

# Heavy Metal Content of Ayurvedic Herbal Medicine Products

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**A**YURVEDIC MEDICINE ORIGINATED in India more than 2000 years ago and relies heavily on herbal medicine products (HMPs).<sup>1</sup> Approximately 80% of India's 1 billion population uses Ayurveda through more than one-half million Ayurvedic practitioners working in 2860 Ayurvedic hospitals and 22 100 clinics.<sup>2</sup> Ayurveda's popularity in Western countries has increased.<sup>3</sup> In the United States, Ayurvedic remedies are now available from South Asian markets, Ayurvedic practitioners, health food stores, and the Internet. Because Ayurvedic HMPs are marketed as dietary supplements, they are regulated under the Dietary Supplement Health and Education Act (DSHEA), which does not require proof of safety or efficacy.<sup>4</sup>

Herbs, minerals, and metals are used in Ayurvedic HMPs.<sup>2</sup> Lead toxicity has been associated with use of Ayurvedic HMPs, including status epilepticus,<sup>5</sup> fatal infant encephalopathy,<sup>6</sup> congenital paralysis and sensorineural deafness,<sup>7</sup> and developmental delay.<sup>8</sup> Since 1978, at least 55 cases of heavy metal intoxication associated with Ayurvedic HMPs in adults and children have been reported in the United States and abroad.<sup>5-17</sup>

Although Ko<sup>18</sup> raised concern about heavy metals in traditional Chinese

**Context** Lead, mercury, and arsenic intoxication have been associated with the use of Ayurvedic herbal medicine product (HMPs).

**Objectives** To determine the prevalence and concentration of heavy metals in Ayurvedic HMPs manufactured in South Asia and sold in Boston-area stores and to compare estimated daily metal ingestion with regulatory standards.

**Design and Setting** Systematic search strategy to identify all stores 20 miles or less from Boston City Hall that sold Ayurvedic HMPs from South Asia by searching online Yellow Pages using the categories *markets*, *supermarkets*, and *convenience stores*, and business names containing the word *India*, Indian cities, and Indian words. An online national directory of Indian grocery stores, a South Asian community business directory, and a newspaper were also searched. We visited each store and purchased all unique Ayurvedic HMPs between April 25 and October 24, 2003.

**Main Outcome Measures** Concentrations ( $\mu\text{g/g}$ ) of lead, mercury, and arsenic in each HMP as measured by x-ray fluorescence spectroscopy. Estimates of daily metal ingestion for adults and children estimated using manufacturers' dosage recommendations with comparisons to *US Pharmacopeia* and US Environmental Protection Agency regulatory standards.

**Results** A total of 14 (20%) of 70 HMPs (95% confidence interval, 11%-31%) contained heavy metals: lead (n=13; median concentration, 40  $\mu\text{g/g}$ ; range, 5-37000), mercury (n=6; median concentration, 20225  $\mu\text{g/g}$ ; range, 28-104000), and/or arsenic (n=6; median concentration, 430  $\mu\text{g/g}$ ; range, 37-8130). If taken as recommended by the manufacturers, each of these 14 could result in heavy metal intakes above published regulatory standards.

**Conclusions** One of 5 Ayurvedic HMPs produced in South Asia and available in Boston South Asian grocery stores contains potentially harmful levels of lead, mercury, and/or arsenic. Users of Ayurvedic medicine may be at risk for heavy metal toxicity, and testing of Ayurvedic HMPs for toxic heavy metals should be mandatory.

JAMA. 2004;292:2868-2873

www.jama.com

medicines (Richard Ko, PharmD, PhD, written communication, 2004) available in California, no studies have spe-

cifically measured heavy metals in Ayurvedic (traditional Indian) HMPs sold in the United States. We deter-

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**Financial Disclosure:** Dr Eisenberg has received honoraria for educational lectures relating to the epidemiology of complementary therapy use, ongoing research in this area at Harvard Medical School, and national trends in complementary medicine research but has neither spoken on the topic of Ayurveda or the efficacy, safety, or toxicity of Ayurveda, or received grant support (federal or private) for investigations of Ayurvedic products.

