

HERBAL CROSSROADS

An information resource from *Kan Herb Company* 6001 Butler Lane, Scotts Valley, CA 95066 (800) 543.5233

The Quality Control Crisis in China and Our Profession

An Open Letter from Ted Kaptchuk

Dear Colleague,

The news reports on quality control for foods and drugs manufactured in China are staggering and have become routine scandalous news. Reports of serious health threats involving Chinese products – from toothpaste and cold remedies adulterated with industrial poisons, to tainted pet food ingredients and fish contaminated with carcinogens and excessive antibiotic residues – are on the front pages on an almost daily basis. Reports are continuing to emerge about Chinese herbal products. On July 13, The New York Times (page A10) quoted a Chinese professor of pharmacology as saying “you don’t know what horrible conditions some drugs makers have been in. For example, in some traditional Chinese medicine companies, workers stirred the drugs with their feet.”

For those of us who have been in the acupuncture profession for a long time these reports have not been a complete surprise. For example, the New England Journal of Medicine (1998; 339:847) reported that a survey of 260 Asian-manufactured patent medicines collected from California retail herbal stores found 7% contained undeclared pharmaceuticals, including chlorpheniramine, methyltestosterone and phenacetin. A systematic review of such surveys performed in Asia found rates of contamination and adulteration as high as 24% (Journal of Internal Medicine 2002; 252: 107-113). A just-published survey in Legal Medicine (2007; 9: 358) of ninety “representative” Chinese “natural” herbal products in New York City’s Chinatown found some products with up to nine western pharmaceuticals (Miller & Legal

Legal Medicine 2007). Drugs found in the “herbal” samples included: promethazine, chlormethiazole, diclofenac, cholordiazepoxide, triameterene, and diphenhydramine. It is no wonder that despite China’s manufacturers becoming a global workhorse, China has not been able to export Western pharmaceuticals to the US: only 20% of Chinese-manufactured Western pharmaceuticals meet FDA standards for quality control (“Medicines from Afar Raise Safety Concerns”, NY Times, October 29, 1998, pp. 1, 32). No one as yet has quantified how many Chinese herbal products would meet FDA standards, but it is likely to be a much lower number than that of western pharmaceuticals.

I do not consider myself a business person. I became directly involved with the Chinese herbal business after a work-study period in Chinese herbal pharmacies and manufacturers in Asia. From these experiences, I realized that the quality control in Chinese herbal products was a potential threat to developing Asian medicine as a viable health care option in the West. After I returned to the United States, I tried to contribute by helping to develop, what I believe, are the first American manufactured Chinese herbal products. I remain proud of my efforts to contribute in this way and hope they helped encourage other Western manufacturers to begin producing high quality Chinese herbal medicines. However, this letter is not intended to promote any particular products. Instead, I want to raise the entire question of quality control, and raise the awareness that practitioners need to confirm the quality of all herbal products used in their practices.

September
2007

September

Our patients' health and our profession's reputation are both at stake. We need to be confident in the quality, safety, and even identity of the products that we prescribe to patients. Some companies advertise that Chinese herbs do not need to be tested for pesticides, heavy metals or bio-burdens and I strongly believe the evidence shows otherwise. As practitioners of Chinese Medicine, I think we should only use products that are tested extensively in American or European laboratories. We need to examine Certificates of Analyses detailing the testing the product has undergone, the limits shown, and the equipment and tests used.

Taiwan, for example, finds 150 part per million for heavy metal screening acceptable. The US Pharmacopoeia has much lower limits, not to exceed 10 parts per million for lead (less for the other metals). One must also look at the equipment used, as well as the standards and procedures, which a good Certificate of Analysis will list. Not all equipment and standards are alike; some equipment is not equipped to detect low levels of activity, or will post false positives or negatives.

