



# Boundary and scope: the dilemma of Chinese herbal medicine practice in the US concerning incidents during the COVID-19 pandemic

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**[Abstract]** During COVID-19 pandemic, Chinese herbal medicine practices in the United States face challenges for Chinese herbal products application. The FDA has issued at least seven warning letters for alleging these products help to prevent, treat, mitigate, diagnose, or cure coronavirus disease 2019. Although Chinese herbal medicine has been imported to America for about two hundred years, the Chinese herbal products are categorized as dietary supplements and Chinese herbal medicine practices have limited scope and larger boundaries, which push the United States with Chinese herbal medicine practices far more behind. A CLAP (compliance, legislation, adaptation, and promotion) action plan is proposed to advance Chinese herbal medicine development in America.

**[Key words]** Chinese Herbal Medicine; Dietary Supplement; Dilemma; COVID-19; United States

## 1 Introduction

The COVID-19 pandemic is a global health disaster which has infected 113 million people with 2.5 million of them having lost their lives (Data on February 25, 2021) <sup>[1]</sup>. Based on the experiences in China in 2020, Chinese herbal medicine played an important role and acquired successful experiences with promising outcomes during the time the SARS-Cov-2 virus was widely spreading <sup>[2]</sup>. China authority had efficiently released the Guidelines or Diagnosis and Treatment Plan for Novel Coronavirus Pneumonia subsequently in seven editions from January to April 2020, which updated its 8<sup>th</sup> Edition in August

2020<sup>[3-4]</sup>. Chinese medicine protocols had been included in the guidelines since the 3<sup>rd</sup> Edition. Especially, "Three Formulas and Three Medications" were widely applied clinically and corresponding trails were published in national or international peer-reviewed journals confirming the value of Chinese herbal medicine for combating COVID-19<sup>[5-8]</sup>. One systematic review and meta-analysis suggested that Chinese herbal medicine may be beneficial for the treatment of COVID-19 in improving clinical symptoms, imaging, and laboratory indicators, shortening the course of disease, and reducing the number of severe cases<sup>[9]</sup>.

However, in the western countries, Chinese herbal medicine has been facing troubles and dilemmas during its practice especially during the time to combat COVID-19 pandemic. It involves

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unavailability or ban to use of certain herbs like Ma Huang (Ephedrae Herba) and Xi Xin (Asari Herba) which are considered as key herbs in the above-mentioned herbal formulas. The legal barrier is the leading factor to inhibit the development of Chinese herbal medicine in the western countries.

## 2 FDA warnings to herbal products which are claimed to treat COVID-19

America becomes the region hit hardest in the world during this COVID-19 pandemic and so far there are 28.4 million Americans tested positive of this viral infection and the death toll due to COVID-19 is more than a half million (Data on February 25, 2021) <sup>[1]</sup>. But Chinese herbal medicine cannot be applied to treat or prevent COVID-19 during the pandemic even though no significant effective drugs can be found and the vaccine, which it has become recently available to a limited population, would take about a year or even longer to have the majority of Americans vaccinated.

The United States Food and Drug Administration (FDA) is a federal agency of the Department of Health and Human Services. According to the law, the FDA is responsible for protecting and promoting public health through the control and supervision of food safety, tobacco products, dietary supplements, prescription, over-the-counter pharmaceutical drugs (medications), and other medical devices and products. Chinese herbal products are under the category of dietary supplements based on current laws.

The FDA has issued warning letters to firms for selling fraudulent products with claims to prevent, treat, mitigate, diagnose or cure coronavirus disease 2019 (COVID-19) <sup>[10]</sup>. There were total 145 warning letters that have been issued from March 6, 2020 to January 12, 2021. The products include herbal teas, herbal tincture, powders, sprays, nasal sprays, creams, liquid products, syrups, mineral products, vitamins, blessed water, essential oils, and products of homeopathic drug, Ayurvedic medicine, salt therapy, Cannabidiol (CBD), products labeled to

contain silver, and also Traditional Chinese Medicine (TCM) products.

There were seven warning letters related to products of Chinese herbal medicine and the alleged herbal products including herbal formulas and famous herbal capsules which were widely used in mainland China such as Lianhua Qingwen capsules and QingFei PaiDu Tang pills.

