#### History of EDTA Chelation Therapy ACAM Chelation Workshop November 20, 2013-Palm Springs CA

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Special thanks to Terry Chappell MD & John Trowbridge MD for creating a timeline for EDTA chelation therapy

#### Disclaimer

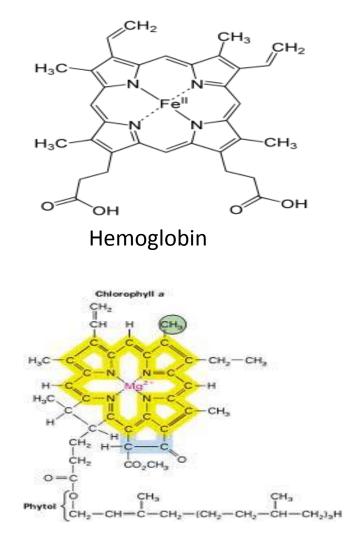
- According to federal law, the Federal Food & Drug Administration is responsible for determining claims for any substance used to treat, prevent or mitigate any disease or condition, such as cancer
- No such claims are being made during this lecture
- Information from this lecture is purely for informational purposes and no claims are being made

#### **Conflicts of Interests**

- At our Center, we do have a dispensary from which we offer patients the option of buying supplements that are recommended.
- They are free to buy most of these supplements elsewhere, such as at a Health Food Store or on the Internet
- Among the supplements, we recommend are Salvestrols, which are discussed in this lecture
- Patients may also purchase these supplements online

#### **Chelation & Chelating Agents**

- Greek word "chele" means claw
- Organic molecule binds to a cation in pincer-like fashion
- Forms a heterocyclic ring structure (1893-Werner)
- Chelated minerals-everywhere
  - Hemoglobin-Iron Chelate
  - Chlorophyll-Magnesium Chelate

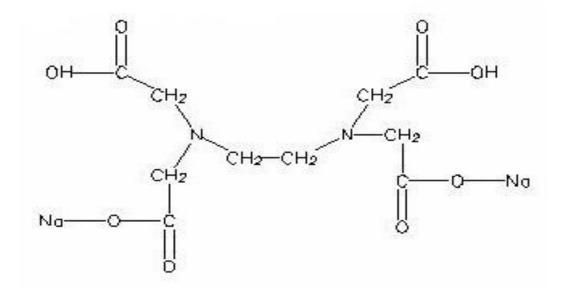


#### **Chelation Therapy**

- Accepted Treatment for 2 forms of EDTA:
  - Removal of toxic minerals like lead, or cadmium from the body, using calcium disodium EDTA
  - Treatment of hypercalcemia with disodium EDTA
- Controversial Treatment: Use of disodium EDTA to treat cardiovascular disease
  - Discovered in the 1950's to benefit patients with coronary artery disease by Norman Clarke and associates

#### Textile Industry Needs to Remove Calcium During Dying Process-1930's

- Synthesis of polyaminocarboxylic acids
- Disodium EDTA was one of these
- Patent granted in Germany in 1935



## EDTA & Calcium Homeostasis: Early 1940's

- Martin Rubin PhD & Frederick Bersworth involved with getting a patent for disodium EDTA in USA
- Laboratory use as an anticoagulant; still used today
- Purple-top tubes
- Rubin collected the world's literature on EDTA & helped get FDA approval for its use in lead poisoning (CaEDTA) & hypercalcemia (disodium EDTA)

#### EDTA for Lead Poisoning-1950's; Improvement in CV Disease

- Norman Clarke Sr. & Albert Boyle separately reported on heart disease improvement in many patients being treated for lead poisoning with disodium EDTA therapy
- Many of these patients suffered from lead toxicity as a result of exposure in auto industry
- Clark reasoned that since calcium was involved in atherosclerosis, perhaps EDTA would help coronary atherosclerosis

#### Chelation for Coronary Artery Disease Clark et al: 1956 and 1960

- Clark et al: 1956
  - 20 patients-16 unstable angina
  - Complete relief of angina in 17
  - 16 asymptomatic at 21 months
  - ECG normalized in 33%
- Clark et al: 1960
  - 76 patients 33 post MI
  - 87% of patients had 90% relief of angina
  - 2 year mortality half that expected
  - 20% had recurrent angina relieved with additional EDTA infusions

