



SCIENCE, FADS, AND APPLIED BEHAVIOR ANALYSIS by Dr. Thomas Zane, Trustee of the Cambridge Center

Chelation Therapy: Warning by the Food and Drug Administration

The United States Food and Drug Administration (FDA) released a press statement (2010) concluding that over-the-counter chelation remedies are considered unapproved drugs and devices, and that unproven claims about their effectiveness will be considered a violation of federal law. Specifically, the FDA targeted eight companies that promote chelation therapy as effective at solving numerous health problems. Although the FDA has approved chelating products only for lead poisoning and iron overload, these particular companies market chelation for problems other than those two metals, and also market screening tests claimed to detect the presence of heavy metals in the body.

This unambiguous and welcomed report provided an opportunity to review the history of chelation therapy, its use as an autism treatment, and how the methods of science and adherence to evidenced-based treatment remain the gold standard that service providers must strive to maintain.

Generally speaking, chelation therapy involves administering (usually by injection) ethylenediamine tetraacetic acid (EDTA; American Heart Association, 2010). Essentially, EDTA chelates (binds) with heavy metals in the body, and then excretes them in the urine. This therapy is frequently used in the case of heavy metal poisoning, such as with lead or mercury. A chelation treatment could last 2-4 hours and costs between (\$50-100), with a patient receiving 5-30 treatments in the first month (American Heart Association, 2010).

Chelation therapy has been proposed for several medical conditions, including cardiovascular diseases (such as atherosclerosis), Parkinson's disease, Alzheimer's disease, macular degeneration, and Autism Spectrum Disorders (ASD). In 2007, the Centers for Disease Control and Prevention reported that approximately 111,000 people aged 18 years and older then used some form of chelation therapy (National News, 2010).

The argument for why chelation therapy may be helpful for persons with ASD stems from the use of mercury in vaccines (Holmes, 2010). Mercury, as well as other metals, has been shown to be toxic to humans in high levels. Thimerosal was used in vaccines given to young children. Thus, the argument goes that ASD could be due in part to the presence of heavy metals in the body. The solution would be to eliminate them from the individual via chelation.

When considering whether chelation could be an effective treatment for autism, one must consider three questions: (1) can autism be caused by toxicity to metals, (2) is chelation dangerous, and (3) is chelation actually effective in improving autistic symptomatology? With regards to the first question, there is no evidence that persons with ASD have significant levels of heavy metal in their bodies. Given the small amount of thimerosal in vaccines, the fact that thimerosal was eliminated from vaccines several years ago, and the continuing increasing incidence of autism, the believability of this premise is quite weak.

Chelation has been shown to be potentially dangerous to humans. The American Heart Association (AHA; 2010) notes that chelation can result in kidney failure, bone marrow depression, shock, low blood sugar, convulsions, cardiac arrhythmias, and respiratory arrest. The FDA (2010) warns of potential dehydration, and the AHA, FDA, and Brown, Willis, Omalu, and Leiker (2006) all report the potential for death by undergoing chelation therapy. It is clearly a risky treatment.

With regards to effectiveness, chelation therapy lacks a foundation of quality research showing effectiveness in improving any illness or condition. The effectiveness of any chelation intervention is currently unsubstantiated. The FDA and the AHA have official policy statements against chelation therapy having scientific evidence of effectiveness. The studies that exist show a lack of effect. For example, in the 1960s, a small study was conducted testing whether or not chelation therapy could improve cardiovascular disease. However, after two participants died and there was no obvious improvement in the others, the study was terminated (AHA, 2010). In other research, EDTA was no more effective than placebo sugar pills (AHA, 2010). The AHA Clinical Science Committee has reviewed the available literature on the use of chelation in the treatment of arteriosclerotic heart or blood vessel disease and finds no scientific evidence to demonstrate any benefit. And along with the AHA and FDA, numerous other organizations have come out against chelation therapy, including the American College of Physicians, the National Heart, Lung, and Blood Institute, the National Institutes of Health, and the American College of Cardiology.

In one sense, the preponderance of professional organizations all supporting the same conclusion about chelation is very compelling and powerful. If there is one fad treatment that has little to no empirical evidence to support its use, it seems to be chelation therapy. It's



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inspiring to note that these diverse professional organizations have looked at the quality of the science behind chelation therapy and all have agreed on both the necessary criteria for empirical evidence, and that chelation therapy is found wanting in that regard.

However, chelation therapy is not going away quietly. Senel (2010) surveyed Turkish parents of children with ASD and chelation therapy was mentioned as one of the top five frequently used complimentary and alternative medicines. The American College for Advancement in Medicine (ACAM; dedicated to "... educating physicians and other health care professionals on the latest findings and emerging procedures in complementary, alternative, and integrative (CAIM) medicine") has launched a certification program to become a certified chelation therapist. Relatedly, Golnik and Ireland (2009) surveyed physicians and found that many of the respondents would not rule out using CAIM therapy with their patients. Although 61% of surveyed physicians admitted they would discourage the use of chelation, still 12% would accept its use, and 26% reported they were not knowledgeable enough to make a recommendation. Sadly, 10-40% of the physicians surveyed acknowledged that they would accept a family's use of CAIM treatments even those these treatments were not yet thoroughly tested for effectiveness or safety.

But, except for the irreducible few believers, chelation therapy has been debunked. Science has done its job and exposed this type of therapy as the dangerous fad it is. The methods of science, and the standards for empirical evidence with which behavior analysts are familiar – operational definitions, controlled experimentation, measurement reliability, and replication – have been used to discover the facts as they are known about chelation therapy. Other investigators can apply these same criteria of evidence and use the scientific method to investigate other treatments that have the aura of effectiveness, but in reality have not yet been fully vetted.

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