On April 6, 2020, a warning letter to one company alleged that some examples of the claims on its website that established the intended use of its products (Chinese herbal tea) and misleadingly represent them as safe and/or effective for the treatment or prevention of COVID-19.

On May 8, 2020, a warning letter to the other company that this company's website claimed that Chinese herbs to maintain healthy immune system during Cold-Damp Phase of Coronavirus (COVID-19) in which the formula included Ma Huang (Substitute could be Zi Su Ye), Gua Lou Shi, Ban Xia, Cang Zhu, Huo Xiang, Zi Su Zi, Fang Feng, Gan Cao, Huang Qi, Fu Ling and Dang Shen. FDA also alleged that this company's website mentioned "Chinese herbs to help maintain immune system health during Coronavirus, COVID-19 and Cytokine storm."

There were four warning letters were issued for the Lianhua Qingwen capsules which were dated as June 26 and July 6, 2020 since those companies claimed this capsule "is effective and can help COVID-19 patients recover and it can weakly inhibit the coronavirus, repair cell injuries and inflammation caused by SARS-Cov-2 virus". The allegation quoted the language which introduced that capsule on website such as "to help prevent corona virus", "fight corona virus", and "It can reduce the occurrence of deterioration with SARS-Cov-2 virus and help patients test negative". The FDA also quoted inappropriate advertisement of Lianhua Qingwen Capsules like "Treats mild fever, cough and fatigue in Cov-2-Virus pneumonia", "Plays an important role in fighting against COVID-19", "Research provides scientific evidence for Lianhua

Qingwen capsules", and "Is widely used in epidemic prevention and control, helping the global epidemic prevention and control".

On the other letters issued on July 6 and July 7, other herbal products were mentioned as unapproved and misbranded products related to Coronavirus Disease which included Shuang Huang Lian, Lung cleaning & Detoxifying pill (QingFei JieDu pian), and QingFei PaiDu Tang. (Anti-COVID pill). Those herbal products were claimed as "anti-viral herbs", "suitable for healthy people to prevent COVID-19", or "indicated for mild, ordinary and serious COVID-19 patients and also it can be used for the severely critical patients subject to the actual condition of patients".

As indicated, the FDA is actively monitoring for any firms marketing products with fraudulent COVID-19 prevention and treatment claims. The FDA is exercising its authority to protect consumers from firms selling unapproved products and making false or misleading claims, including, by pursuing warning letters, seizures, injunctions or criminal prosecutions against products and firms or individuals that violate the law.

### 3 Historic development of Chinese herbal medicine in the US

Chinese herbal medicine has a long history in the United States and the written records dated back to the later colonial periods (1607–1776). One scholar chronicled the dynamic systems of knowledge, therapies, and materia medica crossing between China and the United States from the eighteenth century to the present and also "Chinese medicine" has played an important and often unacknowledged role in both facilitating and undermining the consolidation of medical authority among formally training biomedical scientists in America<sup>[11]</sup>.

From the middle of nineteenth century, thousands of Chinese people came to America as labors for the gold rush and later for construction of the transcontinental railroad. Some of them brought

Chinese medicine into this country which initially was practiced in Chinese communities and later extended to non-Chinese communities. When the large number of Chinese immigrants settled in some cities in California, Oregon, and Washington states, Chinatowns began to grow up and herbal dispensaries and clinics were opened so Chinese community could receive medical treatment from there<sup>[12]</sup>. One article discovered that the fifteen Chinese pharmacies in San Francisco in 1850 served the whole city with Chinese drugs<sup>[13]</sup>. Recently in different published photograph albums, we still can find many photos of earlier time Chinese herbal stores in San Francisco, Los Angeles, Portland, and New York City<sup>[14-17]</sup>.