#### Book: *Metal Binding in Medicine* Marvin Seven, Editor-1960

- Book contained papers on chelation therapy from two major symposia held around that time
- Dr. Seven was associated with the NIH and had great interest in chelation
- Was killed in an auto accident in 1961
- First setback for chelation therapy

#### Dr. Kitchell & Meltzer: 2<sup>nd</sup> Setback for EDTA Chelation Therapy

- Cardiology specialists at Presbyterian Hospital in Philadelphia
- From 1959 to 1963, published series of studies on EDTA for heart disease
- Early papers were positive, though they noted that positive results often delayed after the onset of treatment
- 1963: Reappraisal article published in the American Journal of Cardiology
- Results were positive; but conclusions were negative
- Conventional physicians gave up on chelation therapy following publication of the Reappraisal article

#### Summary of Kitchell & Meltzer 4 Year Experience as Presented by Cranton

- 38 total patients—29 post MI
- 71% improvement of disabling angina
- 45% sustained improvement lasting up to 46 months without follow-up treatments
- Critique of article by Cranton & Frackelton ignored
- Rumors that pressure on Kitchell & Meltzer to publish the Reappraisal article
- Academics and conventional physician turned away from EDTA chelation therapy (2<sup>nd</sup> setback)

## Ray Evers MD-Chelating Physician in Alabama (1960's and 70's)

- Ray Evers MD Used EDTA extensively to treat all kinds of degenerative diseases and particularly cardiovascular diseases
- He sometimes treated patients daily with this treatment
- Although anecdotal reports were generally positive, some reports of severe adverse effects
- Dr. Evers won a precedent setting case with the FDA supporting a physician's right to treat patients with a drug (EDTA) for conditions not approved by the FDA (Off-label prescriptions) 1978

Carlos Lamar MD-Series of Positive Case Reports using EDTA Therapy-1960's

- Carefully documented reports showing benefits for cardiovascular disease and diabetes
- Documented cases of preventing amputation with gangrene of the foot
- Recommended supplements along with EDTA chelation therapy

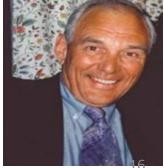
#### Abbott's Patent for Disodium EDTA Expires in 1969-3<sup>rd</sup> Setback

- When the patent for Edetate expired in 1969, economic motivation to promote disodium EDTA for cardiovascular disease ceased
- 3<sup>rd</sup> Setback for EDTA chelation therapy, the others being:
  - Death of Marvin Seven
  - Kitchell & Meltzer negative conclusions of their studies

#### American Academy of Medical Preventics (AAMP) formed 1972

- Harold Harper, Gary Gordon, Ross Gordon Bob Vance and Dave Roberts formed this organization to study, educate and promote EDTA chelation therapy for cardiovascular disease
- Later name changed to American College of Advancement in Medicine (ACAM) with an emphasis on broadening its scope (1985)
- AAMP or later ACAM presented workshops and conferences twice a year, including training in EDTA chelation therapy

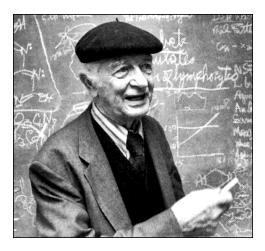




# Linus Pauling PhD-Champion of AAMP

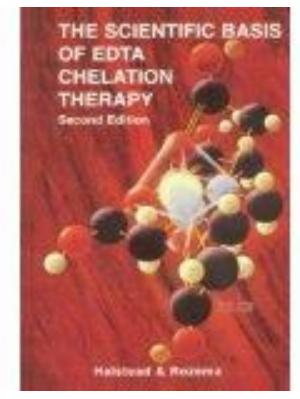
- Linus Pauling concept of orthomolecular medicine supports AAMP
- He is made lifetime member of AAMP in 1975
- Nutrition and supplements utilized by AAMP physicians to help their patients





#### Scientific Basis of EDTA Chelation Therapy: End of 1970

- 1976: Garry Gordon & Robert Vance: Paper on possible mechanisms of EDTA chelation therapy
- 1979-Dr. Bruce Halstead-Explores the molecular basis and mechanisms of the effects of EDTA (Updated by Dr. Ted Rozema in 1997)



