

National Ayurvedic Medical Association (USA)
Ayurvedic Practitioners Association (UK)
Verband Europäischer Ayurveda-Mediziner und -Therapeuten (Germany)

Joint Response to the August 2008 JAMA Article

A study conducted “to determine the prevalence of Ayurvedic medicines available via the Internet containing detectable lead, mercury, or arsenic” has concluded that “one-fifth of both US-manufactured and Indian-manufactured Ayurvedic medicines purchased via the Internet contain detectable lead, mercury, or arsenic.” The article can be found in the August 27 issue of *JAMA*, the *Journal of the American Medical Association* (Vol 300, No.8 p915) titled “Lead, Mercury, and Arsenic in US- and Indian-Manufactured Ayurvedic Medicines Sold via the Internet.”

The National Ayurvedic Medical Association (NAMA), Ayurvedic Practitioners Association (APA) and Verband Europäischer Ayurveda-Mediziner und -Therapeuten (VEAT) welcome all efforts to enhance quality and safety of Ayurvedic products but recommend that this study be interpreted with caution. We recognize and support the need for effective quality control in the use of all Ayurvedic products and promote the use of suppliers who use Good Manufacturing Practices. We agree that there is clearly a challenge with heavy metals throughout the food chain as a whole.

“Metals,” “heavy metals” and “toxic metals” are all terms used for a group of elements which include lead, mercury, arsenic and others that are known or suspected to cause toxicity in certain forms and at certain doses. The detectable *presence* of these elements in dietary products and food or water is not the same as *toxicity*. These elements are present in many of our everyday foods and as shown in this study, Ayurvedic dietary supplements. In the case of foods and herbal products their presence can occur because: 1) they are naturally occurring in the soil, water and air, 2) from pollution as a result of human activity where in both cases these elements are taken up by the plants, 3) from contamination in the manufacturing process, and 4) these elements are intentionally added. Toxicity is the result of too much of the specific form of metal being ingested over time.

In the U.S, there is no current national law precisely regulating the amount of lead, mercury and arsenic in dietary supplements. There are various opinions on what the maximum safe daily limits for lead, mercury and arsenic in dietary supplements should be. For example, four authorities are mentioned in the *JAMA* article and their limits vary considerably. They are: the California Safe Drinking Water and Toxic Enforcement Act (California Proposition 65) that gives a maximum level of 0.5 µg /day for lead as a reproductive toxin; The American National Standards Institute (ANSI)/National Sanitation Foundation (NSF) International Dietary Supplement Standard 173 that gives a maximum level for lead at 20 µg /day, mercury at 20 µg /day and arsenic at 10 µg /day; the US Environmental Protection Agency (USEPA) that gives a maximum level of 21 µg /day for inorganic mercury and 21 µg /day for inorganic arsenic for a 70 kg adult; and The Food and Agricultural Organization / World Health Organization Joint Expert Committee on Food Additives (FAO/WHO) that give total dietary intake maximum levels of 250 µg /day for lead, 50 µg /day for mercury and 150 µg /day for arsenic for a 70 kg adult. In the absence of specific standards it is difficult for the dietary supplement industry and Ayurvedic community to know what limits to meet. NAMA, APA and VEAT welcome government guidelines for the industry. [µg = mcg = micrograms or one millionth of a gram = 0.000001 sometimes referred to as ppm or parts per million -- mg = milligrams or one thousandth of a gram = 0.001]

The *JAMA* article states that “one-fifth of both US-manufactured and Indian-manufactured Ayurvedic medicines purchased via the Internet contain detectable lead, mercury, or arsenic.” However, as discussed above, the simple presence of any of these elements does not in and of itself translate to toxicity. This “one-fifth” (or 20%) was based simply on whether lead, mercury or arsenic was able to be detected in the product, not the specific forms of these metals that are of concern and without consideration of the resulting daily dose. More importantly, all these products were said to “cause ingestions exceeding at least 1 regulatory standard.” The “regulatory standard” with the lowest levels is California’s Proposition 65, with a maximum level of 0.5 µg /day; the lowest by far of all of the limits cited in the article and one that does not take into consideration naturally occurring lead. It is important to note that California Proposition 65 is not a regulation prohibiting sales of these products, but rather requires a specific warning to the consumer if a product contains these elements above its limits. If a different analysis were done using the daily dose limits of ANSI/NSF, USEPA and FAO/WHO, we would find that the percentage of products containing heavy metals and resulting in daily doses above their recommended amounts is approximately 8% of total products, not the 20% stated in the article.

There is one more important issue to consider. Among the products tested, there were some traditional Ayurvedic products that intentionally contain specially prepared forms of lead, mercury and or arsenic. Although these products have been in use in India for hundreds of years with claims of efficacy and safety, they have not been proven by modern medical science to be either safe or effective. NAMA, APA and VEAT recommend that practitioners and consumers should avoid the use of products in which lead, mercury and or arsenic have been intentionally added until these products are better understood by modern science and medicine, and there are clear guidelines both from within the Ayurvedic community and national laws. Finally, if we were to count only those products that do not have lead, mercury or arsenic intentionally added but would still result in daily doses above the authorities other than California Proposition 65, we find about 5%, not “one fifth” 20%.

In order to adequately and effectively meet the existing challenge of heavy metal contamination in Ayurvedic products, NAMA, APA and VEAT make the following recommendations:

- 1) That government and industry establish sound, scientific daily dose limits for lead, mercury and arsenic in all dietary supplements and establish Good Manufacturing Practices that all manufacturers demonstrate compliance through independent third-party testing using validated preparation and testing methodologies, not just for Ayurvedic products and dietary supplements but also for conventional foods.
- 2) That manufacturers, marketers, practitioners and consumers of herbal products stop importing, manufacturing, distributing, selling, recommending and using any product for which lead, mercury or arsenic have been intentionally added until such time as modern western science and medicine have proven the safety of such products.
- 3) We support those companies who adhere to the points in these recommendations, Good Manufacturing Practices, quality control and who are members of one or more recognized industry associations that are committed to safety and quality.
- 4) Until such time as government and industry can agree upon and establish scientifically sound daily dose limits for lead, mercury and arsenic, we recommend that manufacturers and practitioners adhere to any government regulations currently in existence and at a minimum follow the lower of the guidelines established by ANSI/NSF and FAO/WHO which are currently 20 µg /day for lead, 14 µg /day for mercury and 10 µg /day for arsenic. Consumers must make their own decisions on what is safe for them based on sound scientific, medical and expert advice according to their own personal situation.