In 2011, an adult white non-Hispanic male seen at a neurology clinic for a two-year follow-up of a previous intracranial hemorrhage demonstrated worsening neurological deficits. A heavy metal panel reported a blood lead level of 936 µg/dL. The patient reported ingesting two ayurvedic products named in India since June 2010. Test results for one product labeled "Bhisma" revealed 19,400 µg/dL lead and 1,430 mg/Kg arsenic. More than 100 adults living in the rural, predominantly Caucasian, community who also used ayurvedic products were tested over the following six months. The majority of 200 ayurvedic product samples were submitted for heavy metal testing. The company in India supplying the products reported 1,600 customers in the USA and Europe.

### BACKGROUND:
According to a 2009 National Institutes of Health National Center for Complementary and Alternative Medicine (NCCAM) study, complementary and alternative medicine (CAM) is used by 38% of the U.S. adult population. People of all backgrounds use CAM, but use is greater among men and those with higher levels of education and income. Non-American, nonrenalimal, natural products are the most commonly used therapy among adults – 17.7%.

### FINDINGS
45 out of 117 Iowans 16 years of age or older tested between April 2011-2012 who declared using ayurvedic products were identified as cases with an elevated blood lead level (BLL) of 10 µg/dL or greater. Four adults had elevated blood mercury levels (10 µg/dL or greater). The mean age of the Iowa cases was 62 years (range 45-74). The mean initial EBL was 37 µg/dL (range 11-94) with 32 of 45 (71%) having initial EBL results of 25 µg/dL or greater.

### Source of Heavy Metal Exposure

#### Ayurvedic Medicine

**Excerpts from NCCAM online materials**

Ayurvedic medicine is one of the oldest of the world’s oldest medical systems. It originated in India and has evolved over thousands of years. Ayurvedic medicine continues to be used in India, where nearly 80 percent of the population uses it exclusively or combined with Western medicine. Ayurvedic practice involves the use of medications that typically contain herbs, metals, minerals, or other materials.

In the United States more than 200,000 U.S. adults had used Ayurvedic medicine in the previous year according to the 2007 National Health Interview Survey.

### PRODUCT TESTING

Product testing revealed high levels of lead, mercury, arsenic, and other heavy metals in numerous products. Analysis was performed by the State Hygienic Laboratory of the University of Iowa, Ankeny using ICP-MS, and the EPA 6020B method. Many dilutions were required due to the high levels encountered. Subsequent limited mercury speciation testing by Thomas Fisher Scientific Inc. found no organic and low inorganic mercury in the five products tested. The mercury present in the 97 products was most likely elemental, explaining the lack of acute mercury poisoning experienced by this cluster of adults.

### LIMITATIONS

The ability to correlate specific product exposure to persons with abnormal test results was limited. Many of the people using the ayurvedic products declined to participate in the retrospective investigation. Most products submitted for testing had handwritten labels and were not identified by a lot or batch number from the supplier. Some products with similar or identical names had dissimilar test results. For this reason, a list of the products tested by name and their test results is of limited value as a predictor of risk.

In the United States, Ayurvedic medications are regulated as dietary supplements. As such, they are not required to meet the safety and efficacy standards of traditional medicines. For this Iowa cluster, the FDA had limited ability to intervene because the products were reported by the users to be obtained directly from a supplier outside of the USA. Ayurvedic products purchased from the county of residence in Iowa did not demonstrate heavy metal contamination.

### REFERENCES

FDA: Use Caution with Ayurvedic Products. October, 2008


### ACKNOWLEDGEMENTS

The author would like to thank the following people for their assistance during this investigation and report:

Laurenza Furer, M.D., M.S., University of Iowa professor of internal medicine, occupacional, and environmental health.

Michael Wiltchen, Ph.D., Donald Simmons, Ph.D., and Steve Bentholtz, ICP-MS analyst, State Hygienic Laboratory at the University of Iowa.

Robert Walker, M.S., Iowa Department of Public Health.

### CONCLUSIONS – PUBLIC HEALTH CONCERNS

The clinic outside of the U.S. supplying the products acknowledged a problem with contamination by a sub-contractor, in part due to the findings of Iowa metals. Products are meant to be entirely herbal. These products from the rasa shara class of ayurvedic medications were demonstrated to contain mercury with herbs, which they claim would have had no toxicity if the sub-contractor had manufactured them correctly using methods and techniques. The products containing heavy metal can be rendered safe for human consumption remains controversial. There was no clinical result of the product. This was the second known lead poisoning caused by this clinic’s products in Iowa since 2007.

The use of alternative medicine practices and products continues to expand into the mainstream population in the USA. Users may have an increased risk of exposure to toxic substances, especially when the products are manufactured outside of the USA.

Consumers and medical practitioners need to be aware of the potential risks and proactively discuss the use of all supplements to determine the need for testing or intervention.