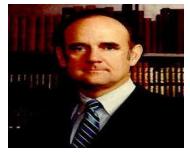
#### Richard Casdorph MD-Cardiologist-Articles of benefits of EDTA-Early 1980's

- Paper: "EDTA chelation therapy, efficacy in arteriosclerotic heart disease" J Holistic Medicine 1981: Showed improvement in ejection fractions of the heart with chelation
- Paper: "EDTA chelation therapy II, efficacy in brain disorders" J of Holistic Medicine, 1981: Improvement in cerebral circulation with EDTA chelation



#### McDonagh, Rudolph & Cheraskin: Numerous Clinical Studies 1980's

- McDonagh & Rudolph: Large chelation practice in Kansas City, Missouri
- Published 30 clinical articles on the use of EDTA chelation therapy; sometimes with Emanuel Cheraskin MD, DMS; all articles positive
- Many studies published in J. Holistic Medicine
- Some of the studies: positive effects of EDTA chelation therapy on:
  - Lipid metabolism
  - Carotid artery blood flow
  - Lung function
- Showed no adverse effect on bone density or renal function



Ed McDonagh DO



Charlie Rudolph DO, PhD



Emanuel Cheraskin MD, DMD

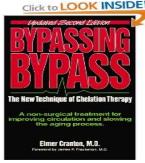
#### Controversy and Other Organizations Formed in the 1980's

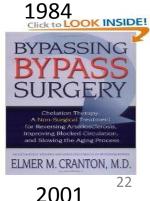
- AMA called for studies to see if EDTA chelation therapy worked
- Conventional cardiologists wrote several editorials critical of it
- American Board of Chelation Therapy (ABCT) formed to test and certify doctors giving chelation therapy (written and oral exams) in 1982 (offshoot of AAMP); in 2003 replaced by the American Board of Clinical Metal Toxicology (IBCMT)
- Great Lakes College of Clinical Medicine formed in 1983 to teach & research chelation and other cutting edge therapies; later called the International College of Integrative Medicine (ICIM)

#### Elmer Cranton MD-Book: "Bypassing Bypass" 1984

- In the 1980's coronary artery bypass surgery (CABG) was becoming more popular
- Elmer Cranton MD was Harvard Medical School Graduate-1964
- He was the 6th president of ACAM
- For many years, practiced in Virginia and then later in the state of Washington; Retired from active practice 2007, but continues to work on his website
- 1984: Book "Bypassing Bypass" published; written for the intelligent layman very well referenced; Suggests that EDTA chelation therapy is safer and more effective that CABG for coronary artery disease
- 2001: Book expanded and updated



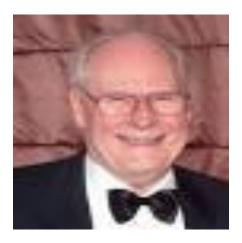




#### Frackelton & Cranton: EDTA and Free Radical Control

- James Frackelton MD-Died in 2012-Practiced EDTA chelation in Westlake Ohio with Derrick Lonsdale MD
- Frackelton was ACAM-7<sup>th</sup> President
- 1984: Cranton & Frackelton published a landmark paper proposing that free radical control was the primary mechanism for benefits of EDTA chelation therapy
- Cranton was ACAM's 6<sup>th</sup> President





#### Walter Reed Army Hospital Study: Not Completed

- In 1986, after complex negotiations, Walter Reed Army Hospital agreed to do a randomized, doubleblind placebo controlled study involving EDTA's effects on intermittent claudication
- Study was halted half way through, allegedly because investigators were called to serve in the Gulf War and didn't return to complete the study
- Following the war, a pharmaceutical company agreed to fund the entire project, but then reneged after hiring a long time opponent of chelation therapy as their new medical director.

