evers. As will be seen from the documents presented, and especially the Olmstead monograph, this case is old and outdated, and should have no bearing on decisions which are being made with regard to EDTA Chelation therapy today, and which are being carried forward into the next millennium.

You do not want to carry this old baggage/garbage into the next century. For example, the Board is probably not aware of the fact that the Aetna Insurance Company pays for EDTA Chelation therapy for cardiovascular disease in New Zealand. Also, Michelin tire and several other self-insured companies pay for Chelation in the U.S.

(Exhibit No. 4).

I am also sure that the Board's chairman, a cardiologist, is very much aware of the fact that there has never been a controlled clinical trial to evaluate the efficacy of placing stents. How's that for a double standard, driven in part by income-generation?

The most comprehensive review of EDTA Chelation therapy is published in a monograph entitled "A Critical Review of EDTA Chelation Therapy in Atherosclerotic Occlusive Vascular Disease". The principal author is Dr. Stephen Olmstead. What is significant about this publication is that it's historical and critical review of the literature aspects have been reviewed by Dr. Peter Frommer of the National Heart, Lung, and Blood Institute, and also by Dr. Robert Keenan of the Food and Drug Aministration. (Exhibit No. 5)

It is almost certain that this monograph, which came out in December 1998, was not available to the Board when it promulgated its rules governing the use of Chelation therapy. This most certainly had to be the case, because the conclusion of the authors and endorsers of this monograph is that "the preponderance of the clinical reports clearly support a claim of efficacy for symptomatic angina pectoris, intermittent claudication and critical leg ischemia. While Olmstead does not recommend its use in mainstream medical practice at this time, he does make a firm call for additional studies and research, and expresses the hope that clinical trials, and not the courtroom, will provide the ultimate answers.

To this end, the National Heart, Lung, and Blood Institute has committed 2.2 million dollars for the Chelation Angina Trial. Various universities have been approached to conduct the trial, including the University of Washington Medical Center, Tulane University Medical Center, and most recently the University of Missouri at Kansas City. The latter university submitted a proposal which on first try did not pass the study section, but which is currently being reviewed by others, revised, and hopefully resubmitted. Congressman Dan Burton of Indiana will also be holding hearings in April on Chelation Therapy and Alternative Medicine, which will focus on research, and hopefully on collusion in the medical marketplace as well.

The Cypher study of nearly 20,000 patients treated with EDTA Chelation therapy and followed before and after with Thermograms has been accepted for publication pending satisfactory revisions in the Journal of Alternative and Complementary Medicine. The condensed title is "Effects of Serial Chelation Treatments on Peripheral Perfusion". (Exhibit No. 6) This study shows vascular improvement after EDTA Chelation therapy in 85 percent of the patients treated. The 15 percent who were non-responders were

mostly Type II Diabetics with poor blood glucose control. The first author is Dr. Philip Hoekstra, who had the assistance of John Gedye, MB, a professor of biostatistics.

Also in phase III trials and about to begin is the study of Dr. Michael Shechter of the Heart Institute, Sheba Medical Center and Sackler Medical School in Israel, together with the Cedars Sinai hospital in Los Angeles. This study can be found at the following WebSite on the Internet www.nhkt.com. (Exhibit No. 7)

This study is a revival of the old Sodi-Pallares treatment for acute myocardial infarction. It therefore administers within hours of a heart attack, intravenous magnesium, potassium, glucose, insulin, and with a new addition which will be EDTA. This will be a multicenter study and the solution to be used has already been patented. I predict that this study will be the beginning of a series of clinical investigations to determine how EDTA Chelation therapy works together with other more commonly used cardiac interventions. For example, can EDTA prevent re-stenosis following angioplasty? Also, can it reduce the numbers of patients going for Coronary Artery Bypass Graft surgery, as has been suggested by preliminary data compiled by Drs. Klaus Hancke and Knud Flytlie in Copenhagen, Denmark? This could drastically influence the types of cases selected for surgery.

Why are these rules being promulgated in the first place ? I can honestly say as an expert in public health that the use of Chelation therapy is in no way a threat to community health. It is not a matter of public health concern. As a matter of fact, when the Walter Reed study was being designed and reviewed by FDA officials, Dr. Raymond Lepickey, the head of the cardio-renal division was quoted as saying that "safety was not an issue". This was assuming of course that the standard protocol was followed, and that patients with advanced renal disease were being excluded from treatment. The issue, according to Lepickey was not one of safety, but one of efficacy. Toxicity studies were waived. An IND N0. 28,847 was issued on Aug. 15,1986.

The Walter Reed study was never completed, because it was interrupted during the Gulf War. A preliminary analysis of the data showed that those patients with intermittent claudication who received EDTA showed substantial improvement, compared to those who received a placebo.

Also, in regard to the safety issue in Louisiana, for those doctors using the standardized protocol and practicing Chelation therapy since Dr. Evers, there have been no reported deaths attributable to EDTA Chelation therapy, nor have their been any instances of permanent or severe kidney damage.

What then is the issue or reason for proposing these rules governing the use of not only EDTA, but other chelating agents as well?

In preparing materials for the staff of the Government Reform and Oversight Committee, I suggested that the real issue was one of protection of market share. This whole issue of coordinated conspiracy and collusion with regard to Alternative therapies, including

Chelation, in the medical marketplace will soon be investigated by Rep. Burton and his committee.

Right now, as a result of a consent decree signed by the American College for the Advancement of Medicine with the Federal Trade Commission (based on the College's promotional materials and insufficient legal funds), there is a coordinated effort to outlaw Chelation for the treatment of cardiovascular disease in several states where they do not have Access to Medical Treatment laws on the books, and where the Boards are likely to be successful.

The expert witness for the case against Chelation usually called by the State boards is Dr. John Renner. Dr. Renner is a member of the National Council against Health Fraud. He has his own organization, Consumer Health Information Research Institute (C.H.I.R.I.), which advises insurance companies on so-called fraudulent or unproven alternative therapies and diagnostic practices. It is worthy of note that Dr. Renner was an expert in Illinois and that documents submitted by the plaintiff clearly point out to the court that Dr. Renner does not meet the legal standards/definition, which would qualify him as an expert. (Exhibit No. 8)

In addition, correspondence is on record between the Executive Director of the Kansas State Medical board and Dr. Renner about how they could work together to raise large sums of money from insurance and pharmaceutical companies by exposing "quack remedies and quack doctors". (Exhibit No. 9)

What then will be the likely outcome if the proposed rules are implemented ? It is almost certain that their implementation will only be temporary. This is because it is impossible to resolve controversies in medical science by a legal means. Also we have witnessed in other states where this has been tried, the conversion of a physician-disciplinary issue into a patients rights issue. It is also likely that the "Friends of Chelation" movement will continue to grow and gather momentum, and that public demand will force these rules to be rescinded. (Exhibit No. 10) There is also the possibility that an Access to Medical Treatment Act will be passed in Louisiana and/ or federal legislation will be passed.

In addition there is the real possibility that Federation representatives and State Medical Board officials will be called to testify before Congress, to explain their actions, and to show how such behavior does not amount to collusion and racketeering in the medical marketplace. Sometimes they have had the active collaboration of federal government officials. For example, in a speech given by a senior Federal Trade Commission staff attorney at a meeting of the Federation of State Medical Boards a few months after the FTC opened its investigation of the American College for the Advancement of Medicine, this attorney told the state board members "that the FTC staff have moved beyond looking at claims, are sympathetic to problems the boards have had in stopping the practice of Chelation therapy, and are grateful to representatives of the boards for providing instruction to the FTC staff on how to prosecute a case involving the American College for the Advancement of Medicine."

In the past, Federation representatives and Medical boards have not listened to reason, even when an olive branch was offered by a chelating physician, who is also an official in the Mennonite church. Dr. Terry Chappell's offer of dialogue and discussion was met with the Ohio State Board going after his license.

It is almost certain that such abuses will not be tolerated indefinitely. This kind of manipulation and tyranny is at the root of our economic health care crisis, and it won't be long before government officials and managed-care administrators realize what has been and still is going on.

I would like to conclude with two quotes. The first is from one of the articles of the International Code of Medical Ethics which was part of the Declaration of Helsinki in 1964. It reads as follows, "In the treatment of the sick person, the physician must be free to use a new diagnostic and therapeutic measure, if in his or her judgment it offers hope of saving life, re-establishing health or alleviating suffering."

The second quote is at the entrance to Central Intelligence Agency headquarters in Langley, Virginia. It reads as follows, "Seek the Truth and You Shall be Free".

Also attached is a just over one page summary of what I have just said, and the essential points that should be considered regarding the proposed rules.

Summary of Comments on Proposed Rules Governing Use of Chelation Therapy

James P. Carter, M.D., Dr.P.H.

