

Proposal for “Industry Perspectives on CHM Use”

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Chinese herbal medicine (CHM) plays an important role in traditional Chinese medicine (TCM). CHM accounts for the majority of Chinese material medical (CMM), which includes also some animal and mineral sourced materials.

CMMs have been used for several thousands of years in China. It came to the U.S. in the late 1800s along with the first generation of Chinese immigrants. Since then, the use of CHM has saved lives not only in the Chinese American community, but also in the general public.

On the website of Offbeat Oregon History, there is an article titled "*Doc” Hay, Oregon's pioneer Chinese herbalist*" that starts with *Settlers in John Day in the late 1800s learned the healer of Kam Wah Chung could cure diseases others couldn't.*” It wrote: “Not a single one of Doc Hay’s patients died during the terrible Spanish Flu epidemic that killed so many people around the world — about 3,500 of them in Oregon — in 1919. Not one.” (http://www.offbeatoregon.com/H005_DocHay.html) (Note: Kam Wah Chung is the place Dr. Hay practice his Chinese medicine).

CMMs can powerfully treat many acute and chronic diseases that current modern drugs fail to. A recent well-known example is the SARS outbreak happened in 2002 in China. TCM and CMM have made great contribution for Chinese becoming to the most populous nation in the world. Now we should let it serve people all over the world. In comparison with the side effects or toxicities of modern drugs, the rate of toxic incidence of Chinese herbs is much less.

However, the American journalists of the public medias seem not aware of the above facts, and have only been interested in incidents that caused by improper use.

A well-known case is ephedra, a commonly used Chinese herb that is very effective for treatment of common cold and cough. It was banned because it was tied to the death of the athlete Steve Bechler in 2003, who used it as a performance-enhancing agent. However, ephedra was never prescribed for this purpose in TCM.

On March 10, CBS San Francisco had a report with the headline: “Two People Become Critical Ill after Drinking Tea from SF Chinatown Store”. It revealed that: “A lab test found that the tea contained aconite, a plant-based lethal poison.” Later on March 20, another news of “Women Dies After Drinking Deadly Chinatown Tea” was followed. They reported this without detailed investigation. In fact, no conclusion of the real death cause has been made yet.

Most people do not know that raw aconite is poisonous, but processed aconite is a safe and effective herb that can save lives of patients with chronic heart failure and treat other symptoms if used appropriately within indicated dosage. Many experienced TCM doctors use this herb to effectively treat heart diseases, pain, and chronic kidney disease.

In fact, currently in China, among several thousands of CMMs, only 101 are listed as health foods, while 28 are listed as poisons by the Chinese medical authorities that include the raw aconite.

Although aconite has been listed as a potentially unsafe herb that may be subjected to detention and/or may be required a permit to import, Chinese herbs are currently regulated as dietary supplements by FDA. Therefore, many consumers assume that they are safe to use. As a result, safety issues have often occurred due to misuse or abuse by consumers or the sellers’ inappropriate advertisements. This raised a question

that many TCM practitioners have concerned: Is the current regulation on the use of Chinese herbs appropriate?

For effective and safe application of CMM, the following facts must be known when taking Chinese herbs:

- (1) TCM treatment emphasizes syndrome differentiation. If it is not used for the right syndrome, side effects or even toxic reactions may occur. For example, aconite is usually prescribed for patients who have cold limbs or are averse to cold.
- (2) TCM treatment emphasizes compatibility. One of the major differences between modern Western drugs and CHM is that the former is usually made of a single ingredient, while CHM is mostly used in a formula. One main purpose of compatibility is for synergistic efficacy and/or attenuated side effects. The side effect of one herb can often be decreased or neutralized by another herb with the opposite effect. For example, aconite is often prescribed together with ginseng, licorice or dry ginger to reduce its toxic effect.
- (3) Processing of raw materials is an effective method to attenuate the toxicity of some Chinese herbs. Processing can lead to quantitative and/or qualitative changes of chemical constituents of the herbs. Consequently, the properties and functions of these herbs change. For example, aconite is the collateral root of plant *Aconitum carmichaeli*. The main roots are used as aconitum. Aconitine has been known as the main poisonous component in both aconite and aconitum. Ancient Chinese found that toxicity of aconite and aconitum can be significantly reduced by boiling the materials in water for 2 hours or soaked in water for long time. Modern studies have revealed that heating can decompose the structure of toxic aconitine by breaking down its two ester bonds.
- (4) Similar to Western medicine, the toxicities of CMMs are related to the dose and the length of use. Increased dose or extended use may easily cause toxicity.
- (5) Chinese herbal formula should be prescribed by qualified TCM practitioners under the guidance of TCM theories and on the basis of TCM diagnosis. Herbs like aconite should be prescribed by trained practitioners with proper license, rather than sold as a dietary supplement that is available to everyone.
- (6) To avoid herb-drug interaction, consult the expert who is knowledgeable in both modern and Chinese pharmacology.

The unfortunate incidents with aconite in San Francisco could be due to any of the above reasons, or may be not even caused by the herbal tea.

How can we ensure the effective and safe application and regulate herbs like ephedra and aconite that have saved countless people's lives but may also potentially cause harm due to misuse or abuse?

The following are recommendations to the California Department of Public Health and FDA:

- (1) Inviting a group of CMM experts of practice and research who graduated or trained from universities of TCM in China to set up a consultation committee and work with the FDA and other related agencies to discuss the proper regulation to ensure effective and safe application of CMMs.
- (2) Inviting a group of CMM experts write guidance for proper application of Chinese medicine to consumers.
- (3) Establishing a special management team to propose new regulations for Chinese herbs, especially for herbs such as ephedra and aconite that are very effective in treating common diseases but have potential risk if being misused or abused.
- (4) Issuing license to these who sell certain CMMs with safety risk such as ephedra and processed aconite with training.
- (5) Strengthening import management and providing FDA inspectors special training on identification of CMM materials.
- (6) Having accredited labs analyze the imported CMMs and products containing Chinese herbs for safety. This is the best way to prevent the import of adulterated Chinese herb