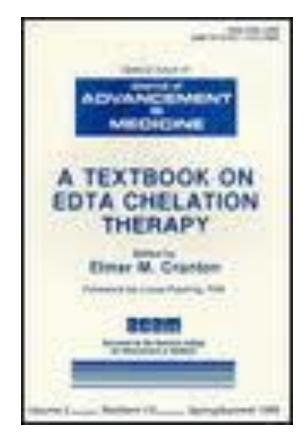
#### Efrain Olszewer MD & James P Carter MD, DrPH-EDTA Chelation Studies

- Ephraim Olszewer MD is from Brazil; published numerous books and articles on nutrition and EDTA
- James P Carter MD, DrPH: Was on faculty of Tulane University School of Public Health; practices in near New Orleans
- 1988-Published study in Medical Hypothesis: Retrospective study involving vascular disease: coronary, peripheral and cerebrovascular
- Patients receiving EDTA chelation therapy showed great benefits: No controls
- Small double-blind study 1990-benefits for peripheral vascular disease



## Journal of Advancement in Medicine Established 1988

- Journal printed a number of studies on controversial topics, especially EDTA chelation therapy
- Volume 2; Numbers 1 and 2 is shown here
- Reprinted many of the articles on EDTA chelation therapy previously discussed
- If EDTA Chelation Therapy is so Good, Why Is It Not More Widely Accepted? James P Carter MD, DrPh



#### Journal of the Advancement in Medicine: Two Editors

- First Editor was Elmer Cranton for a only one year
- Second & only other editor was Derrick Lonsdale, partner of James Frackelton in Ohio; for 10 years
- Frustrated because always had trouble getting sufficient articles
- Authors were reluctance to submit because not on Index Medicus
- Many good ideas not seen by many practitioners
- Ceased publication in 1999



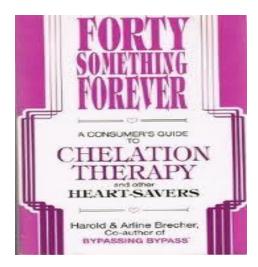
**Elmer Cranton** 

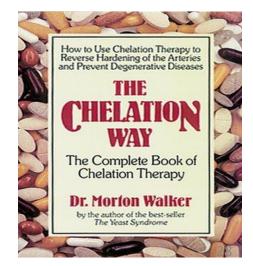


Derrick Lonsdale

## Popular Books on EDTA Chelation Therapy

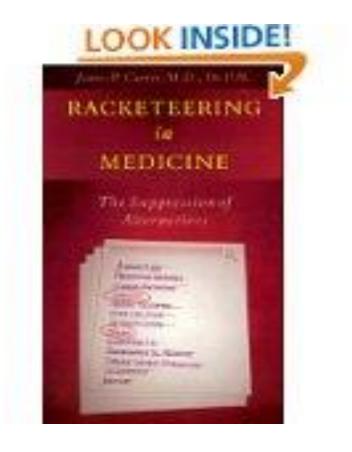
- Several popular books advocating use of EDTA chelation therapy: Writers passionate
- Arline Brecher: Toured the country & lectured
- Podiatrist and medical journalist Morton Walker also wrote a popular book
- Chelation patients came from other patients or from these books: Not from MDs
- Most physicians began to chelate because member of family did well; rare to find MD to turn away from it after starting to treat





## Racketeering in Medicine by James P Carter MD, D.Ph.

- Dr. Carter elaborates on his paper as to why EDTA chelation therapy is not more accepted
- Discussed medical politics
- Turf struggles between medical specialties & factions in health care professions
- Book published in 1992



#### Early 1990's: Three Small Conventional Studies Critical of EDTA Chelation Therapy

- All published in major journals
- These articles were severely criticized by advocates of EDTA chelation therapy for methodological issues & conclusions not justified by data
- Studies allegedly double-blinded with placebo, but there were questions about this as well
- All concluded no evidence of benefit
- Basically supported the quackbusters & opponents of chelation

## Positive EDTA Chelation Therapy from Denmark in 1992

- Retrospective study of 470 patients who received EDTA chelation therapy in Denmark
- Vast majority-significant improvement
- Of 65 on waiting list for CABG, only 7 were given the procedure during or after chelation therapy
- Of 27 scheduled for amputation due to severe peripheral vascular disease, only 3 needed the surgery
- Study done over 6 years & chelation treatment saved the Danish Government about 3 million dollars