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mined the heavy metal content in a sample of Ayurvedic HMPs sold in Boston-area retail stores. We also estimated daily heavy metal intakes for each HMP and compared these with maximum allowable regulatory standards.

## METHODS

### Collection of Ayurvedic HMPs

We identified Boston-area stores selling Ayurvedic HMPs manufactured in South Asia by searching online Yellow Pages<sup>19</sup> using the categories *markets*, *supermarkets*, and *convenience stores*, and business names containing the word *India*, Indian cities, and Indian words; and an online national directory of Indian grocery stores,<sup>20</sup> a South Asian community business directory,<sup>21</sup> and a newspaper.<sup>22</sup>

Between April 25 and October 24, 2003, we visited all identified stores that were 20 miles or less from Boston City Hall as measured by Microsoft Streets and Trips 2002 (Microsoft Corp, Redmond, Wash). In each store, we purchased 1 package of each HMP available that met the following inclusion criteria: Ayurvedic herbal remedy, manufactured in South Asia, and intended for oral use. When more than 1 store carried the same HMP (ie, identical name, manufacturer, and formulation), the HMP was purchased from 1 store only. If 2 HMPs had the same name but were made by different manufacturers or had different formulations (eg, powder and tablets), these HMPs were considered to be different for the purposes of our study and were therefore both purchased. The name, manufacturer, manufacturer's location, lot number, formulation, indications, recommended dosages, and cost per package were recorded for all HMPs purchased. Non-English labels were professionally translated. Because this study did not involve human participants, the Harvard Medical School's institutional review board determined that its approval was not required.

### Data Collection

All HMPs were transferred to plastic pharmacy-grade vials (Tri-State Distribution, Sparta, Tenn) and labeled with

a numerical identifier only. Vials were sent without interruption in chain of custody to the New England Regional Environmental Protection Agency (EPA) laboratory for analysis. Laboratory personnel were blinded to the identity of the HMPs. Solid HMPs were weighed and homogenized thoroughly to reduce the risk of matrix interference from particle size differences. To determine the metal concentration of the HMP, samples were analyzed once by x-ray fluorescence spectroscopy<sup>23</sup> using the Spectro X-Laboratory 2000 XRF equipped with a tungsten x-ray tube, a Si(Li)-semiconductor detector, and software version 2.2R03 I (Spectro Analytical Instruments, Kleve, Germany). National Institute of Standards and Technology solid standard reference materials (SRMs) 2709, 2710, 2711,<sup>24</sup> and liquid certified standards (SCP Science, Champlain, NY) containing specified heavy metal concentrations served as positive and negative controls. We reported metal concentrations in  $\mu\text{g/g}$ . The instrument's minimum detection limits were lead 5  $\mu\text{g/g}$ , mercury 20  $\mu\text{g/g}$ , arsenic 10  $\mu\text{g/g}$ , and cadmium 10  $\mu\text{g/g}$ .

To assess reproducibility, we returned to the grocery stores from November 17 to 26, 2003, and attempted to repurchase 1 package of each HMP found on initial testing to contain lead, mercury, arsenic, and/or cadmium. We also used a computerized random number generator to select 14 HMPs for repurchase among all HMPs found on initial testing to have no detectable heavy metals. One package of each of the 14 negative HMPs was repurchased. Positive and negative HMPs were repurchased irrespective of their lot numbers. Each repurchased HMP received a new numerical identifier and was similarly transferred to vials, which were sent to the EPA. At the laboratory, each HMP was split into 2 samples and each sample was assayed twice alongside SRM controls.