February 24-March 1, 1999

EDTA Chelation therapy is an FDA approved treatment for lead poisoning. It's off-label use for the treatment of occlusive atherosclerotic vascular disease has been growing in popularity since the late 1960s. Off-label use of a drug previously approved for another purpose has been upheld by the Federal courts.

The Louisiana Department of Health and Hospital's Board of Medical Examiners intends to adopt rules and regulations governing the use of EDTA Chelation therapy. These rules and regulations will effectively prohibit the use of this drug in the treatment of occlusive atherosclerotic cardiovascular disease.

Within the past two years, the federal government has taken a new look at EDTA Chelation therapy for cardiovascular disease. At the encouragement of the newly established Office of Alternative Medicine, the National Heart, Lung, and Blood Institute has set aside 2.2 million dollars for a Chelation Angina Trial. In December 1998 a monograph, also commissioned by the Office of Alternative Medicine, entitled *A Critical Review of EDTA Chelation Therapy in the Treatment of Occlusive Atherosclerotic Vascular Disease* was published. The author is Stephen Olmstead, M.D. of the Merle West Center for Medical Research in Oregon. This review also carries the endorsements of Dr. Peter L. Frommer, Deputy Director of the National Heart, Lung, and Blood Institute in Bethesda, Maryland and Dr. Robert E. Keenan, Deputy Director of the Cardio-Renal Division of the Food and Drug Administration in Rockville, Maryland. The conclusion of the monograph is that "the preponderance of the clinical reports in the medical literature support the claim of efficacy for symptomatic angina pectoris, intermittent claudication, and critical leg ischemia". The monograph calls for additional carefully planned, rigorously conducted, and objective clinical trials to determine "whether the generally favorable anecdotal experience with EDTA Chelation therapy is a true pharmacological effect". How does EDTA work? In retrospect, it is the "grandaddy" of all of the calcium channel drugs, although it is not a "blocker"; it is a "remover".

Clinically, it is an established fact that EDTA Chelation therapy is effective in the above conditions. For example, Aetna insurance company pays for Chelation therapy for cardiovascular disease in New Zealand. Michelin USA and a few other self-insured companies pay for its use for this purpose in the United States.

EDTA Chelation therapy is administered intravenously, usually two or three times a week, for 30 treatments. The cost can vary anywhere from $90 dollars $140 dollars per treatment. Over the years, the American Board of Chelation therapy has developed a standardized protocol, which when followed makes this a relatively safe drug and procedure. When a new drug application (IND) was issued for the evaluation of EDTA in cardiovascular disease by the FDA in 1986, toxicity studies were waived. The head of the Cardio-Renal Division, Dr. Raymond Lepickey was quoted as saying that "Safety is not the issue. Efficacy is the issue". Over a million people have been safely treated with this drug/procedure in the United States alone.

EDTA has been used in Louisiana at least since the early 1970s. Initially, there were reports of patients being harmed who were under the care of Dr. Ray Evers who had a clinic in Belle Chase. Dr. Evers did not follow the protocol developed by the American Board of Chelation therapy. Since Dr. Evers, who was eventually denied a permanent license to practice in Louisiana, other doctors who have used Chelation therapy have not experienced any deaths or evidence of cases of kidney damage because of administering EDTA. It is still being used routinely by pediatricians in the treatment of lead poisoning in children. In most of these cases, it is administered intramuscularly. The purpose of the rules, which are being proposed by the Board of Medical

Examiners, therefore, cannot be to protect the public from harm. There is absolutely no evidence that EDTA Chelation therapy is a threat to public health.

Many patients are dependent on Chelation therapy for management of their symptoms of occlusive atherosclerotic cardiovascular disease. The implementation of these rules is being presented as a physician disciplinary issue. In fact, it is a patient access issue. The rules would deny patients access to an efficacious treatment of their choice, sometimes when other medical interventions have failed.

A better course of action, if indeed any action is needed, especially in view of the renewed interest at the Federal level in Chelation therapy, would be to delay implementation of these rules, until such time as the additional clinical studies which are being called for and funded by the NIH have been conducted.

3/14/99

Federal Trade Commission
Office of the Secretary
600 Pennsylvania Ave., N.W.
Washington, D. C. 20580

To Whom It May Concern at the Federal Trade Commission,

This is to express my deep concern for your recent efforts to limit what information ACAM will be allowed to provide to individuals with serious cardiac or vascular disease who are interested in learning about chelation therapy.

My concern has two elements of basis. First, I am a physician and the son of a former long-standing chief surgeon for The University of California at Davis. Like any modern physician, I am well aware of the severe limitations towards real success provided by conventional drugs and surgery for most patients with clogged arteries. I could quote you hundreds of cases where the patient would have been left better off by never having endured their prescribed cardiovascular surgery. And then there is my next door neighbor here in Lake Tahoe--a successful man in his sixties who died of a heart attack just one month after his cardiac bypass. What's wrong with ACAM providing options? What can surgeons do for clogged arteries in the brain, or for diabetics facing their first, second, or third amputations? I've never seen double-blind studies that prove merit for expensive angioplasties or bypasses. I only know that these surgeries often don't work, must frequently be redone, or as in the case of my neighbor, are suspected for playing a significant role in the actual cause of death and morbidity.

My other reason for concern is more personal. My 86 year-old grandmother was scheduled for amputation in 1987 of both her feet due to poor circulation. Two weeks prior to surgery she received

requested information from ACAM and then sought chelation. Prior to chelation she had dying toes and could only walk two steps because of severe pain in her lower legs (claudication). After 30 chelations her toes returned to normal color and sensation, and she could walk 1/4 mile! She lived to be 91 with no amputation needed. Her surgeon and primary physicians said they had never witnessed such a recovery. Anyway, at the time I was the Associate Director of an emergency room for UC Davis, and I immediately began to refer patients with precarious vascular disease to a local chelating physician, and was shocked at the success of the treatment in the vast majority of cases!

I was shocked because I hadn't even heard of the treatment at my prestigious medical school, or the university hospital where I worked. I now sincerely believe that it has been solely because of concerted efforts by those with financial and political agendas of their own that more of us haven't been educated about the safe option of chelation. Frankly, I pray that your efforts to now limit ACAM's distribution of pamphlets aren't part of similar efforts. Again, I've never seen double-blind studies proving that angioplasties or bypasses are either medically or cost effective despite the pamphlets cardiologists and surgeons frequently hand out to patients which suggest otherwise.

Respectfully,

Sean Degnan

Sean Degnan, MD

Cc: Congressman Dan Burton
Chairman of Committee on Government Reform
U.S. House of Representatives

Dear Congressman Burton, I later went on to become the founder of perhaps the largest and best-run chelation clinics in the world (you may ask Ted Rozema or Terry Chapell) in Palm Springs. You may call me anytime

3/14/99

Dear Congressman Burton,

Thankyou for your interest in and fairness towards chelation. Because of the experiences I witnessed (as described in the accompanying letter to the FTC), I went on to study chelation for one year at a well-known chelation center and became even more impressed. As you can learn from Dr.'s Terry Chappell or Ted Rozema, I eventually developed perhaps the busiest and one of the most respected chelation centers in the world (in Palm Springs). I also started the Friends of Chelation Society and was pleased to learn you have spoken with my former patient Larry Bell.

I feel I have two items of worth to mention to you. The first is that my experience is similar to others--chelation works beautifully in the majority of cases, especially in unfortunate diabetics with clogged arteries of their legs. Larry Bell can provide you with a 3-part local news story of my work in Palm Springs produced by a reporter with an R.N. degree.

My second bit of input I would like to offer is that I think it is most unfortunate for chelation that it is usually lumped together with all other forms of alternative therapies (when one is considering non-accepted treatments). I am well versed in other alternatives such as acupuncture, herbs, vitamins, homeopathy, etc., but I have never witnessed anything so medically profound as chelation (except the delivering of babies) towards bringing new life to patients. What a beautiful safe option for old folks faced with otherwise dismal possibilities! But, in my opinion, not all forms of alternative medicine are worth fighting for. While a staunch advocate of supporting American's rights to choose, I often find myself wishing I didn't have to defend all the other alternatives along with chelation because it dilutes chelation's unique success.

Thank God someone like you has decided to get involved. If I may be of any help, please feel free to contact me anytime.

With appreciation,

Sean Degnan

Sean Degnan, MD

Sean Degnan, MD
219 Beach Drive
South Lake Tahoe, CA 96150
Ph 530-544-4442
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CARDIOVASCULAR DISEASE: IS THE FEDERAL GOVERNMENT DOING MORE HARM THAN GOOD? EDTA CHELATION THERAPY

TESTIMONY OF
MICHAEL JANSON, M.D.