To assure safety, products should be tested for a wide array of pesticides, as well as heavy metals and bio-burdens, using the latest technology by laboratories that are well established, or with in-house laboratories that are regularly tested and validated in the United States or Europe. Microbiological testing should include total plate count, *E. coli*, yeast and mold, staphylococcus, and salmonella. Total plate count excluded, these bio-burdens should not be found in products.

Identity of herbs should be properly established as well, ask your manufacturer about their procedural controls. Companies that choose to have their products manufactured in an Asian country should do proper testing locally to ensure that their products actually contain what they are supposed to contain, in appropriate levels and quality. With the release of final cGMP's by the FDA, products in the US will have to meet rigorous standards and testing for purity, efficacy, safety and quality, further ensuring a quality product. I would like to urge all my colleagues to only use herbal products that have undergone quality control checks at independent Western-based laboratories. Certificates of Analysis from China should no be considered reliable. Patients should be told about our efforts at quality control.

We cannot continue to assume that all Chinese herbal products are safe and of the required quality, we must do our part to demand and ensure that they are. Our schools need to teach the upcoming practitioner generation the skills to question and judge quality control processes.

Following the ongoing response from Chinese authorities regarding the numerous and ongoing reports of adulteration, it has become clear that China does not have in place the means to control and inspect products for either internal consumption, or for export. The fact that the adulterated toothpaste is still being sold in China is an example of how far the Chinese authorities have to come before we can be assured of ongoing and effective quality processes and controls.

Finally, I expect that some of my colleagues may believe that this letter has misrepresentations in terms of facts, inferences or correct approaches to the crisis of quality control in China. Disagreement is inevitable as we face a difficult crisis. I would like to plead that any discussion or debate this letter may provoke should not be personally- or commercially-driven, but be undertaken in the spirit of how best to meet the challenges of providing the highest quality care to our patients. We have to work as a community to insure the quality of our work.

Sincerely,

Ted Kaptchuk
Cambridge, Massachusetts

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September

A new formula added to Kan Herbals

Available in both extract and tablets

Formulated by Ted Kaptchuk, L.Ac, O.M.D.

Steady Centeredness



Astringes Liver

Extinguishes Liver Wind and

Sinks Liver Yang

Nourishes Liver-Kidney Essence

Astringes and Stabilizes Kidney

Historical Antecedent: Ledebouriella Soup (*Fang feng tang*) & Gastrodia Uncaria Drink (*Tian ma gou teng yin*)

Besides being responsible for much of human dynamics, both the Liver and Kidney are responsible for steady stability and centeredness. When the Liver-Kidney axis loses this contained steadiness and steady focus, many types of inappropriate, disruptive, destabilizing movements, thoughts, emotions and behaviors can develop. Steady Centeredness is the Kan Herbal version of a long tradition of herbal formulas that seek to harmonize the Liver's ability to store the Blood with the Kidney's ability to hold the Essence. Steady Centeredness is a critical remedy to astringe the Liver-Kidney Essence, address instability and reckless movement, and restore a person's sense of focused trust.

Steady Centeredness is used to treat Liver excessive symptoms (Wind and/or Yang) and at the same time add the tempering power of the Kidney Essence's "softness". It is uniquely constructed to address instability and is especially helpful in the common situation where a person has both Cold and Hot signs or there is an absence of any salient or predominant Hot-

Cold signs. It is also completely compatible for patterns that are clearly Hot or Cold. The most common physical symptoms include headaches, numbness, dizziness, facial palsy, tingling sensations, vertigo, heat flushes, ringing in the ears and vision impairment. Its action is less about suppressing Yang or cooling Heat, and more about rooting the Liver Blood/Essence into the Kidney Jing's sense of imperceptible time and timelessness.

On the emotional level, Steady Centeredness is for a person who is caught between the Liver's pent-up tightness or pent-up anger and rigidity, and the Kidney's fear and inability to provide a safe haven of patience, stability and trust. Steady Centeredness astringes and holds the Liver's non-corporal soul (Hun) and allows it to be vibrant and interactive while remaining connected to the inner astringent energy of the Kidney's dynamic stillness.