### Data Analysis

We calculated the proportion of HMPs containing heavy metals. The coeffi-

cient of variation for the metal concentrations was calculated using data from the split-sample duplicate assays. If an HMP contained lead, we used the lead concentration (measured in the original set of HMPs purchased), unit dose weight, and recommended dosages to calculate the amount of lead that would be ingested daily. If there was a range of suggested dosages, the daily ingestion was presented as a range. For lead, we compared the daily ingestion for an adult with the *US Pharmacopeia (USP)* specifications for the maximum allowable lead content (4.5  $\mu\text{g}$ ) in a 1500-mg daily dose of calcium carbonate.<sup>25</sup> For children, we compared our estimated ranges with the *USP* specifications for the maximum allowable lead content (1  $\mu\text{g}$ ) in a 2.5-mL daily dose of ferrous sulfate suspension (assumes 2-mg elemental iron per kg/d for a 10-kg child taking a 0.8-g elemental iron per 100-mL suspension).<sup>25,26</sup> For HMPs containing mercury, arsenic, or both, we similarly calculated the amount of mercury, arsenic, or both that would be ingested daily. We compared estimated ranges of mercury and arsenic intakes with their respective EPA established reference doses (RfDs) for oral chronic exposure (0.3  $\mu\text{g/kg}$  per day for both mercuric chloride and arsenic).<sup>27</sup>

## RESULTS

### General Characteristics of Ayurvedic HMPs

Using our search strategy, we purchased 70 unique Ayurvedic HMPs, manufactured by 27 companies (26 based in India and 1 in Pakistan) in 30 Boston-area stores. The HMPs carried a wide variety of indications, most commonly gastrointestinal (71%). The median cost per package was \$2.99 (range, \$0.50-\$5.99).

### Heavy Metal Analyses

A total of 14 (20%) of 70 HMPs (95% confidence interval, 11%-31%) contained lead, mercury, and/or arsenic (TABLE 1). TABLE 2 lists the 14 products containing heavy metals, their manufacturers, and their heavy metal concentrations. Seven HMPs specifi-

cally recommended pediatric use. Twenty-four of the 30 stores sold at least 1 heavy metal-containing HMP.

### Estimates of Daily Heavy Metal Ingestion Compared With Regulatory Standards

Each estimate is based on daily ingestion of the manufacturer's recommended dose. The FIGURE displays the estimated daily lead, mercury, and arsenic ingestion for heavy metal-containing HMPs recommended for adults and children. All 10 HMPs containing lead and recommended for adults could result in ingestions higher than the comparable USP standard. Six HMPs were orders of magnitude higher.

The estimated daily lead ingestion for each of the 6 lead-containing HMPs recommended for children could result in ingestions of equal to or above the USP standard.

Similar comparisons were made for arsenic and mercury. All 4 mercury-containing HMPs intended for adults could result in estimated daily mercury intakes of at least 1 order of magnitude higher than the EPA reference dose for a 70-kg adult. Two of 3 mercury-containing HMPs recommended for children have estimated ranges of daily mercury intake of 2 to 3 orders of magnitude higher than the EPA reference dose for a 10-kg child. Four of 5 arsenic-containing HMPs

recommended for adults would result in daily intakes of 1 to 3 orders of magnitude higher than the EPA reference dose. Chronic ingestion of the 3 arsenic-containing HMPs intended for children would also result in daily intakes of more than the reference dose.

### Duplicate HMP and SRM Testing

We were able to repurchase 10 of the 14 positive HMPs for split-sample retesting. For the HMPs unavailable for repurchase, we performed split-sample retesting using the original HMPs. All 10 repurchased HMPs had heavy metal concentrations similar to the original samples: lead, average of

**Table 1.** Heavy Metal Concentrations in Ayurvedic Herbal Medicine Products (N = 70)\*

	Metal							Any Metal*
	Lead	Mercury	Arsenic	Tin	Silver	Gold	Cadmium	
No. of HMPs with detectable levels of the metal (% of total No. of HMPs)	13 (19)	6 (9)	6 (9)	5 (7)	4 (6)	3 (4)	0	14 (20)
Median concentration among those HMPs with detectable levels of the metal (IQR), µg/g	40 (8-300)	20 225 (4380-72 100)	430 (54-2800)	22 800 (3940-23 500)	14 310 (2475-26 575)	†	NA	
Range, µg/g	5-37 000	28-104 000	37-8130	150-26 400	230-29 250	†	NA	

Abbreviations: HMPs, herbal medicine products; IQR, interquartile range; NA, not applicable.

