

## BRIEF REPORT

## Impact of Federal Safety Advisories on Health Food Store Advice

Edward Mills, DPH, FRIPH, Rana Singh, BSc, ND, Cory Ross, MSc, DC, DPH, CHE, Edzard Ernst, MD, PhD, FRCP (Edin), Kumanan Wilson, MD, MSc, FRCP(C)

**In early 2002, the FDA and Health Canada issued federal advisories that people should discontinue taking the herbal antianxiolytic kava kava, until further information regarding safety and potential for liver damage were determined. We conducted a field study 2 months following the advisories in Toronto, Canada to determine whether kava kava continued to be recommended to consumers at retail health food stores. Eight participants asked employees at all stores what was recommended for anxiety and whether the products were safe. Twenty-two of 34 stores recommended kava kava, 9 of which mentioned safety concerns. Physicians should be aware that federal advisories may not affect sales of unsafe products.**

**KEY WORDS:** anxiety; health food stores; kava.

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The use of natural health products by the general population is on the rise.<sup>1,2</sup> The increase in use of these products for patients with specific medical conditions has drawn attention to their potential for adverse effects and drug interactions. Several herbs used commonly for mild psychiatric disorders have been shown to be potentially harmful as well as to interact with prescription medications such as selective serotonin reuptake inhibitors and anti-anxiolytics.<sup>3</sup> In March 2002, the FDA issued a warning concerning the potential for fatal liver toxicity from kava kava (*Piper methysticum*), an antianxiolytic.<sup>4–6</sup> In November 2001, European country regulatory authorities placed restrictions on the sale of food supplements and herbal medicines containing kava and/or the kava extract and kavalactones.<sup>6</sup> UK authorities made an initial voluntary withdrawal statement followed by a ban.<sup>7</sup> Canadian regulators issued a similar warning advising against the

use of kava kava-containing products,<sup>8</sup> which culminated in a nationwide stop-sale in August 2002.<sup>9</sup>

The effectiveness of these advisories to protect the public is largely related to how effectively they are disseminated, both to providers of natural food products and from these providers to consumers. We sought to study this issue by examining the recommendations of employees of natural health food stores provided to people seeking treatment for anxiety disorder. We specifically focused on whether kava kava was recommended during the period of federal advisories and whether warning regarding its potential for harm was provided to patients.

### METHODS

In May 2002, we conducted a field study to determine what recommendations were made by health food store employees to people stating they have anxiety disorder. We also sought to examine the education of these employees and their knowledge of drug interactions and adverse effects of herbal medicines.

We identified all health food stores in central Toronto through the local business pages and yellow pages of telephone directories. Further stores were located through word of mouth. In total, 34 stores met our inclusion criteria of being a retail natural health products sales outlet. We specifically excluded stores selling exclusively Asian herbal products due to language difficulties, our lack of product knowledge, and difficulties of standardization.

Eight simulated patients (6 female, 2 male) of varying ages and appearance were recruited to act as customers (*participants-as-observers*). The participants were final year postgraduate students with knowledge of herbal medicines. All participants were trained by the study authors to act similarly in each store. The participants were informed to browse in the store until approached by an employee. At this time the participants would declare that they suffered from anxiety. The participants were instructed to disclose that they were on a medication (a benzodiazapene) if asked. The participants would then ask what the employee recommended for this condition. All participants followed a structured, memorized pretested questionnaire, which asked about product usage, dosage, cost, employee education, and safety/drug interactions. One employee from

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Received from the Department of Research (EM, RS, CR, KW), Canadian College of Naturopathic Medicine, North York, Ontario, Canada; Department of Complementary Medicine (EE), University of Exeter, Exeter, UK; and Department of Medicine (KW), University of Toronto, Toronto, Ontario, Canada.

Address correspondence and reprint requests to Mr. Mills: The Canadian College of Naturopathic Medicine, 1255 Sheppard Ave. East, North York, Ontario, M2K1E2, Canada (e-mail: emills@ccnm.edu).

Table 1. Products Recommended by Health Food Store Employees

Product Name	Stores Providing Recommendation, N	Mean Cost for a Monthly Supply (USD)	Recommended Daily Dosage	Type of Product
Kava kava	22	11.63	1 to 6/day	Herbal extract
St. John's Wort	13	11.11	2 to 3/day	Herbal extract
B-complex	9	6.32	1 to 2/day	Vitamin
Bach Rescue Remedy	8	10.88	as required	Flower extract
5-HTP (5-hydroxy-L-tryptophan)	3	20.39	1 cap/day	Amino acids
Valerian extract	3	6.79	Directions on bottle	Herbal extract
Homeopathic remedies	2	8.83	as required	Homeopathic dilutions
Sleep Plus	2	13.59	Directions on bottle	Herbal combination
Serenity Plus	1	13.59	Directions on bottle	Herbal combination
Herbal decoction	1	11.56	1 cup/day	Herbal combination
Herbal Factor	1	7.88	Directions on bottle	Herbal combination
Unwind	1	7.34	1/day	Herbal combination
Siberian ginseng	1	9.17	1 cap/day	Herbal extract
Lemon balm	1	2.37	Directions on bottle	Herbal extract
Valerian root	1	4.07	Directions on bottle	Herbal extract
Silent Night	1	4.07	1 cup	Herbal tea
Sleepy Time	1	4.07	1 cup	Herbal tea
L-Tyrosine	1	16.98	1 cap/tid	Amino acid
Methionine	1	33.98	NA	Amino acid
Stress Form	1	7.88	1 cap/day	Vitamin complex
Multistress	1	22.42	1 cap/day	Vitamin complex
Cal-mag	1	12.16	Directions on bottle	Minerals

\$1 CDN = \$0.679 US.