SUBMITTED TO THE
HOUSE OF REPRESENTATIVES
COMMITTEE ON GOVERNMENT REFORM

****

MARCH 24, 1999

WASHINGTON, D.C.

March 23, 1999

The Honorable Dan Burton, Chairman
Committee on Government Reform
US House of Representatives
2157 Rayburn House Office Building
Washington, DC 20515-6143

Dear Mr. Chairman,

I appreciate the opportunity to submit this letter for inclusion in the record of the Government Reform Committee's March 10 hearing on chelation therapy. I am a physician in Massachusetts with an office in Barnstable, on Cape Cod. I received my M.D. from Boston University in 1970, and then did a four-year residency in pathology in Cambridge, Massachusetts. I developed an interest in nutrition, preventive medicine and vitamin therapy after graduation, and proceeded to found the Cambridge Center for Holistic Health in 1976 and, in 1990, the Center for Preventive Medicine, in Barnstable, on Cape Cod. After initial skepticism, I added chelation therapy to my practice in 1983.

I am past-president of the American Preventive Medical Association and a charter member of the American Holistic Medical Association. I am an author and a physician educator, and I speak at medical and public conferences around the country and around the world. I am also the current president of the American College for Advancement in Medicine (ACAM). In that capacity I have been involved in ACAM's discussions with the FTC. However, I am making this submission primarily as a private physician with a personal interest in chelation therapy and other innovative therapies that have been called "alternative medicine."

I signed the consent order on behalf of ACAM in a good faith effort to bring the FTC's lengthy investigation to a close, so that ACAM could begin to refocus its resources on its scientific, educational and public health purposes. Should the Commission ultimately decide to give the order final approval, as an officer of ACAM I will accept its terms. The Board of ACAM decided that the consent agreement was the only way to resolve the situation with the FTC because the only alternative was prolonged litigation which would have required a ruinous commitment of both financial and human resources

If the FTC gives final approval to this order, I believe there will be detrimental effects on good medical practice, including alternatives to the current conventional medical care. And in the long term, it will not be good for patients nor the public in general. Throughout its investigation, the FTC defined "advertising" to include communications between physicians and patients; publications sold from a list of educational resources for physicians and laypeople; and even ACAM's scientific publication, the Journal of Advancement in Medicine. The common theme? Information about medical treatments the FTC does not agree with. The FTC also required that the consent order include an agreement by ACAM to send a letter to each of its members, informing them that while the order is not directly applicable to them, they could be targets of law enforcement actions like the FTC action against ACAM.

With these facts as background, I believe the order – if it is given final approval by the FTC – will necessarily have an impact far beyond the prohibitions described in it. It may

well have the perverse effect of reducing or eliminating the dissemination of information about innovative, potentially life-saving medical treatment options. In particular, physicians would be inhibited from expressing their personal medical judgements to patients, even when those judgements are based on reasonable scientific and medical evidence. This perceived threat also might influence the ultimate decision by physicians of whether to practice chelation therapy at all. I have no doubt that many other means of communicating truthful information would also be affected.

I believe this action may have far-reaching, negative repercussions on the practice of medicine. I am deeply concerned, not only about the effect the order would have on my own medical practice and the relationships I have with my patients, but also about the precedent this action against ACAM would set for other physicians and for the concept of the doctor-patient relationship.

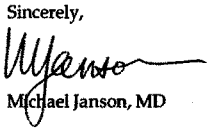
The FTC order against ACAM would prohibit information about chelation therapy – including information physicians discuss with their patients – unless "substantiated" by multiple, double-blind, controlled clinical studies. Only a small fraction of medicine as practiced, however, is based on the gold standard of multiple clinical studies that the FTC is using to judge chelation. That is not bad. It simply reveals medicine as an art as well as a science. Physicians learn and apply therapies in their best medical judgement in the context of the doctor-patient relationship. They apply old treatments in new ways and new treatments in innovative combinations.

Innovation is always viewed by the mainstream with caution at best and often with derision and scorn. And while conventional views are constantly reiterated in medical offices, medical journals, and the popular press, reliable sources of educational information for innovative therapies are relatively scarce. ACAM is one of those sources. The action of the FTC, whether intentionally or not, would stifle that and many other voices. As a result it would deprive a large segment of the population of the resources to make informed personal decisions about their health care.

In my medical practice in Massachusetts over the past 23 years, I have seen over ten thousand patients. It is clear that many people are willing and competent to make their own choices regarding health care, including EDTA chelation therapy. They know what is at stake, and they are willing to spend their own money, not federal or state money, for the right to choose how to improve their health, treat, and prevent disease. **A real public health danger would result from restricting the spread of information about alternatives.**

I am confident that the committee will carefully consider all of the issues that the FTC investigation of ACAM raises, and the potential consequences for the development of medicine and the health of the public. Information about alternatives in medicine will not come easily from the conventional medical or media sources. Public demand for such information is high, and the available sources need to be encouraged, not silenced.

Sincerely,



Michael Janson, MD

JOE ST. JOHN MACEY
8331 WRENFORD CT
SPRINGFIELD, VA 22152
March 23, 1999

The Honorable Dan Burton
Chairman, Government and Oversight Reform Committee
2157 Rayburn House Office Building
Washington D.C. 20515

Dear Chairman Burton:

Enclosed is my written statement to be inserted in the record of the Hearings on Chelation Therapy which were held on March 10, 1999. As Dr. Levin indicated during the hearing, I am a patient of his and I have had more chelation treatments while under his care than any of his other patients.

Thankyou for providing me the opportunity to express my view on chelation therapy and the benefits which chelation has had for me.

Sincerely,

Joe S. Macey

copy: The Honorable James Moran
2239 Rayburn House Office Building
Washington, D.C. 20515

STATEMENT OF JOE ST. JOHN MACEY

Before the Government and Oversight Reform Committee

United States House of Representatives

Hearings on Chelation Therapy

March 10, 1999

My name is Joe St. John Macey. By way of background, let me state that I am a 62-year old attorney with a B.A. in biology and a minor in chemistry, a J.D., and an LL.M. (in taxation). My home is in Springfield, Virginia. My father, an orthopedic surgeon, was a U.S. Navy doctor during WWII; he suffered his first heart attack at age 37, and his second one killed him at age 45 in 1951. My brother is an obstetrician/gynecologist, and my father-in-law was an internist. Because of my association with conventional medicine, I am aware of the attitudes of conventional medicine towards alternative medicine, in particular chelation therapy (CT). In fact, my brother and I have had discussions about the efficacy of chelation therapy for atherosclerosis. Even though he acknowledges the apparent benefit I have received from utilizing CT, he remains skeptical. Unfortunately, my younger brother, who believes everything conventional physicians tell him, had a quintuple by-pass three years ago at age 57.

Six years ago, in the summer of 1993, I experienced angina while working in my yard. Although my cardiologist wanted to perform an angiogram, I declined because of the potential risk of serious complications associated with angiograms and angioplasty. I did undergo a thallium scan, but decided to do chelation therapy rather than subject myself to the risks of an angiogram, and quite likely, the resultant angioplasty. Angioplasty is a temporary solution at best, as it merely pushes plaque aside only to have it return at a later date, sometimes as soon as 6 months after the procedure, and it can can damage the interior wall of the artery leading to additional plaque formation. In fact, in many cases, having the first angioplasty starts one on a downward slope in that it leads to an arthrectomy, then a by-pass, then stents to prop open the arteries. Dan Reeves is a good example of this progression.

I first heard about CT with EDTA approximately 15 years ago from an alternative physician in

Washington, D.C., who suggested that the best way to widen the blood vessels in my problematic eyes was with chelation therapy. Although I didn't undergo CT at that time, I did research the procedure. Consequently, I knew that the procedure was safe and reportedly effective. While ACAM material, the books it offered for sale, and the articles from the Journal of Advancement in Medicine were helpful in my research, the most important items were the trade books on sale in health food stores.

By the time I started CT 6 months later in February 1994,[1] I was taking 240 mg. per day of Cardiziam CD, a calcium channel blocker, as well as nitroglycerin tablets. I had no energy; I had angina just sitting at my desk; and my co-workers said I looked terrible. I met with my chelating physician (Norman Levin, M.D. who testified before this Committee) and told him that I wanted CT, that I was familiar with it, and that I had been diagnosed with coronary occlusion.

After 14 treatments of chelation taken at two per week for 7 weeks, I reduced the Cardiziam to 180 mg. per day and needed no more nitroglycerin because I no longer suffered with angina. After 12 treatments at one per week, I reduced the Cardiziam to 120 mg. per day and went to one treatment every two weeks for 36 weeks. After those 44 treatments, I reduced the treatment schedule to one per month. I have continued having one per month and as of this month have had a total of 92 treatments. During the winter of 1995-1996, a winter in which the snow accumulation was bad enough to close Government offices in Washington for 4 days one week, I shoveled snow for approximately 2 hours on each of three successive days with no angina. In December of 1997, I stopped taking the Cardiziam completely and have not needed it since that time.