Claus Hancke MD & Flytlie

## Meta-Analysis on EDTA Chelation Therapy Studies

- Chappell & Stahl published a meta-analysis study in 1993 involving EDTA therapy for CV disease
- They Identified 40 published studies and 19 met the criteria they had established
- More than 22,000 patients were included
- A high correlation coefficient of 0.88 was established for the statement that EDTA chelation therapy was helpful to patients with cardiovascular disease

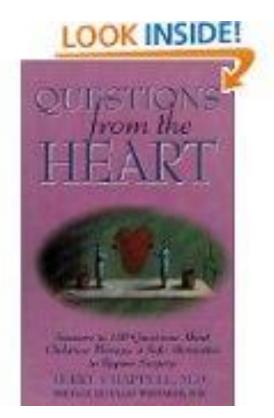


 88% of the patients showed improvement with objective testing

L. Terry Chappell MD

## Questions from the Heart by Terry Chappell MD-1995

- Meta-analysis of published studies in appendix
- To avoid publication bias, Dr. Chappell conducted another Meta-analysis from case reports on patients not included in published studies
- Results the same
- Also, reprinted in appendix of this book
- 100 Questions patients might ask about chelation with answers-ideal for patient considering chelation



#### Protocol for EDTA Chelation Therapy & Historical Overview-1996

- Overview, Historical Background and Current Status of EDTA Chelation Therapy for Cardiovascular Disease in 1996 by Michael Schachter MD (J. of Advancement in Medicine; Volume 9, Number 3)
- Protocol being used in the EDTA chelation workshops was refined & published in the Journal by Ted Rozema in 1997 (J. Advancement in Medicine; Volume 10, Number 1)



### Quackbusters: See www.quackwatch.com

- Organization that was critical of any practice outside of conventional medicine, including chelation therapy
- Long history of attacks on homeopathy, naturopathy, chiropractic, others
- Encouraged action of Medical Boards to discipline chelating physicians
- Encouraged patients to sue



Victor Herbert MD-Deceased



Stephen Barrett MD

## Quackbuster Activity Against Chelation Therapy

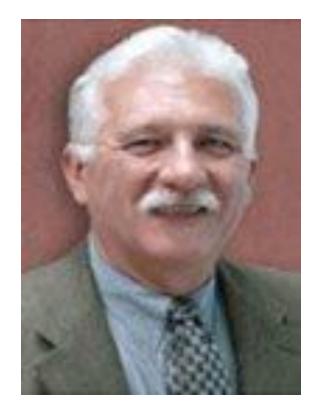
- Infiltrated the Federation of Medical Boards & encouraged disciplinary actions against chelating physicians all over the USA
- ACAM has a legal team now that helps to protect members
- California: Attempted to make EDTA chelation therapy illegal; ACAM representatives testified & the proposed law was defeated (Late 1990's)

# Federal Trade Commission (FTC) Fiasco; Late 1990's

- FTC brought legal action against ACAM for a statement in its brochure that EDTA chelation therapy was safe & effective for atherosclerosis
- ACAM submitted 100 articles and spent over a million dollars in legal fees; BUT
- FTC insisted that randomized double-blind studies had to be done for such a claim
- ACAM gave up & agreed not to make that statement

# Stephen Olmstead's Monograph on EDTA Chelation Therapy

- Late 1990's-Stephen Olmstead MD, cardiologist wrote a scholarly 100 page monograph on the chemistry, mechanisms and scientific evidence for EDTA chelation therapy
- Said preponderance evidence suggests EDTA chelation beneficial for peripheral and possibly cardio vascular disease
- This document was distributed to every medical school library in the United States



#### Stephen Olmstead MD

#### Congressman Dan Burton Pressures Govt Agencies to Study Chelation Therapy-1999

- Congress Burton, Chairman of the Congressional Oversight Committee held hearings about EDTA chelation therapy
- Testimony from NIH representatives
- Testimony from prominent chelating physicians like Terry Chappell & Ted Rozema; Olmstead monograph offered
- Conclusion was that a large scale study was clearly indicated
- <u>http://www.chelationtherapyonline.com/</u> <u>articles/p12.htm</u>
- Subsequently, the NIH sent out a call for proposals