NA, not available.

each store was approached for this study. Participants took notes of the information immediately after leaving the store.

Ethical approval for this study was granted by the Canadian College of Naturopathic Medicine Institutional Review Board. We have performed member checks to ensure prompt disclosure and debriefing was provided to each health food store as soon as was possible.

## RESULTS

A total of 22 different products was recommended by the 34 stores we sampled. The mean cost of the recommended products was \$11.08 (U.S. dollars)/month. Table 1 summarizes the recommended products, dosage, and monthly cost. Eight employees (23.5%) asked whether the participants were taking prescription drugs.

Kava kava was recommended in 22 (65%) stores. Nine employees mentioned the potential for adverse effects with kava kava. Three of these employees suggested that this information was not accurate. Five employees discussed the potential for kava kava herb-drug interactions. St. John's Wort was recommended in 13 stores (38%). One employee mentioned the possibility of adverse effects of St. John's Wort and a further 4 discussed potential for interactions. B-complex vitamins were recommended in 9 stores (28%), and Valerian root and extract were recommended in 4 stores (12%). No employees recommending these products advised of potential adverse effects or possible drug interactions.

Nine employees (26.5%) received their knowledge on the products from suppliers, 7 from a variety of books

(20.6%), 3 (8.8%) from in-store training, and 10 (29.4%) employees reported formal training related to complementary and alternative medicine. Information on product knowledge was unobtainable with 5 employees (14.7%). Of the entire sample, 7 (20.6%) employees had formal education in complementary and alternative medicine at a college or university level.

## DISCUSSION

This study identified several public health concerns regarding uptake of federal advisories by health food stores. The recommendations of products indicated considerable variability in product, duration of use, and dosage. Uptake of information of federal advisories against the use of kava kava was limited, and the information disseminated by regulators was judged by several employees to be incorrect. We also identified an inconsistency of knowledge regarding safety of the products and potential for drug interactions. Finally, it should be noted that the advice to use products other than kava for reduction of anxiety is not based on evidence from clinical trials.<sup>10</sup>

In this study, we utilized the participant-as-observer method to obtain information on recommendations provided by health food store employees.<sup>11</sup> Using this method allows us to observe what is being recommended in a real-life setting and avoids the Hawthorne effect (an improvement in performance of the employees due to knowledge that their actions were being observed). A limitation of this study is that the sample only represents

1 city, and health food store practices may be different in other cities. However, we selected the largest city in Canada and would expect practices to be similar across the country. Our findings are consistent with previous studies examining health food store recommendations in Canada and the United States.<sup>12,13</sup>

A potential concern to the conduct of this study relates to its ethical implications. In essence, this was an investigation on human subjects without consent. Informed consent is the cornerstone of research ethics.<sup>14</sup> However, there are situations where informed consent is not a necessary precondition. We believe that this study is such an exception: first, there is little conceivable harm in not obtaining consent in this particular setting; second, with informed consent the investigation would not have been possible; and third, our aim was to investigate an area of potential harm to consumers, which can be viewed as overriding concerns about the potential of harm to shop assistants in this setting. On balance, the study was therefore ethically justifiable, a judgment that was shared by the review board that approved it. We believe that informing the employees of the research study would have modified the results. Thus, we did not utilize tape recorders or take notes in front of the employees.

The federal advisory issued regarding the potential liver failure associated with kava kava is well documented,<sup>5,6,8</sup> was highlighted by the media,<sup>15</sup> and was published in the medical literature.<sup>16</sup> Our study indicated that uptake and application of this information was limited. In Europe, 30 cases of liver injury, 4 of which required transplantation, have been attributed to kava kava use.<sup>17</sup> At least 2 cases have occurred in North America, while the actual number remains undetermined as the causal links with kava kava are still being scrutinized. Although the mechanism of toxicity is not adequately known and why some people may be sensitive to kava kava is unclear, FDA research suggests that < 1% of the severe adverse events that occur with the use of dietary supplements are reported to FDA.<sup>18</sup>

Natural health products are regarded as dietary supplements and are not required to pass strict registration processes as would be expected of prescription drugs.<sup>19</sup> However, the increasing information regarding their safety and the possibility of herb–drug interactions suggests that more stringent regulations may be required. In addition to recommending a potential hazardous product (kava kava), it is also concerning how few employees asked about current medication use by their customers. The potential for herb–drug interactions with some of the recommended products is well documented.<sup>3</sup>

We also identified that the education of employees regarding natural health products was heterogeneous, with several employees expressing that formal education was unnecessary. Others considered that working in the health food environment for several years was experience enough. The lack of formal education may be associated with an increased likelihood of not being aware of current

issues regarding the health food products they sell. Access to unbiased information may help educate employees.

## CONCLUSION

There are important messages from this study for physicians. Physicians should recognize that the presence of an advisory against the use of natural health products may not prevent the sale of these products. Physicians should therefore carefully inquire about whether their patients are taking any natural health products, particularly when they present with unexplained health problems or are failing to respond to medications. Physicians also need to communicate information on the risks of these products to patients who may be at high risk of suffering adverse effects from them.

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