I have spent approximately $9,200 on 92 treatments over 5 years which is substantially less

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[1] I waited six months to start CT because of financial reasons. My insurance company, Government Employees Hospital Association, refused to pay for chelation, but my wife's flexible benefit plan which covers medical items not covered by insurance but which are approved by the IRS for deductibility from taxes needed to be funded for me to use to pay for CT.

than conventional medical treatments would have cost. Had I had an angiogram and angioplasty, I would have spent $20,000, $40,000 or more if the angioplasty had to have been repeated, and quite possibly might have needed by-pass surgery, in which case I would have spent substantially more.

Currently I work out on an elliptical trainer for 25 to 30 minutes at a time and have used it for as long as 56 minutes with no angina. I am a perfect example that CT works and works well, and it does so at a substantial cost savings when compared to what conventional medicine has to offer.

I hope this Committee can generate enough Congressional interest to pass legislation that will protect alternative physicians from the prejudicial and monopolistic treatment dispensed by state medical boards. The FDA, conventional medicine and the pharmaceutical companies are not inclined to grant alternative physicians equal treatment. One of the greatest hindrances to alternative medicine, orthomolecular and vitamin therapy, and chelation therapy is the attitude of the FDA, an agency with perhaps the largest revolving door to private industry and particularly to the pharmaceutical companies. If the FDA were to approve the use of EDTA, the chelating agent used in CT, for removing arterial plaque, state medical boards would be unable to attack chelating physicians; insurance companies would pay for CT; individuals and insurance companies would save money; and cardiac surgeons, cardiologists and hospitals would suffer reduced income. Medicare should require CT in all cases in which by-pass surgery has been recommended. Unfortunately, that won't happen until the FDA approves CT for atherosclerosis.

ROBERT A. NASH, M.D.
TESTIMONY

This is the testimony of Robert A. Nash, M.D. to the Committee on Government Reform given during the week of March 18, 1999.

Introduction and Overview:

I will testify that chelation therapy is a 50-year-old, safe, effective treatment for the symptoms of vascular disease. I will limit my comments to heart disease only. The health care trends in the USA, re-evaluation of the current medical care delivery system (stressing safety, costs and efficacy), and possible government problems delaying implementation of research and cost reduction will be concluded with recommendations to the committee specifically regarding chelation therapy.

Background and Current Positions:

I am a medical doctor board certified in the American Medical Associations specialties of Neurology (American Board of Psychiatry and Neurology) and Pain Medicine (American Board of Pain Medicine). I am a physician acupuncturist, licensed in Virginia and am board certified in chelation therapy. I am on the board of the American College for Advancement in Medicine (ACAM) and am Vice Chairman of the American Board of Chelation Therapy (ABCT). I am a 1959 graduate of the U.S. Naval Academy and hold a master's degree in electronics engineering (1964). See Curriculum Vitae for details.

Current Trends:

In 1990 33% of those polled (potential voters) used alternative therapies, spending 22% of the total out of pocket dollars for health care. In 1997, 42% of those polled used alternative therapies, spending a minimum of 31% of the out of pocket dollars. Two studies in 1998 place the population percentage using alternative therapies at 50% and 69% respectively.

Two thirds of the U.S. Medical schools now offer some type of educational experience in alternative, complementary or integrative medicine.

Even the AMA journals have taken an interest. In 1997 the combined professional journals of the AMA ranked alternative medicine at # 68 out of 73 interest areas. In 1998, alternative medicine ranked # 2 out of 86 interest areas.

It appears that the current trend is for patients to abandon the current delivery care system and turn increasingly to alternatives. Why?

TESTIMONY

ROBERT A. NASH, M.D.
TESTIMONY

Reasons for Change:

Since the trends are massive, persistent and scientifically documented, what are our citizens seeking? I reflected and began by defining medicine. My definition is that "Medicine is the art and science of preventing, diagnosing and treating disease and alleviating pain and suffering in a compassionate and ethical manner." We doctors have perhaps overly stressed the science, diagnosing and treating aspects, to the detriment of the art of delivery, prevention of disease and compassion and ethical care considerations.

The rank-ordered four principles of biomedical ethics are autonomy (respect for the patient); non-maleficence (first do no harm); beneficence (well-intended actions to help a competent patient); and justice (the just distribution in society). During the past several decades when the trend began, alternative practitioners have honored autonomy and nonmaleficence. The establishment has seemed more concerned with beneficence and justice.

Health maintenance organizations (HMO's) have accelerated patient dissatisfaction with traditional medicine. Employee physicians have been given bonuses for not hospitalizing, not referring to specialists, ordering older tests which insurance carriers always pay for, and prescribing the least expensive medications. Physicians, because of workload and other considerations, now allot approximately five to seven minutes per patient. Patients are now viewed by some as widgets on an assembly line. This is dehumanizing and patients justifiably resist this approach.

The medical establishment, although attempting to change, is a large, old, bureaucratic grouping of institutions incapable of rapid change to meet the populace's expectations. Establishment journals still write condemnatory articles on alternatives, further alienating patients from establishment medicine and driving them to seek alternatives. Beneficial outcomes and markedly decreased costs have increased patient satisfaction with alternatives. Alternative therapies and practitioners tend to treat the entire patient (holism) and stress wellness promotion, disease prevention and quality of life. This is often done by concomitant usage of vitamins, herbs, healthy lifestyles and safe, effective treatment alternatives such as acupuncture and chelation therapy. This is an ongoing process while establishment medicine is re-evaluating its effectiveness.

ROBERT A. NASH, M.D.
TESTIMONY

Re-Evaluation:

Dr. Thomas Graboys, medical director of the Lown Cardiovascular Center, Harvard, is conservative and eloquent in his views that invasive cardiac treatments like angiography, angioplasty and coronary artery bypass grafting (CABG), are overused by as much as 70% to 75%. A 1997 "Heart" Journal article addressed the ten year follow up of CABG patients in Scotland. At ten years, 25% had no angina; 29% had angina; 13% had had repeat CABG; and 33% were dead. At twelve years 44% were dead. The article stated, "The long term benefits of CABG surgery are disappointing."

In a June 1998 article in the New England Journal of Medicine, a study was published by William Boden, et al, showing that conservatively treated patients with non-Q-wave myocardial infarctions (heart attacks), had a markedly lower death rate and secondary heart attack rate at hospital discharge (270% less), one month (203% less), and at one year (129% less), although at two years the differences were less. Conservatively treated patients received medications, while aggressively treated patients received angiography, angioplasty and CABG, the U.S. standard of care since 1987.

The study was so significant that it prompted an editorial in the same issue entitled, "Use and Overuse of Angiography and Revascularization for Acute Coronary Syndromes." This editorial stated emphatically that the protocol be used to guide treatment, "rather than physicians' preferences or other, nonmedical incentives."

In the April 15, 1998 issue of the Journal of the AMA, Dr. Bruce Pomeranz published a very revealing article. The fourth leading cause of death in the U.S. during 1997 was properly prescribed medications given in hospital. Only 2% of patients receive their medications in hospital. That was the bad news. The good news is what had been the eighth leading cause of death, aggressive cardiac intervention causing an estimated 33,000 deaths per year, dropped to number nine. When number four and number nine of the top ten causes of death in the U.S. are caused in part from the ethical principle of beneficence, perhaps the principle of nonmaleficence -- first do no harm-- should be reconsidered. Chelation therapy is such a nonmaleficent treatment for heart disease.

ROBERT A. NASH, M.D.
TESTIMONY

Chelation Therapy:

Ethylene diamine tetra acedic acid (EDTA) Chelation Therapy (CT) is the Food and Drug Administration's treatment of choice for lead poisoning. Since the mid-1950's patients' cardiac symptoms, such as anginal pain, have improved markedly with CT, initially as a side benefit and subsequently through purposeful treatment. During the past 40 years it is estimated that 1,000,000 Americans have received CT. Johnny Mann (The Johnny Mann Singers) and Chi Chi Rodriguez (golfer) are two vocal satisfied spokesmen. CT is a three-hour intravenous office treatment with few side effects.

Safety:

In the past 50 years fewer than 15 deaths from CT are known to have occurred. Initially, as many as 22 grams of EDTA were given in 24 hours as contrasted to today's standard of three grams. A protocol was established in 1973 and when followed has resulted in no fatalities. Even if we triple these fatalities, they still number only 45 since 1948 when CT was first used. Forty-five fatalities in 50 years and none in the past 25 years is acceptable.