#### Congressman Daniel Burton

#### NIH Trial to Assess Chelation Therapy (TACT)

- The first proposal to the NIH was rejected; but the 2<sup>nd</sup> one was accepted
- Gervasio (Tony) A. Lamas MD, a prominent cardiologist researcher at the University of Miami (now part of Columbia University) was chosen to conduct trial
- University medical schools and chelation therapists agreed to participate



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Gervasio (Tony) Lamas MD
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# TACT: Sponsors & Type of Study

- Sponsor: <u>National Heart, Lung, and Blood Institute (NHLBI)</u>
- Collaborator: <u>National Center for Complementary and</u> <u>Alternative Medicine (NCCAM)</u>
- 30 million dollar study
- > 120 sites; our office participated in the trial; patients received a total of 40 infusions (30 weekly & 10 monthly)
- Randomized double-blind, placebo controlled 5-year study (turned out to be much longer); patients followed for 3 years after completion of treatment
- Adverse events in patients receiving EDTA or placebo were monitored carefully

## TACT Hurdles

- Many cardiologists discouraged participation
- Enrollment proceeded slowly
- Quackbusters complained and said trial should be stopped immediately & the trial was delayed temporarily
- Same group convinced a reporter in Chicago Tribune to write a negative article even though results not yet released
- Around this time, an autistic child was given disodium EDTA as a push and died (reported by CDC); NEVER GIVE DISODIUM EDTA AS A PUSH as it may cause hypocalcemia & cardiac arrhythmias

# TACT Study Vindicated, Resumes & is Completed

- Complete investigation resulted in conclusion that nothing wrong with TACT and it resumed
- > 1700 patients enrolled in study
- Results presented at AHA meeting on Nov 4, 2012
- Results: EDTA treatment group showed statistically significant benefits and the paper was published in JAMA on March 27, 2013
- Statistically significant subgroups involved diabetics and the location of the coronary artery disease, though other parameters positive in right direction

# Conservative Conclusions of Gervasio (Tony) Lamas MD

- EDTA chelation therapy appears to be safe
- The treatment in the study (EDTA, ascorbate & other components) showed some evidence of benefit for post-MI patients already on evidence-based therapy
- The findings were unexpected and additional research is needed to confirm or refute our results and explore possible mechanisms of therapy
- TACT does not constitute evidence to recommend the clinical application of chelation therapy

# EDTA Chelation Therapy Treatment Controversy Rages On

- Quackbusters, some conventional medicine sources and mainstream media begin to spin TACT study in a negative way, while others are positive
- Major discussions since the AHA presentation and after the JAMA article
- Medical professionals who advocate EDTA chelation therapy generally refrain from making any claims publically.

#### "Chelation Therapy: What To Do With Inconvenient Evidence?" Forbes Magazine

- Harlan Krumholz MD: Professor of cardiology, epidemiology, and public health at Yale and director of the Center for Outcomes Research and Evaluation
- Testified against Merck in Vioxx and showed excessive diagnostic radiation causes cancer; but still mainstream



Harlan Krumholz MD

- Forbes Magazine article on TACT: "However, this study has opened my mind to the possibility that there may be something more to this therapy than I originally thought "
- Conflicts of Interest: No pharmaceutical companies

#### Concerns About Reliability in the Trial to Assess Chelation Therapy (TACT)-JAMA

- CV Medicine at the Cleveland Clinic
- Published-JAMA in same issue as TACT
- Main criticism is that >60% of study sites run by integrative practitioners
- High dropout rate in placebo group
- Suggests unblinding took place
- Suggests ignore the study



 Conflicts of Interests: Dr Nissen reports grants/grants pending from Lilly, the Medicines Company, Amgen, Takeda, Novo Nordisk, Vivus, Orexigen, Novartis, Pfizer, and Resverlogix; May be next head of the FDA

# Current Lead Quackbuster: David H Gorsky MD, PhD-Surgical Oncologist

- Criticizing the Trial to Assess Chelation Therapy (TACT) is defending sciencebased medicine (Orac)
  - Shame on JAMA! Shame on NCCAM
    and the NHBLI for funding this
    nonsense! And, yes, shame on all the
    shruggie cardiologists who are
    apparently unwilling or unable to look
    beyond the hype.

