

Chinese Herbs Recalled Due to Possible Contamination

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In January, two California companies issued a recall of eight brands of Chinese herbs after testing by the Food and Drug Administration has found some bottles of herbs to be contaminated with a chemical that can cause severe kidney damage. The two companies - Lotus Herbs, of La Puente, and QualiHerb/FineMost, of Cerritos, began recalling their products after the FDA detected amounts of aristolochic acid in some test samples.

Aristolochic acid is highly toxic to the kidneys and has also been shown to cause some forms of cancer. Last summer, the FDA stopped imports of aristolochia products after learning of several cases of kidney failure in Belgium and Great Britain. While no injuries have yet been reported in the United States, the FDA discovered the ingredient in some Chinese herbal products already in U.S. stores, prompting the recalls.

The recalled products are:

Lotus Herbs

Mu Tong, lot number SL04461, expiration date 09/2004;
Fang Ji, lot number SW12261, expiration date 12/2004.

QualiHerb

Ba Zheng San (dianthus formula), item no. 20209;
Fang Ji Huang Qi Tang (stephania and astragalus combination) item no. 20711;
Chuan Mu Tong (clematis armandi), item no. 10424A;
Wei Ling Xian, (clematis), item no. 12401;
Han Fang Ji, (stephania tetrandra), item no. 10731;
Ma Dou Ling (aristolochia), item no. 11052

In response to the recall, *Acupuncture Today* contacted both companies to obtain product information. While a statement from QualiHerb was unavailable at press time, Lotus Herbs issued the following notice regarding aristolochic acid and the regulation of herbal products.

Statement from Lotus Herbs

The purpose of this letter is to inform you of the facts in regards to aristolochic acid and the current regulatory situation.

1. Background Regarding Aristolochic Acid

In the early 1990s, a weight loss clinic in Belgium was dispensing a weight loss regimen that contained numerous drugs and two Chinese herbs. The drugs used were fenfluramine (a stimulant and appetite suppressant), diethylpropion (a stimulant), acetazolamide (a urinary alkalizer), and belladonna (the deadly nightshade). The herbs

used were *stephania tetrandra* (*han fang ji*) and *magnolia officinalis* (*hou po*). However, instead of using *stephania tetrandra*, the incorrect herb, *aristolochia westlandi* (*guang fang ji*) was used. After ingesting this combination of drugs and herbs over a long period of time, several illnesses were reported.^{1,2}

In 1998, in the United Kingdom, two illnesses were reported following years of ingestion of herbs. Upon examination, it was found that there was a dispensing error. Instead of using *clematis armandi* (*chuan mu tong*), the incorrect herb *aristolochia manshuriensis* (*guan mu tong*) was used.³

Despite these errors, the exact cause of illness is still undetermined, according to numerous authoritative sources. The *American Journal of Kidney Diseases* stated that "The exact nature of the nephrotoxin is still speculative."⁴ The European Agency for the Evaluation of Medicinal Products stated that due to lack of data, "no final conclusion can be drawn concerning the subchronic and chronic as well as reproductive toxicity of its (*aristolochia* plants) ingredients."⁵ The *New England Journal of Medicine* stated, "The role of Chinese herbs (specifically, *aristolochia* species) as a cause of renal failure and urothelial carcinoma is still a matter of debate."⁶ Nonetheless, Belgium and the United Kingdom have banned *mu tong* and *fang ji*, regardless of whether the correct species is used.

2. Current Regulatory Situation

While the FDA acknowledges that no illness has been reported in its letter to the health care professional,⁷ it has begun to take regulatory actions against herbs that contain, may contain, or may be adulterated with aristolochic acid. The list of single herbs implicated includes, but is not limited to, *aristolochia fangchi* (*guang fang ji*), *akebia* (*mu tong*), *asarum* (*xi xin*), *clematis* (*chuan mu tong*), *clematis chinensis* (*wei ling xian*) and *stephania* (*han fang ji*). The list of herbal formulas implicated include any formula that may include the single herbs listed above, including but not limited to, *ba zheng san*, *long dan xie gan tang*, *dang gui si ni tang* and *xi yi wan*. This action will undoubtedly impact our practice.

We will continue to keep you informed of any new development.

Sincerely,

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