



STATE OF NEW YORK DEPARTMENT OF HEALTH

Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York 12237

Richard F. Daines, M.D.
Commissioner

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Executive Deputy Commissioner

July 2010

To: Local Health Departments, Medical Providers and Hospitals

From: NYSDOH Bureau of Maternal and Child Health

**Alert to Parents and Health Care Providers Regarding Over-the-Counter
Chelation Therapy Agents**

Please distribute to all staff in Obstetrics & Gynecology, Primary Care, Family Medicine, Pediatrics, Emergency Medicine, Internal Medicine, Gastroenterology, Laboratory Medicine, Neurology, Occupational and Environmental Medicine and Complementary or Alternative Medicine. Please also share with your non-hospital based colleagues.

This notice contains important information for health care providers who are managing children with lead poisoning and autism spectrum disorders. Recently, the US Food and Drug Administration (FDA) issued a statement concerning the use of over-the counter (OTC) “chelation therapy” products promoted for home use to prevent or treat disease. The New York State Department of Health (NYSDOH) is sharing this important information because of concern about 1) the online marketing without FDA approval of these non-prescription chelation products for consumer purchase, and 2) the potential risks of side effects associated with use of these agents without the oversight of a licensed medical professional.

On February 4, 2010, the FDA issued the following statement in italics below, regarding OTC chelation therapy products.

The US Food and Drug Administration FDA advises consumers to be wary of so-called “chelation therapy” capsules, tablets, or suppositories marketed over-the-counter (OTC) that are promoted for home use to prevent or treat diseases. Various forms of “chelation” therapies are purported to cleanse the body of chemicals (such as mercury-containing chemicals) or to improve the cardiovascular system. “Chelation” has been proposed as a treatment for autism or hardening of the arteries; and for many other serious conditions. Many of these products are promoted on the internet.

FDA has never approved any marketing application for a nonprescription oral or rectal chelation product. Such products have not been studied in adequate and well-controlled clinical trials, and clinical data sufficient to support either the safety or efficacy of drugs used for these “chelation” purposes has not been reviewed by FDA. These products are illegally

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marketed and have not been subject to the rigorous manufacturing scrutiny required for FDA-approved products. FDA is concerned about the potential direct health risks posed by these products because of the lack of safety information, and because serious side effects can occur when a “chelation” product is used without the oversight of a licensed health-care professional. The products also pose serious indirect health risks to patients using these products that may be foregoing effective conventional medical treatment. [Emphasis added.]

Families of children and adults with autism spectrum disorders are encouraged to speak to their health-care professional about treatment options, including pursuing new therapies with clinical investigators engaged in research monitored under an Institutional Review Board approved Investigational New Drug application, to make sure the risks are as low as possible and are worth any potential benefits.

Chelation therapy for lead poisoning requires management by medical practitioners aware of the potential side effects of treatment. The NYSDOH Lead Poisoning Prevention Program (LPPP) strongly recommends consultation with a Regional Lead Resource Center (RLRC) for questions concerning chelation therapy and/or other medical management considerations for lead poisoned children. A list of NYS RLRCs is attached to this message.

For more information about lead poisoning prevention, visit the following websites:

New York State Department of Health

www.health.state.ny.us/environmental/lead/

New York City Department of Health and Mental Hygiene

www.nyc.gov/html/doh/html/lead/lead.shtml

For more information about early intervention and autism spectrum disorders, visit:

New York State Department of Health

http://www.nyhealth.gov/community/infants_children/early_intervention/index.htm

http://www.nyhealth.gov/community/infants_children/early_intervention/autism

New York City Department of Health and Mental Hygiene

<http://www.nyc.gov/html/doh/html/earlyint/earlyint.shtml>

**LEAD POISONING PREVENTION PROGRAM
REGIONAL LEAD RESOURCE CENTERS**

**WESTERN NY LEAD POISONING
PREVENTION RESOURCE CENTER
(KALEIDA HEALTH/WOMEN &
CHILDREN'S HOSPITAL OF BUFFALO)**
Judge Joseph S Mattina Community Health Ctr
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