\*A total of 14 (20%) of 70 HMPs (95% confidence interval, 11%-31%) contained lead, mercury, and/or arsenic.

†Presence of gold detected qualitatively only.

**Table 2.** Ayurvedic Herbal Medicine Products Containing Lead, Mercury, and/or Arsenic\*

Ayurvedic HMP	Manufacturer	Formulation	% Stores Selling HMP	Metal, µg/g		
				Lead	Mercury	Arsenic
Bal Chamcha†	Jalaram	Powder	3.3	10	ND	ND
Bala Guti†	Zandu	Tablet	3.3	5	ND	ND
Bala Sogathi†	Navjeevan	Powder	3.3	43	28	ND
Balguti Kesaria†	Kesari Ayurvedic Pharmacy	Tablet	3.3	7	17 600	37
Gesari†	Harinarayan Pharmacy	Tablet	3.3	7	ND	ND
Karela	Himalaya	Capsule	6.7	7	ND	ND
Maha Sudarshan Churna	Dabur	Powder	3.3	17	ND	ND
Maha Sudarshan Churna	Zandu	Tablet	6.7	40	ND	ND
Mahalakshmi Vilas Ras with gold	Baidyanath	Tablet	3.3	300	72 100	2800
Mahayograj Guggulu with silver and Makardhwaj	Baidyanath	Tablet	3.3	37 000	22 800	8100
Navratna Rasa†	Unjha Ayurvedic Pharmacy	Tablet	3.3	600	104 000	60
Safi†	Hamdard Pakistan	Liquid	70.0	ND	ND	54‡
Shilajit	Syncom	Capsule	6.7	8	ND	ND
Swarna Mahayograj Guggulu with gold	Baidyanath	Tablet	3.3	7870	4380	800

Abbreviations: HMPs, herbal medicine products; ND, not detected (heavy metal assay reporting levels: lead  $\geq 5$  µg/g, mercury  $\geq 20$  µg/g, and arsenic  $\geq 10$  µg/g).

\*A list of HMPs without detectable heavy metals is available from the authors.

†Label specifically recommended pediatric use.