Contrast ***33,000 fatalities per year from aggressive cardiac intervention***, which is the standard. That's 90 deaths per day or 45 deaths per twelve hours, around the clock. The safety of EDTA CT is shown: 45 deaths in 50 years (none in the past 25 years) due to chelation therapy, versus 45 deaths in a twelve hour period for aggressive cardiac intervention.

Costs:

The average number of CT treatments for cardiac patients are 30 the first year and then one each month. Although costs vary, a reasonable estimate of $150 per treatment, yields approximately $4500 for year # 1 and $1800 during year # 2. With office visits, laboratory tests and supplements, the overall cost for year one is approximately $6,000 and for year two, approximately $2400.

ROBERT A. NASH, M.D.
TESTIMONY

Aggressive cardiac treatment costs also vary, but I will use those personally given to me by my patients. Initial emergency room intake or outpatient EKG, laboratory tests from $500 to $2500. Angiography is $14,000 and is usually followed in three weeks with angioplasty at $18,000. One-third of all angioplasties fail within six months resulting in a portion going on to coronary artery bypass grafting (CABG). An uncomplicated CABG procedure costs approximately $50,000. One patient's mother had complications and extended hospitalization and surgery before her death six months later; cost: $350,000.

I think it's fair to state that CT is a bargain at $6,000 with no deaths, versus the standard care at approximately $80,000 to $100,000 with 33,000 fatalities per year.

Which is better?

Several published studies since 1988, show the same result. CT is approximately 86% effective in decreasing angina and other cardiac symptoms. If future research changes these numbers and only 50% of cardiac patients now receiving CABG (500,000 per year) can avoid the surgery by getting chelation therapy, the cost savings to the government would be substantial: approximately $25 billion. Even if the $1.5 billion dollars for CT were subtracted, $23.5 billion dollars per year might be helpful in assisting Medicare.

Perceived problems:

Dr. Forker, Chief of Cardiology, University of Missouri School of Medicine, submitted a proposal to test intravenous EDTA CT in angina patients. It was a well thought out prospective study costing less than $3 million. It was rejected because it was a CT research study.

The American College for Advancement of Medicine (ACAM) has a large scale registry study ready to go over many years, to gather meaningful data and document heart patients and their outcomes with CT. It could be immediately implemented for $2 million.

Even though years' of interest, encouragement and lip service for objective studies to test the CT hypothesis with heart disease have past, no studies have been funded.

ROBERT A. NASH, M.D.
TESTIMONY

This is significant in view of presentations made to the Federation of States Medical Boards several years ago by the FTC, specifying by name that chelation therapy and all practitioners must be eliminated. The full federal bureaucracy, in concert with the Federation of States Medical Boards and Federation of States Attorneys General, met in Dallas to pursue this vendetta. This continued at the Federation of States Medical Boards meeting in Orlando in 1998 and continues to this date. CT has been singled out because it works, is safe, is cost effective and threatens an existing multi-billion dollar industry.

The unwarranted FTC abuse of the intent of congress by overstepping it's regulatory charter and coercing ACAM to sign a consent order borders on regulating the practice of medicine and harassment of not-for-profit professional organizations. ACAM has had 25 years of teaching physicians chelation therapy.

The FDA likewise shut down the most significant manufacturer of EDTA for many regulatory violations. Although lip service again was paid, no future date for resuming production is known.

Are the above events coincidental or a collusion of the establishment to prevent research and restrict the American public's access to low cost effective treatments for heart disease? Is an expenditure of $5 million worth a potential yearly savings of $23.5 billion? Is this the America we want? That blocks research, abuses the regulatory system and singles out one treatment modality, CT, because it works? I think not.

I have practiced medicine for 25 years. I have never seen any treatment as safe, effective and as user-friendly as Chelation Therapy. It's the best kept secret in medicine but over 1,000,000 Americans have already benefited by it. Please help freedom, medicine and the nation's health. I propose the following for your consideration to show good faith in our system:

Recommendations:

1. Facilitate fast track review, approval and funding for Dr. Forker's, University of Missouri School of Medicine's study of CT and angina.

2. Facilitate fast track review, approval and funding of ACAM's Registry Study for Chelation Therapy and documented heart disease. Dr. L. Terry Chappell is principal investigator.

TESTIMONY

ROBERT A. NASH, M.D.
TESTIMONY

3. Set aside the FTC's unwarranted and coercive consent order signed by ACAM.

4. Instruct all appropriate Federal Agencies to cease all actions against CT, CT practitioners, EDTA manufacturers or others who are attempting to educate the public, colleagues and insurance carriers as to the safety, efficacy and cost savings of chelation therapy.

5. Instruct Heads of Federal Agencies to send letters to each state's medical licensing board and attorney general to cease any action against any practitioner of CT solely because he is an alternative physician who practices chelation therapy.

Closing Comments:

A patient of mine, Robert K. Leopold, a retired Navy Captain, wrote a three-page impassioned letter to the FTC regarding ACAM, File No. 962-3147. I will briefly quote to underscore why Americans are turning to alternatives, especially chelation therapy. "I believe that by trying to discredit chelation, the Medical and Insurance powers-that-be are guilty of defrauding the medical consumer. They do this in many ways. One is by not educating medical doctors about the truth of chelation. To say that the procedure is unproven, experimental or "bunk" is fraud in the truest sense of the word.'

Captain Leopold and I and the millions of Americans who can be helped by chelation therapy implore your good offices to facilitate the needed research and to stop the persecution, real or apparent, of chelation therapy practitioners, suppliers and their friends.

I sincerely thank each of you for your needed efforts in government reform and know chelation therapy will become more readily available because of your committee's hearings.

John M. De Noyer, Ph.D. and Ann H. Csonka
600 Austin Lane, Herndon, VA 20170
703-471-4337; email: jdenoyer@erols.com

March 22, 1999

TESTIMONY SUBMITTED TO: The Honorable Dan Burton, Chairman, and Members
Committee on Government Reform
U. S. House of Representatives, Rayburn HOB #2157

ATTENTION: Elizabeth Clay

FOR THE TOPIC: **Cardiovascular Disease: Is the Government Doing More Harm than Good?**

EDTA CHELATION THERAPY

as an alternative to surgical bypass and other invasive procedures

We respectfully submit the following information for your consideration:

- OBSERVATIONS AND PERSPECTIVES
- A CASE HISTORY with COST-AND-EFFECTIVENESS COMPARISONS (Attachment 1)
- 1993 reaction to disinformation in media (Attachment 2)

We have specific and personal knowledge of both chelation therapy and surgical bypass procedures for treating occlusive atherosclerotic vascular disease. Even after undergoing an aortal bifemoral bypass, Ann would probably not be alive to write this letter if a friend had not told her about restorative chelation therapy, and then insisted that she visit a chelation therapy practitioner.

BACKGROUND

We are not "health nuts". We have become somewhat more health-conscious in our later years, because perhaps decades of neglect and hard-driving lifestyles have worn us down physically. Fortunately, our minds are not as closed as Ann's blood vessels were.

We are not medical experts. Ann is an artist and environmental educator (primarily science exhibits and nature interpretation). John is an earth scientist, educator, and Town Councilman -- with a Ph.D. in geophysics and a lifetime of broad experience in many disciplines including geology, hydrology, and remote sensing and satellite systems, as well as extensive senior executive experience. We just want to keep on doing the things we do...mostly in public service and educational areas. We are extremely active retirees.

We are intelligent, well-educated, thoughtful people who tend to think independently. We are active in our community, rarely miss voting, and pragmatic in most situations, though Ann is more volatile and John is more reasoned in style. We believe in our governmental system, though our trust is tempered by experience, and we would like to respect the medical profession, though that respect has been severely eroded over time.

continued

FACTS

> Generally, physicians and health services do not recognize chelation therapy as a viable alternative to invasive surgical methods...and many purveyors of conventional medicine attack any alternatives, especially chelation.

> Patients are not informed that there may be another appropriate alternative which may, in most cases, have the same benefits as the routinely recommended angioplasties and bypasses.

> Most people tend to rely on their doctor's advice when they have a medical problem.

> Most people cannot afford or will not pay for entirely out-of-pocket alternative treatments.

> Blue Cross/Blue Shield (and other insurers) and HMO's will not cover costs for chelation therapy. BC/BS will pay some for blood tests, "regular" labs, and office visits. They rarely question the costs for hospital care and surgical procedures that are "high-tech" and widely accepted in the entrenched medical marketplace.

> The "crisis-mode-spot repair" surgical approach to treating conditions caused by atherosclerosis is like a fad that's gone wild and won't go away. It reflects our technologically-enslaved society. Advances in medical, as well as all other techniques and technologies, are fantastic, but no one approach or treatment should be considered a panacea.