(<u>http://scienceblogs.com/insolence/2013/03/28/criticizing-the-</u> <u>trial-to-asess-chelation-therapy-tact-is-defending-science-based-</u> <u>medicine</u> )

# Possible Influence of Pharma on David Gorski MD

- David Gorski's possible influence by the pharmaceutical company Sanofi-Aventis, which issues grants to Dr. Gorski's department at Wayne State University
- For a series of E-mails related to this issue as it relates to Gorski's attack on anyone who questions vaccines, see Jake Crosby's article with Dr. Gorski's responses at:
  - http://www.ageofautism.com/2010/06/david-gorskis-financialpharma-ties-what-he-didnt-tell-you.html

#### Retrospective Analysis of Events Related to EDTA Chelation-Terry Chappell MD

- 2005: Chappell and seven colleagues published a retrospective study showing patients with known CV disease treated with EDTA had a much lower incidence of cardiac events (MI, need for surgery, etc...) than a comparable group treated with conventional cardiac care
- Conventional care included: Angioplasties, coronary artery bypass surgery and medical management

# Dr. Chappell's Study (continued)

- Same endpoints as TACT trial, but much smaller study and not prospective, randomized or doubleblind with placebo
- Mirrored the results of TACT showing that EDTA chelation therapy appeared to prevent future cardiac events; Study published 7 years before presentation of TACT results
- Both studies showed that the main event that occurred was an invasive procedure (angioplasties, stents, CABG)



L. Terry Chappell MD

### Comparison of Dr. Chappell's Retrospective Cardiac Events Study with TACT

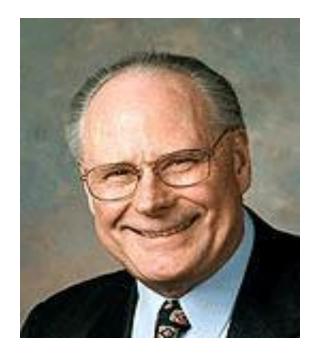
	Retrospective	ТАСТ
Patients Treated	220	854
Sites	8	134
Age	64	65
Previous Cardiac Surgery	71	683
Number of Treatments	58	32
Years of follow-up	3	3 to 5 (or 2)
Deaths (Predicted or Placebo	0 (6)	87 (93)
Heart Attacks	0 (15)	52 (67)
Bypass, Angioplasty/Stents	8 (47)	130 (157)

# Possible Reasons for Retrospective Results Being Better than TACT

- (1) TACT group patients at more severe risk as evidenced by them having more vascular surgery prior to the treatment;
- (2) Retrospective group received on the average a almost twice the number of EDTA infusions;
- (3) Retrospective group had more maintenance treatments
- (4) Probably much more emphasis on nutrition and lifestyle changes in the retrospective group
- (5) Retrospective group probably received much more elaborate supplement program than the TACT group.

# More Information about Disodium EDTA Chelation Therapy

- <u>http://drcranton.com/chelation.htm</u>
  - Slide presentations
  - Specific papers
  - Patient testimonials
  - Videos
  - Lectures
  - Book: A Textbook of EDTA Chelation Therapy: Edited by Cranton; Available from Amazon



### Presidents of ACAM

	ACAM Presidents	
1. Harold Harper MD (D)	8. Richard Casdorph MD	15. Allan Magaziner DO
2. Garry Gordon MD, DO	9. Michael Schachter MD	16. Kenneth Bock MD
3. Bruce Halstead MD (D)	10. L. Terry Chappell MD	17. Jeanne Drisko MD
4. Murray Susser MD	11. Ralph Miranda MD	18. Eleanor Hynote MD
5. Ross Gordon MD (D)	12. Michael Janson MD	19. Neil Speight MD
6. Elmer Cranton MD	13. Ted Rozema MD	20. Allen Green MD
7. James Frackelton	14. Ronald Hoffman MD	

# Where Do We Go From Here?

- Controversy will continue with strong attacks against EDTA chelation therapy for CV disease and pressure not to do any more studies
- Medical system is failing both clinically and financially largely because of the complicated relationships among corporations, governmental agencies, organized medicine and the media
- How can all of this be reversed and the health system be improved? (It won't be easy!!!)