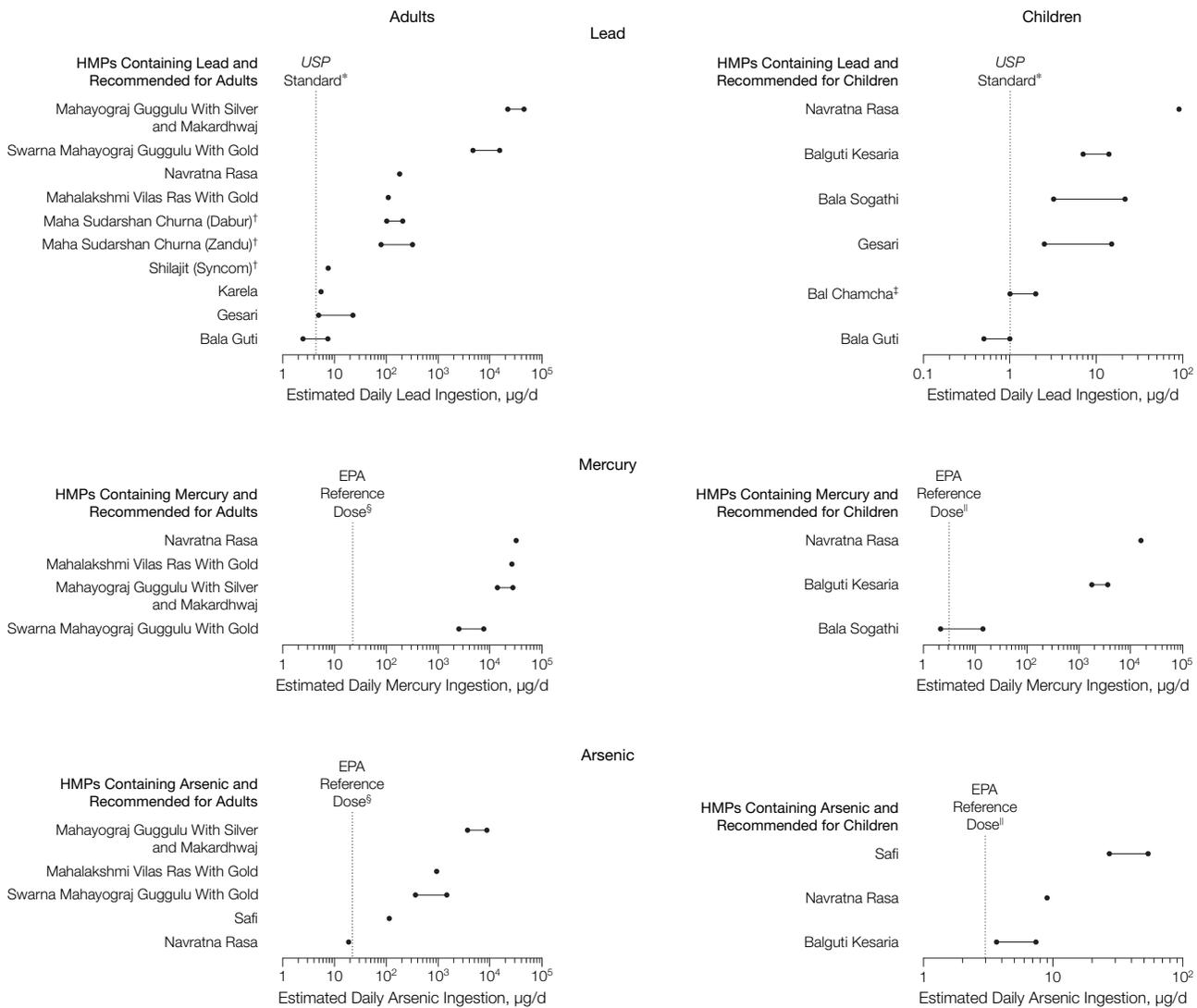
‡Concentration of metals in aqueous liquid herbal medicine products expressed as µg/mL.

112% of original concentrations; mercury, average of 118% of original concentrations; and arsenic, average of 112% of original concentrations. The mean coefficients of variation for lead, mercury, and arsenic concentrations in the split-sample retesting were 0.05, 0.03, and 0.05, respectively. This

amount of variability is not significant enough to lower the estimated daily amounts of metal ingestions from the HMPs below acceptable regulatory standards. The 14 negative HMPs randomly selected for repurchase did not contain any heavy metals on retesting. Measurements of heavy metals in solid

SRMs and certified liquid standards (data not shown, available on request) were on average less than 8% different than their certified concentrations (lead +4.8%, mercury +7.8%, and arsenic -7.3%), consistent with the confidence limits of the standards and our instrumentation.

**Figure.** Estimated Daily Lead, Mercury, and Arsenic Ingestion for Heavy Metal-Containing HMPs Recommended for Adults and Children



The estimated daily lead, mercury, or arsenic ingestion levels were estimated using a single measure of lead, mercury, or arsenic concentration in the originally purchased herbal medicine products (HMPs), the unit dose weight, and recommended dosages stated on the label. If the manufacturer recommended a range of suggested dosages, a range of potential daily lead, mercury, or arsenic ingestion is displayed.