> Bypass surgery is a quick and costly procedure that only spot-treats.

> EDTA chelation therapy has been clinically proven to be an effective, life-giving treatment for many people.

> The main difference between these two approaches is that the surgical techniques correct symptomatic problems in specific locations. In contrast, chelation therapy treats the disease throughout the body.

> All of these factors, and many more which have been presented to you in detail, create an appalling situation in which people die needlessly (on operating tables and slowly between crises) and/or quality of life is destroyed.

> We have observed many friends and acquaintances (and celebrity figures) who have chosen to believe their doctors' ridicule of chelation...undergo surgery...then before long we attend funerals or send condolences. Unavoidable? Sometimes, but in many cases chelation could have been a life-giving option.

> Ignoring, and even deriding, the efficacy of effective alternative therapies is negligent and unacceptable.

> The government of our country defiles public trust by refusing to even fairly study alternative and integrative medicine to save lives, apparently because the government is indentured to the "medical mafia" that is more concerned with supporting the GNP than supporting the health of people. The high degree of bias is inexcusable.

RESULTS COUNT

Ann's "first person" comment: Before chelation therapy--*and after my aortal bifemoral bypass*-- my mind and body were operating so sluggishly due to lack of oxygen that I would not have been able to compile these observations to share with you! I couldn't remember what I was doing from the top to the bottom of a page... or would be too tired to do it!

Medical test records documented the improvement of my circulatory system; specifically, the change in arterial blood flow through cerebral and carotid arteries that resulted from chelation therapy. For example, the blood flow in an artery to the short-term-memory-center in my brain was about 85% blocked and flow was restored to nearly normal after only 20 NON-SURGICAL EDTA infusion treatments. The results were terrific — I could remember again, almost "think straight", and could do little things like nailing upward, as well as hiking and leading nature walks, gardening, and playing with our grandchildren. How many people have lost these opportunities?

continued

QUESTIONS

1. Which treatment would YOU choose if you had blocked arteries:
   a) fixing one spot at a time and waiting in fear for the next crisis, or
   b) living fully, with a sense of security that your entire circulatory system is working?
2. What is the HUMAN cost-benefit ratio of these two contrasted medical approaches (given similar cases)?

REALITY CHECK ON SCIENCE

(Comment on the scientific efficacy of clinical trials)

I *(John)* have been a practicing scientist for over 40 years. I fully recognize the importance of established protocols for many types of testing. Protocols for drug testing have been established to protect society from dangerous drugs and from false claims of products.

It is no less scientific to use the "scientific method," *i.e.*, observation, hypothesis, testing, and verification to establish validity. This appears to be the approach to justifying many surgical methods including vascular surgery. I admit that double blind tests for heart transplants would not be practical. It would be a certain death sentence to the total control group. There are times when experience and results have to considered. There have been hundreds of thousands of intravenous treatments with EDTA and I am not aware of any significant harmful effects when practitioners use standard treatment protocols. There are also thousands of people who have benefited from EDTA treatments. Ann's case is a dramatic one that I have observed closely over the past seven years.

My own experience with chelation started about five years ago. For several years I experienced increasing difficulty with irregular heart rhythms. My angiogram only showed minor blockage of the major arteries. Minor eposides became a daily occurrence and major episodes that required medical intervention occurred two to three times a year. After starting chelation therapy, the minor episodes have almost disappeared. The major episodes still happen, but I am able to convert most of them without going to the emergency room. The problem may have been caused by a combination of blockage of the small arteries in the heart and partially by a defective heart valve. While my results are not as dramatic as Ann's, I do feel that chelation has benefitted me. It certainly has not hurt me and I am convinced that it has slowed down the aging process which is of great importance to people in their 70's.

I take a moderate dosage of digoxin daily to ensure a regular heart rhythm (conventional treatment). This medication has been a constant before and since I started chelation therapy. An incidental benefit of chelation for me is that it prevents toxic accumulation of residual digoxin in my body. Illness from chemical toxicity is a common problem that results from too much "pill pushing".

REALITY CHECK ON BYPASS

Although bypass and other vascular surgeries are truly medical miracles, when really needed, they should not be the only option. It is common knowledge that bypass procedures also involve continuing risk. For example:

1. "Our dentist warned us...but the regular doctor and surgeon didn't." Inadequate medical practice takes many forms. Ann's bypass was performed by a highly-regarded peripheral vascular surgeon, to whom we had been refered by our regular physician, also well-qualified in his profession. The next year, when our dentist was in the meticulous process of implant surgery for Ann, he warned us of the special risks of infection because he knew of Ann's bypass surgery. Dentists and oral surgeons must exercise special care and use

continued

prophylactic antibiotic therapy prior to, and after, oral surgical procedures when patients have had bypasses, shunts, or joint replacements.

These surgically repaired sites are especially vulnerable to endocarditis infections, which develop when bacteria from mouth infections are released into the bloodstream during dental procedures and oral surgery. Endocarditis infections can cause serious damage at the sites and to heart valves.

Why was it our dentist who warned us of the special risk of infection that bypass patients should be aware of. Why not the cardiovascular surgeon or the referring physician? The M.D.s only observed mechanical processes and not only neglected the art of healing, they failed to provide basic cautionary information that could cause devastating health effects.

2. Ann's comment on her major health concern today:

Major arteries in my body are part-Gortex, therefore, I have one frightening concern. Whenever I pull a muscle or catch a flu-like ailment that creates intestinal distress, i.e., whenever anything feels wrong in the vic- inity of the surgically replaced arteries I wonder, "Are they giving out?" I don't dwell on it, but it's always there.

According to my esteemed peripheral vascular surgeon, "They don't really know how long they last, but not to worry...I haven't had a patient lose one yet." My question: "How long have you been in this specialty?" Medical response "A long time." Sounds rather unscientific. DOES THIS DEMONSTRATE CLINICAL PROOF OF ONE OF THE MOST WIDELY ACCEPTED PRACTICES IN MODERN MEDICINE? Perhaps this type of exchange accounts for the degree of skepticism and fear that real thinking people have for the wonders of bypass surgery.

It is likely that chelation would have corrected my vascular occlusion without the trauma of surgery and the continuing risk. But the door of opportunity for alternatives was tightly closed.

Anecdotal evidence is scoffed at by the "medical machine"...physicians providing chelation therapy are attacked by other doctors and harrassed by state medical boards...preventive and alternative therapies are demeaned...chelation is specifically ridiculed as "quackery"...*but it is chelation that allows my blood to circulate to supply ALL parts of my body and allows me to be a happy, active, and productive person. I find that reality much more reassuring than the assumed effectiveness of arterial patchwork.*

There are bonafide "quacks" in every calling and every medical specialty. In our opinion, those who label chelation therapy practitioners "quacks" and work so hard to disprove the science and common sense of an effective treatment are probably more deserving of the label.

CLOSE

You have been provided with information about many studies by experts on surgical procedures and alternatives to correct vascular problems. You have been provided with considerable information from government agencies, at least some of which seems bureaucratically obfuscated, defensive, and detached from reality.

Our comments are primarily intended to put a personal face on the situation. Our professional backgrounds, life experiences, and specifically related treatment experiences do provide a special perspective.

continued

CLOSE, continued

Medicine and health care is about whole people, one at a time. Dr. Norman Levin is our doctor. He considers patients as whole people -- living systems with brains and hearts that have capability, sensitivities, and value beyond their function as biological organisms. Thank God there are a few physicians who understand healing and holistic medicine and manage to break free of exclusive allegiance to robot-medicine with pills and knives.

Integrative medicine is essential to the health of this nation and should be part of every medical curriculum and every M.D.'s thinking and actions. It should be a routine part of the administration of HMOs and all agencies involved with health care. Allegiance to conventional medicine -- to the exclusion of all other possibilities for healing -- is killing too many people. Government leaders and agencies, and medical leaders should take off the blinders and "get off their high horses" long enough to broaden their vision, tolerance, and scientific understanding.

At this point the government is definitely doing more harm than good. We appreciate efforts to protect the public from danger, but in the case of chelation, the protection is being provided only to purveyors of invasive procedures and the watchdogs are dangerous. This is wrong. We are convinced that many lives can be saved and the quality of life for others can be greatly improved. It is time for our national government to break out of the entrenchments and look at medicine and health care with a more holistic and preventative attitude.

Thank you for taking the time to review our perspectives. We appreciate the opportunity to share our views and trust that you will insist on opening the doors of reason.

