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 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 of newspapers on an almost daily basis. Reports are beginning to emerge about Chinese herbal products. On July 13, the *NY Times* (page A10) quoted a professor of pharmacology in China 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, methyltestostderone 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). A just-published survey in *Legal Medicine* (2007; 9: 358) of ninety "representative" Chinese "natural" herbal products purchased in New York City's Chinatown found some products adulterated with up to nine western pharmaceuticals. Drugs found in the "herbal" samples included: promethazine, chlormethiazole, diclofenac, cholordiazepoxide, triameterene, and diphenhydramine. It is no wonder that despite the fact that China has become a global workhorse, it has not been able to export Western pharmaceuticals to the US: only 20% of Chinese-manufactured Western pharmaceuticals meet FDA standards for quality control (*NY Times*, October 29, 1998, pages. 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 became directly involved with the herbal industry after an internship period in Chinese herbal pharmacies and factories while training in Chinese medicine in Asia. From these experiences, I realized that poor quality control in Chinese herbal products threatened the development of 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 American manufactured Chinese herbal products. I remain proud of my efforts to contribute in this way and I hope my work helped encourage other excellent Western manufacturers to begin producing their high quality Chinese herbal medicines.

This letter is not intended to promote any particular products. Instead, I want to discuss what efforts are generally needed to insure quality control. 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 EU laboratories. We need to examine Certificates of Analyses: the tests performed, the limits shown, and the equipment used. Our patients' health and our profession's reputation are both at stake.

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 EU. 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 any products. Identity of herbs should be properly established. All these measures becomes even more essential with the release of final cGMP's by the FDA which will require products sold in the US to meet rigorous standards and testing for purity, efficacy, safety and quality.

Our schools will need to develop courses that teach future practitioners quality control methodologies. Old-timers may have to learn some of these new skills. Given the response of Chinese authorities regarding the numerous reports of adulteration, it has become clear that China does not yet have in place the means to control and inspect products for either internal consumption, or for export.

Finally, I need to address the issue of conflict of interest. Because I work as a consultant for an herb company that obviously has a commercial stake in this crisis I can never claim to be a fully objective observer concerning these issues. Bias is unavoidable. Perhaps there are better solutions to this problem than I have stated. I fully expect and genuinely hope that some of my colleagues will feel free to critique this letter and offer different interpretations, inferences or approaches to the crisis. Respectful disagreement is critical to finding innovative solutions. I believe we are ALL trying to provide the best options for patient care even if we have prejudices and conflict of interest. The bottom line is that as individuals and as a community we have to insure the quality of our work to protect our patients and to continue to serve as responsible health care professionals.

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