\*For adults, *US Pharmacopeia (USP)* maximum allowable lead content (4.5 µg) for a daily dose of 1500 mg of calcium carbonate<sup>25</sup>; and for children, *USP* maximum allowable lead content (1 µg) allowed in a daily dose of ferrous sulfate suspension (0.8-g elemental iron per 100 mL) administered to a 10-kg child at 2-mg elemental iron per kg/d.<sup>25,26</sup>

†Name of manufacturer is given in parentheses.

‡Estimated intake based on an assumption of 0.1 to 0.2 g of Bal Chamcha used per dose.

§US Environmental Protection Agency (EPA) reference dose for chronic (>365 days) oral intake of mercuric chloride or arsenic for a 70-kg adult (21 µg).<sup>27</sup>

||EPA reference dose for chronic (>365 days) oral intake of mercuric chloride or arsenic for a 10-kg child (3 µg).<sup>27</sup>

**COMMENT**

Ayurvedic HMPs containing heavy metals are readily available in most of the South Asian grocery stores in Boston, recommended for adults and children, and relatively inexpensive. One of 5 available Ayurvedic HMPs contained lead, mercury, and/or arsenic. Taken as recommended, each of the 14 heavy metal-containing HMPs we identified may result in heavy metal intake above regulatory standards.

Our data are consistent with studies of Ayurvedic HMPs sold outside the United States and herbal remedies from other indigenous healing traditions. In England, 30% of Ayurvedic HMPs sampled contained lead, mercury, or arsenic.<sup>17</sup> Of 22 Ayurvedic HMPs purchased in India, 64% contained lead and mercury, and 41% contained arsenic.<sup>16</sup> Traditional medicines from China,<sup>18</sup> Malaysia,<sup>28</sup> Mexico,<sup>29</sup> Africa,<sup>30</sup> and the Middle East<sup>31</sup> have also been shown to contain heavy metals.

Two lines of evidence suggest our sample of HMPs has unacceptably high heavy metal content. First, metal concentrations in our specimens correlate with concentrations associated with both toxic blood concentrations and symptomatic poisoning in previously reported cases. The lead concentrations we observed overlapped with those associated with toxicity in a recent US case series (range, 21-96 000 µg/g)<sup>5</sup> and in patients from Croatia (range, 0.90-72 990 µg/g).<sup>15</sup> Specific HMPs containing heavy metals in our sample (eg, Mahayograj Guggulu) have been associated with serious toxicity in case reports.<sup>5,9</sup> Arsenic poisoning was described in 47 children and adults in Singapore using a Chinese HMP with 12 000 µg/g of arsenic.<sup>32</sup> Second, epidemiological evidence of insidious adverse effects (eg, decreased childhood IQ,<sup>33</sup> increased blood pressure,<sup>34</sup> progression of chronic renal insufficiency<sup>35</sup>) from low levels of lead exposure previously thought to be acceptable suggests that even HMPs with relatively lower levels of lead (<100 µg/g) may be deleterious.

Ayurvedic theory attributes important therapeutic roles to metals such as

mercury and lead.<sup>2,36</sup> Ayurveda experts estimate that 35% to 40% of the approximately 6000 medicines in the Ayurvedic formulary intentionally contain at least 1 metal.<sup>2</sup> Metal-containing HMPs are purportedly “detoxified” through multiple heating/cooling cycles and the addition of specific herbs.<sup>36</sup> Whether the heavy metals in our sample were already present in raw plant materials<sup>37</sup> or intentionally or incidentally added in the manufacturing process is uncertain.

