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On Drugs and Therapeutics

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Nonstandard Uses of Chelation Therapy

Chelation therapy involves oral administration, intravenous infusion or intramuscular injection of drugs that increase excretion of heavy metals. The Medical Letter's last article on this subject found no evidence that it was effective for treatment of cardiovascular disease.¹ Since then, off-label use of chelation therapy has expanded to include treating children with autism and adults with Alzheimer's disease, cancer and other chronic diseases.²

RATIONALE — Proponents of chelation therapy assert that heavy metal toxicity is an underlying cause of disease and that detoxification with chelation therapy is beneficial. They claim that autism, for example, is caused by accumulation of mercury from thimerosal, a preservative used in several vaccines.³ (Thimerosal was eliminated from virtually all childhood vaccines several years ago, but autism rates have not declined.⁴)

PROVOKED URINE TESTING — The most common diagnostic test preceding chelation therapy is a urine test in which a timed specimen is collected after administration of a chelating agent.⁵ This procedure transiently increases elimination of lead and mercury in urine to levels which chemistry laboratories may report as "elevated" or "very elevated."

CHELATING DRUGS — Penicillamine (*Cuprimine*) is an oral chelating agent approved by the FDA for use in Wilson's disease and rheumatoid arthritis; it can cause fatal aplastic anemia. Succimer (*Chemet*) is an oral chelating agent FDA-approved for use in lead poisoning; it can cause gastrointestinal symptoms, transaminase elevations and neutropenia. Dimercaprol (*BAL*) is a chelating agent formulated in peanut oil that must be injected deep intramuscularly. Used mainly for treatment of arsenic, gold and mercury poisoning, it causes pain on injection, fever in about 30% of children, and an increase in blood pressure accompanied by tachycardia. Edetate calcium disodium (EDTA; *Versenate*) was approved

many years ago to treat lead poisoning and is still used for this purpose. It can cause nephrotoxicity and renal failure.

Edetate disodium (also called EDTA; *Endrate*) was approved many years ago as an emergency treatment for hypercalcemia. When injected intravenously, it binds to calcium and can cause fatal hypocalcemia. In 2008, after two deaths were reported,⁶ the FDA issued a public warning and the manufacturers of the drug withdrew their New Drug Applications, which means that it is no longer FDA-approved or legally marketable for any purpose, but some compounding pharmacies still prepare and sell it.

COSTS — The protocols used by chelationists differ from standard protocols for treating lead poisoning. Standard therapy is guided by blood levels and completed within a few weeks. Chelation therapy for unsubstantiated uses may be administered over many months or even years. Courses of 20-50 infusions are common, according to Medical Letter consultants, and some patients have received many more. Intravenous chelation commonly costs from \$100 to \$300 per session, but patients have reported spending over \$100,000 for additional nonstandard products and services at chelation clinics.

CONCLUSION — Medical Letter consultants believe that the use of chelation therapy in non-standard protocols for unsubstantiated indications should be discouraged. The results of provoked urine testing are not an acceptable basis for such treatment. □

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6. CDC. Deaths associated with hypocalcemia from chelation therapy – Texas, Pennsylvania, and Oregon, 2003-2005. *MMWR Morb Mortal Wkly Rep* 2006; 55:204.

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