John M. De Noyer, PH.D. and Ann H.Csonka

cc: Norman W. Levin, M.D., Aldie, Virginia

John E. Stauch, Ph.D., Integrated Medical Services, Inc., Annandale, Virginia

The Honorable Thomas E. Davis, Representative, 11th U.S. Congressional District, Virginia

COMPARISON OF TREATMENT APPROACHES, COSTS, AND BENEFITS FOR SURGICAL AND CHELATION THERAPY PROCEDURES

Anecdotal case evidence

PATIENT PROFILE: ANN H. CSONKA
Female, born 08-10-36. Small frame, 5'5", (from 115 lbs. at 30 to 138 later). Employed full-time.
Family medical history: Circulatory, stroke, and coronary heart problems, both sides of family.
Osteoporosis and breast cancer, mother's side. Poor eyesight, father's side.

Medical: 4 childbirths Partial hysterectomy. Hormone replacement therapy: Premarin.
Cigarette smoker 1952 to 1984. Pipe smoker (plain tobacco) 1985 to present. Past history of kidney stones, stomach ulcers and other stress-related problems, chronic sinusitis, and digestive problems.

Physically very active until onset of severe symptoms in 1989.

ILLNESS/SYMPTOMS REQUIRING TREATMENT, 1990:

SYMPTOMS: Extreme fatigue, shortness of breath, no stamina, limited activity (can't even walk to the mailbox), progressive short-term memory loss, inability to concentrate, small cuts/etc. very slow to heal.

DIAGNOSIS: Atherosclerosis, arterial and vascular occlusive disease, peripheral vascular blockage.
Recommended treatment: surgery. Other options: None (except continuing decline and death)

Medical treatment, 1990: Aortal bifemoral bypass surgery

Medical treatment, 1992: Chelation therapy and corrective medication for digestive disorder

NOTE: In 1992, a "non-traditional practice" nutritionist working with the chelating M.D. also identified malabsorption syndrome (digestive disorder) and probable hypoglycemia (per symptoms, no addt'l. test). This diagnosis was made on the FIRST visit to these "alternative medicine" doctors. Simple replacement-therapy of digestive acid and pancreatin immediately corrected the worsening digestive problems. This digestive disorder had been misdiagnosed, mistreated, and untreated by "regular doctors" for twenty years.

RESULTS FROM PROCEDURES

1990 SURGICAL BYPASS (aortal bifemoral): Restored circulation & function in legs.
Caused additional severe short-term memory loss due to prolonged anesthesia during the procedure.
Did not restore overall function, i.e., did not improve conditions of general fatigue, low stamina, inability to perform any tasks requiring reaching over the head, arms going to sleep at night, or short-term memory loss (which persisted after effects of anesthesia should have been gone).
Options offered by physician: go to additional specialists in vascular surgery for other spots.
Patient response: Go to hell! Symptoms worsened (except for legs).

1992 CHELATION THERAPY (after 20 treatments): Gave back a whole life.
Restored reasonable overall function: physical and mental capabilities, including memory & healing rate
Significantly improved condition of fatigue, restored stamina and restored short-term memory.
Provided a positive action option, rather than just waiting for the bypass to fail or another spot to block.

Later, continuing "maintenance" chelation (average: 1 treatment every 2 months). 1992 to present.

Unexpected possible dividend noted by dentist: virtually no plaque buildup on oral implant (all lower teeth), even with less-than-diligent patient care (flossing, etc.)

COSTS

We have summarized the costs of the two medical approaches to treat Ann's health problems.

Please note how the site-specific surgical approach may also increase both the costs of health insurance and out-of-pocket costs to patients. Therefore, by simple common-sense deduction, it is obvious that preventive and alternative medicine is derided by the medical industry because highly remunerative "cut-and-paste medicine" is good business for providers.

COMPARISON OF TREATMENT COSTS

MEDICAL ITEM	1990 SURGICAL PROCESS	1992 CHELATION THERAPY
M.D. Evaluations (OV) Discussion and review of medical conditions and options w/patient	$ 240	$ 300
LABS & DIAGNOSTICS	$ 4,355 (X-rays, arteriogram, aortogram, ABD cath--angio bil.ext.. blood, EKG. etc)	$ 1,050 (Non-invasive Doppler, x-ray, blood, EKG, +Heidelberg test for stomach problem)
DOCTOR'S FEES Surgeon and Anesthesiologist only	$ 5,113	(not applicable)
HOSPITAL CHARGES Room, OR, nursing, etc. (8-page printout) Hospital *labs/diagnostics are excluded* when identifiable. Hospital figures are derived as well as I can decipher them from hospital and Blue Cross records.	$ 18,513	(not applicable)
EDTA INFUSION THEPAPY Including periodic blood monitoring, evaluation of condition w/Doppler.	(not applicable)	$ 2,810
Vitamin/mineral/trace element supplementation* Does not include meds. for digestion)	(not applicable)	$ 320
Percent of Cost Covered by Insurance (Fed. Blue Cross - Blue Shield)	76% (Catastrophic Coverage Plan)	24% (Regular)
"Out-of-Pocket" Costs to Patient	$ 6,776 *	$ 3,519
TOTAL COSTS	**$ 28,221**	**$ 4,480**

* Cost to patient should also be measured in loss of credit for 1200 hrs. of accumulated sick leave that was used in 1990 (which would otherwise have been added to length of service and would have increased retirement income), and to leave without pay.

PATIENT "DOWN-TIME":	5 days pre-op, 8 in hospital, 6 months to return to partial or limited function	22 days (allowing a full day "shot" for each treatment). Actual total hours for entire treatment series = 132, including travel time

CURRENT OUT-OF-POCKET ANNUAL COST FOR AN AVERAGE OF 8 TREATMENTS, Ann (Our goal is once a month, but we just don't make it that often--get too busy)....	$ 800
Approx. annual costs for supplements* -- including digestive replacement items (Ann).....	$ 960
Office visits/consultation and periodic lab tests	$ 200
Approx. total annual cost for integrative, preventative medical care	**$ 1,960**

* Minerals and some other elements need to be replaced because they are removed by the chelation process. Vitamins, amino acids, trace elements, etc. are for general health (not removed by process). Our supplements also include a small amount of oral EDTA.

A copy of a letter, with data, that we submitted to Ted Koppel of ABC's "Nightline" program in 1993, follows.

We decided to append this old letter, because it is typical of the rampant "witch-hunt" approaches to "analyzing and reporting" on alternative therapies. It also reflects the anger and frustration of a patient subjected to a radical invasive surgical mindset...and forced to waste money, time, and life undergoing a bypass procedure.

The letter is a relatively candid reaction to purveyors of lies and insecurities. This letter was not even acknowledged by ABC (as expected).

FILE COPY

Ann H. Csonka
600 Austin Lane
Herndon, VA 22070

703-471-4337

March 4, 1993

This "reactive letter" is a personal account
COMPARING COSTS & EFFECTIVENESS OF A SURGICAL BYPASS PROCEDURE and CHELATION THERAPY

Ted Koppel
ABC NEWS - NIGHTLINE
1717 De Sales Street, NW.
Washington, D.C. 20036

SUBJECT: Nightline program of Wed., March 3, 1993
Discredit of a therapy discredits your reporting

Dear Mr. Koppel:

I have always held your Nightline program in high regard, with a sense of trust that you provide supportable factual material. At least 95% of the time I have no specific personal knowledge of the subjects of the program. I do have specific and personal knowledge of the chelation therapy portion of the March 3 program. Therefore, I was apalled at your coverage, because I would probably not be alive to write this letter if a friend had not told me about preventive chelation therapy. I also have had personal experience with the "crisis-mode spot repair" surgical approach to treating conditions caused by atherosclerosis.

On the March 3 program, you reported the visit of a physician to the Annandale Medical Services, Inc. in Virginia. The physician (Dr. Renner) formerly practiced in my town, in a capacity that one might label "average practitioner", that is, it may be presumed that he would be inclined to identify any "alternative medicine" that he did not practice as "quackery". He would probably be as inclined as my regular physician to ignore preventive treatment options and wait for a crisis that could be surgically spot-treated. The choice of this person to visit Annandale Medical would therefore seem to preclude an unbiased report.

The limited context of your program, "fraud, waste and abuse in medical testing", did not adequately report on test rationale, proven effectiveness or results of chelation therapy. In the interview with Dr. Patel at Annandale Med. Services, her comments on the therapy program were cut off and you cut to conclusions without regard for her effort to describe context and effectiveness of treatment (which can be substantiated by case histories). The follow-on comments by another physician included the term "quackery", and the conclusion of an uninformed viewer would clearly be that chelation therapy is quackery. You did not choose to report on the many tests performed as prerequisites to surgical arterial procedures (comparing actual relative costs) or on the actual damage that may be done to blood vessels by those tests...nor did you choose to report on many aspects of bypass surgery, such as mortality rates and the inadequate testing of those procedures. These facts about the medical and insurance system that perpetuates "costly crisis medicine" above all else, are becoming increasingly well-known.