Our study has several limitations. First, increased concentrations of lead of more than 5000 µg/g or of mercury of more than 15 000 µg/g could theoretically produce spectral interference and falsely increase the results for other metals. To assess this, we tested samples of metal salts at high concentrations and found negligible spectral interference with other metals of interest. We also analyzed diluted HMP samples and found similar results to the original data. In addition, the spectra of non-target elements present in the HMPs (eg, sulfur, calcium, iron, copper) were found not to interfere with the spectra of lead, mercury, or arsenic. Second, we were not able to ascertain the metals' chemical forms, which can impact bioavailability and toxicity, especially in the case of mercury.<sup>38</sup> Finally, our data were limited to 70 Ayurvedic HMPs manufactured in South Asia and found in Boston-area stores. Whether these findings can be generalized to those HMPs sold elsewhere in the United States requires further study.

Despite these limitations, the presence of heavy metals in Ayurvedic HMPs and the numerous reports of associated toxicity may have important public health, clinical, and policy implications in the United States and abroad. Although the prevalence of heavy metal-containing Ayurvedic HMP use is unknown, the number of individuals at potential risk is substantial. Recent analysis of the US National Health Interview Survey 2002 Alternative Medicine Supplement estimates 750 000 adults consulted an Ayurvedic practitioner in the past.<sup>39</sup> In

India, an estimated 80% of the population uses Ayurveda.<sup>2</sup> Epidemiological studies of Ayurvedic HMP use and heavy metal toxicity in the United States and abroad are therefore warranted. Public health and community organizations should consider issuing advisories to current or previous Ayurvedic HMP users, encouraging them to consult their physicians about heavy metal screening. Use of specific heavy metal-containing HMPs in our study should be discouraged. Physicians should also consider Ayurvedic HMP intake in the differential diagnosis of unexplained heavy metal toxicity. Current US law stipulates that regulations governing dietary supplements produced and sold domestically (DSHEA) should also be applied to dietary supplements imported into the United States.<sup>40</sup> Our findings support calls for reform of DSHEA that would require mandatory testing of all imported dietary supplements for toxic heavy metals.

**Author Contributions:** Dr Saper had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

**Study concept and design:** Saper, Kales, Burns, Eisenberg, Davis, Phillips.

**Acquisition of data:** Saper, Paquin.

**Analysis and interpretation of data:** Saper, Kales, Burns, Eisenberg, Davis.

**Drafting of the manuscript:** Saper, Kales, Burns.

**Critical revision of the manuscript for important intellectual content:** Saper, Kales, Paquin, Burns, Eisenberg, Davis, Phillips.

**Statistical analysis:** Saper, Davis.

**Obtained funding:** Saper, Eisenberg, Phillips.

**Administrative, technical, or material support:** Saper, Kales, Paquin.

**Study supervision:** Saper, Burns, Eisenberg, Phillips.

**Funding/Support:** Dr Saper was supported by an Institutional National Research Service Award for training in Alternative Medicine Research (T32 AT00051) from the National Center for Complementary and Alternative Medicine (NCCAM), National Institutes of Health, Bethesda, Md. Dr Phillips is supported by a Mid-Career Investigator Award (K24 AT00589) from NCCAM. Herbal products were purchased with funds from the Division for Research and Education in Complementary and Integrative Medical Therapies of Harvard Medical School.

**Role of the Sponsor:** Harvard Medical School had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; or preparation, review, or approval of the manuscript for submission.

**Disclaimer:** The content of this article is solely the responsibility of the authors and does not necessarily represent the official views of the NCCAM, the National Institutes of Health, or the US Environmental Protection Agency.

**Acknowledgment:** We gratefully thank Mary Beth Hamel, MD, MPH, and Michael Shannon, MD, for their review of an earlier version of the manuscript; David

Solondz, BSE, for assistance with sample collection; Brian Ambrefe, RPh, CDE, for donation of sample vials; Naseem Hines, PhD, for label translation; Anusha Seghal, BAMS, for helpful discussions regarding Ayurveda; and Nadia Khouri for editing.

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