

Awa and the Liver

by Ed Johnston, Project Coordinator, Association for Hawaiian 'Awa

Over the past six months, the world 'awa market declined severely due to fears arising in Europe that 'awa products may cause liver damage. This has caused a drastic reduction in Hawai'i 'awa exports to Europe, which totaled about \$200,000 per month in 2001 (Nakaso 2002). In addition, small businesses featuring 'awa have been developing around the islands, and they may soon be affected as well.

According to Dr. Christine Taylor of the Food and Drug Administration (FDA), "This kind of liver damage appears to be extremely rare. But because it's severe liver damage, we felt consumers needed to be aware of it" (Neergaard 2002).

The controversy surfaced when, in November 2001, the German Federal Institute for Drugs and Medical Devices (BfArM) reported they may be taking 'awa based products off the market due to possible toxic side effects to the liver. Their announcement was based on 24 cases of liver toxicity associated with the use of 'awa products. (Keep in mind that German sales figures indicate annual use of 70 million doses in that country alone.) Twelve more cases were reported in the rest of Europe — a total of 36 in a continent where 100 million doses have been administered (Gruenwald, 2002).

In the months to come, certain 'awa preparations were banned in Switzerland, and 'awa was banned outright in France and Ireland. It was banned in over-the-counter products in Germany and voluntarily withdrawn in Great Britain (Blumenthal, 2002).

The world media began running prominent stories warning the public of 'awa's possible link to liver damage. Stories were carried in *Time*, *USA Today*, *The New York Times*, *Washington Post*, Associated Press, and on television news.

However, the evidence presented to date does not establish conclusively that 'awa causes liver injury. It is not certain at this time whether the 'awa products used by the patients caused their liver conditions. The damage could have resulted from a number of causes: side effects from other medications taken with the 'awa products, a history of alcohol abuse, pre-existing liver problems, and/or allergic reactions to 'awa affecting only certain rare people.

Various organizations associated with the 'awa industry have subjected the original cases from BfArM to professional analysis (Gruenwald 2002, Schmidt 2001, American Herbal Products Assn. 2002). The website of the American Herbal Products Association quotes one such analysis, written by toxicologist Donald P. Weller, Ph.D., which states there is "no clear evidence that the liver damage reported in the U.S. or Europe was caused by the consumption of kava." In the few cases where 'awa might possibly be implicated, it appeared to him that the reactions were "hypersensitivity or idiosyncratic based" (AHPA, 2002).

In many of the reported cases, the patients had a history of alcohol abuse or pre-existing liver problems, and/or potentially hepato-toxic drugs had been taken in addition to the 'awa products. Experts who have reviewed the BfArM cases are also concerned that they lack sufficient detail to allow thorough evaluation. Firm conclusions must await additional information.

Prompted by the European cases, the FDA issued a letter to health care professionals across the U.S. and posted a consumer advisory on its website. The letter and advisory mention the cases occurring in Europe as well as the report "of a previously healthy young female who required liver

transplantation” in the U.S. The FDA has asked to be informed of any “liver or other injuries” connected with ‘awa use.

The German Pharmaceutical Industry Association and the German Nonprescription Drug Manufacturers Association have filed comments with BfArM concluding that the data presented does not justify withdrawing ‘awa products from the over-the-counter market.

AHPA Update. [Http://www.ahpa.org/kava2.html](http://www.ahpa.org/kava2.html). Feb. 21, 2002.

Blumenthal, M. Kava safety questioned due to possible link to liver toxicity. [Http://abc-dev.iensemble.com/browse.php/kavaupdate](http://abc-dev.iensemble.com/browse.php/kavaupdate)

Gruenwald J. and J. Freden. Kava: The present European Situation. *Nutraceuticals World*. Jan/Feb 2002, pp. 22-24.

Nakaso, D. Kava warnings cripple state’s industry. *Honolulu Advertiser*, Mar. 26, 2002.

Neergaard, L. ‘Awa may be linked to serious liver injury, FDA warns (Associated Press story). *Hawai’i Tribune-Herald*, March 26, 2002, p. 1.

Schmidt M. Analysis of kava side effect reports concerning the liver. Nov. 2001 (translated from German by M. Lindenmaier and J. Brinckmann, Dec. 2001).