Your report included statements that systemic chelation therapy (to clear all arteries of atherosclerotic blockage) have not been adequately clinically tested. You did not report that "spot-fixes" for the same blockage problems by surgical methods (and for open-heart surgery) have not been clinically tested either. Therefore, your report was not only unbalanced, it was clearly biased toward the "industry-standard" (and it's a huge industry that generates huge costs for people and insurance companies). Both the preventive and "crisis-fix" methods have produced positive results. Either

may be beneficial in specific cases. Chelation Therapy is not offered as an option by most physicians, even though patients SHOULD BE INFORMED OF VALID CHOICES. The most important point in comparing the surgical approach and chelation therapy for similar atherosclerotic conditions is:

> **The difference between these two approaches is that the surgical techniques correct symptomatic problems in specific locations, in contrast to chelation therapy, which treats the disease throughout the body.**

In addition, incorrect statements made on your program included:

• 1. COST OF CHELATION THERAPY is entirely "out of pocket" for patients.

FACT: Costs of the therapy are NOT entirely "out-of-pocket" for the patient. Blue Cross has paid for 24.5% of my treatment at the Annandale Med. Ctr.(nominal cost of supplements excluded). If I were eligible for Medicare, it would cover the infusion treatments as well as the tests associated with treatment.

• 2. UNNECESSARY TESTING FOR HIV.

FACT: HIV testing has beoome routine in most hospitals, clinics, etc...for obvious reasons.

• 3. TESTING FOR HEAVY METALS IN THE BODY IS UNNECESSARY

FACT: Free radicals and heavy metals are part of the "gunk" that blocks arteries. Their presence can be detected by appropriate specific tests, including hair analyses. Accumulation in the body can be a health problem. This problem is increasing as we introduce more into our general environment (for example: How much mercury is in the fish you eat?; and your healthy lettuce salad has high aluminum content because aluminum is released by widespread acid rain and is present in many of our vegetables in increasing quantities. (Ref: *Consumer Reports* & *Garbage*, as well as technical/professional literature)

• 4. TAKING VITAMINS & MINERALS DURING CHELATION THERAPY IS A WASTE OF MONEY.

FACT: (apply just a bit of common sense and/or do basic "homework", please). Both the minerals that have accumulated in arterial deposits and minerals needed throughout the body are removed by chelation therapy. It is essential to remove excessive accumulations, but during the process, the body still needs these substances that are removed...ergo, take 'em during the process. This is an insignificant "smoke-screen" point made by a critic. Responsible reporting requires reasonable examples and comparisons (how about costs/effects of anesthesia for the many hours required for bypass surgery?).

"REALITY CHECK" ON COSTS

I have summarized a comparison of the costs of two approaches to treatment for my own health problems, and the results of each approach. This is attached for your reference. Please review and it will become obvious why I was incensed by your coverage on March 3.

> Please note how the site-specific surgical approach may also increase both the costs of health insurance and out-of-pocket costs to patients. Therefore (again, by simple common-sense deduction) it is obvious that preventive and alternative medicine is derided by the medical industry because the highly remunerative "cut-and-paste" medicine is good business for providers.
>
> WHAT HAS HAPPENED TO HIPPOCRATIC PRINCIPLES?
>
> WHAT IS THE PURPOSE OF "HEALTH CARE" --
> *wellness of people or economic health of the hi-tech medical industry*
> *-- i.e., WELLNESS OR WEALTH?*

Cases are different, of course, but I am not an isolated case. I just have the dubious advantage of having experienced these two very different approaches to health care.

Incidentally, before chelation therapy (and after my aortal bifemoral bypass) my mind and body were operating so sluggishly due to lack of oxygen that I would not have been able to compile these costs or observations to share with you! I couldn't remember what I was doing from the top to the bottom of a page...or would be too tired to do it!

I can also provide you with medical records that document the improvement in my circulatory system -- specifically, the change in arterial blood flow through cerebral and carotid arteries that has resulted from chelation therapy. For example, the blood flow in an artery to the short-term memory center in my brain was about 85% blocked and flow was restored to nearly normal after only 20 NON-SURGICAL EDTA infusion treatments. The results are terrific -- I can remember again, almost "think straight", and can do little things like nailing upward, hiking, gardening, playing games and running around with grandchildren!

QUESTIONS:

- Which treatment would YOU choose if you had blocked arteries -- fixing one spot at a time and waiting in fear for the next crisis, OR living fully with a sense of security that your entire circulatory system is working?
- What is the HUMAN COST-BENEFIT RATIO of these two contrasted medical approaches, given similar cases?

Your coverage of this part of the March 3 subject was appallingly cavalier and biased -- but how many people know that? I do know this subject and unfortunately, I will now strongly question the credibility of every other Nightline report that I see...if we continue to watch it. Damn! Now I will presume that you pursue rapid-fire sound-bites rather than credible reporting. Dissillusioning. Sad! M.A.S.H. might be a better alternative!

Though I am, by training and experience, an artist-designer-producer inclined to be impulsive and emotional, my husband is a noted scientist and views the world quite objectively! He has read and agrees with my comments to you.

We hope that you will explore this subject more adequately. At least you should correct the grossly unfair and unwarranted impression that you purveyed about a proven, valuable and life-giving therapy. Fair and objective reporting could save productive happy years for many people. Biased reporting could COST many people those years (and many more dollars).

Thank you for the opportunity to comment.

Ann H. Csonka

703-471-4337 ANN H. CSONKA

NO ATTACHMENTS /ENCL. INCLUDED WITH 1999 Documents Copy

I concur. John M. De Noyer

JOHN M. DE NOYER, PH.D.

ENCLOSURES:

1. COST & BENEFIT SUMMARY: personal health problem/treatments
2. Booklet: "Avoid Bypass Surgery", a good overview of chelation therapy
3. Book: "Forty-Something Forever", a somewhat silly title, and not clearly-organized, but contains some valuable information. The author lives in Reston, Va. -- convenient for you?

CC:

Hillary Rodham-Clinton, Health Care Reform Task Force,
with enclosures 1, 2 and 3 above, plus videotape of Nightline program, Wed. Mar. 3

Sohini P. Patel, M.D. and John E. Stauch, Ph.D., Annandale Medical Services, Inc.

March 10, 1999

Dear Federal Trade Commission,

I would like to briefly inform you of two thoughts. The first is that my beloved mother's feet were saved from amputation thanks solely to intravenous chelation therapy. Her surgeon has stated there is no other plausible explanation.

Secondly, I would never have been adequately informed about this wonderful treatment had it not been for my freedom to obtain literature from the American Academy for the Advancement of Medicine.

While you may be concerned there aren't enough studies to confirm chelation's success (who's going to pay the expensive price tag for such studies?), I only know it worked 100% for my elderly mother and gave her back a full life! Why would you want to pick on a small organization that offers so much in the way of options to depressed individuals otherwise faced with amputations, dangerous heart surgeries, or death? Frankly, it seems unconstitutional.

I beg you to serve your intended purpose as our FTC, and stay out of the business of restricting American citizen's access to information about their medical alternatives. I suspect that in the long run you may find such a policy will reflect most poorly on your agency.

Sincerely,

Andree Henny

Andree Henny

Copy to Congressman Dan Burton, c/o US House of Representatives

LEAFORD BEARSKIN
Chief
Phone (918) 678-2297
Phone (918) 678-2298
Fax (918) 678-2944

JAMES R. BLAND
2nd Chief
P.O. Box 250
Wyandotte, OK 74370

March 31, 1999

The Honorable Dan Burton
Chairman, Committee on Government Reform
U.S. House of Representatives
Washington, DC 20510

Dear Mr. Chairman:

I have been advised that a portion of my medical record pertaining to chelation therapy has been forwarded to you as an example of results I have achieved from the use of chelation therapy. The results I have experienced have been outstanding. The Doppler tests you have seen on my medical condition verifies these statements.

When I first started taking chelation therapy, I was suffering from poor circulation in my feet and legs. My carotid arteries were partially restricted and I constantly felt tired and listless. My last Doppler test reveals my carotid arteries are satisfactory, my feet and lower legs are receiving much improved circulation, and I feel like a new man.

While taking chelation therapy treatments, I have talked to many many people who were receiving treatment at the same time I was. I have heard miraculous statements made by all of them of the benefits they have received by this treatment.

It is my opinion that the Food and Drug Administration and the American Medical Association should be investigating the outstanding results this treatment can give our American people. It is also my opinion that every person who reaches the age of fifty years should voluntarily start this treatment.

Sincerely,

Leaford Bearskin, Chief
Wyandotte Tribe of Oklahoma

P.S. I am an American Indian and am in complete favor of alternative medicine.

xc: Beth Clay