The herbal stores in late nineteenth century were not only in the biggest cities but also in rural areas. There is a portrait of a Chinese name Lee Me Him posting proudly in the front of his herbal store in Rock Spring's Chinatown, Sweetwater county, Wyoming, around 1895<sup>[18]</sup>. One herbal store called Kam Wah Chung & Co. served the community from 1887 to 1948 in a small town named John Day in the east region of Oregon. The building and all goods and herbs inside are still kept, becoming a museum now. The site currently is a state park and national historic landmark<sup>[19]</sup>. Doc Ing Hay (Wu Yunian)'s story in this building has been widely spread in the west especially his achievement of combating 1918-1919 influenza pandemic with Chinese herbal decoction and Guasha therapy. None of the people he treated died during that special time<sup>[20]</sup>.

Not until 1970's, Chinese herbal medicine started to be a part of legal practices in some states like Nevada and California but is under the title of Oriental Medicine or acupuncture. But many states only had acupuncture practice acts that didn't include Chinese herbal medicine. So far there are 47 states including the District of Columbia which have passed practice acts of acupuncture, however only 22 of them included Chinese herbal medicine<sup>[21]</sup>. In New York state, acupuncture became a legal practice

as earlier as 1975 but "recommendation of dietary supplements and natural products" was not as a part of professional practice of acupuncture until 2016<sup>[22]</sup>. In those decades, Chinese herbal medicine practice was in a gray area. Anyway, a street survey in 1975 based on advertisements discovered that there were at least 32 herbalists, acupuncturists and orthopedics who practiced Chinese herbal medicine in New York City's Chinatown. Also 13 of them had their herbshops<sup>[23]</sup>. The authors also learned that those 32 traditional practitioners were as compared with 40 MD's and 34 stored selling herbs as against 5 pharmacies in the NYC Chinatown at that time<sup>[24]</sup>.

In the United States, acupuncture education began in the early 1970's and the first Master of Acupuncture program was officially accredited in 1985 soon after in 1988 the Master of Oriental Medicine program which included acupuncture and Chinese herbal medicine was also accredited<sup>[25]</sup>. Recently, the degree title of the Master of Oriental Medicine has been changed to Master of Acupuncture with a Chinese herbal medicine specialization. To assess educational outcomes, national certification exam for acupuncture started in 1982 and Chinese Herbology exam added in later years.

Thus, it is clear that acupuncture is an established and independent profession legally practicing in the most states in America but Chinese herbal medicine is associated with acupuncture and also Chinese herbs are categorized as dietary supplements, which cannot be considered as medications.

To regulate dietary supplements, the corresponding jurisdiction laws include, but are not limited to, the Federal Food, Drug, and Cosmetic Act (FD&C Act, 1938 and latest amended in 2007), the Dietary Supplement Health and Education Act (DSHEA, 1994), the Bio-Terrorism Act (2002), the Nutrition Labeling & Education Act (1990), the Food Allergen Labeling and Consumer Protection Act (FALCPA, 2004), the Title 21 Code of Federal Regulation, the Dietary Supplement and Nonprescription Drug Consumer Protection Act (2006), the Final Rules on

cGMP of Food Supplement (2007), and state health, agriculture, and food & drug regulations.

Through the DSHEA, Congress expanded the meaning of the term "dietary supplements" beyond essential nutrients to include such substances as ginseng, garlic, fish oils, psyllium, enzymes, glandulars, and mixtures of these. The DSHEA established a formal definition of "dietary supplement" using several criteria. A dietary supplement:

(1) Is a product (other than tobacco) that is intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients are intended for ingestion in pill, capsule, tablet, or liquid form.

(2) Is not represented for use as a conventional food or as the sole item of a meal or diet.

(3) Is labeled as a "dietary supplement".

(4) Includes products such as an approved new drug, certified antibiotic, or licensed biologic that was marketed as a dietary supplement or food before approval, certification, or license (unless the Secretary of Health and Human Services waives this provision).

Thus it is important for clinician to know that context of use defines category of product. If herbs are labeled (or the patient is verbally provided) with biomedical indications and claims (i.e., treatment, cure, prevention, mitigation, or diagnosis of a disease), then the product will be categorized as a drug by FDA<sup>[26]</sup>.

Through the above introduction, it will not be difficult to understand the reason for the FDA issued warning letters for those herbal product companies during COVID-19 pandemic.

## 4 Strategies for promoting Chinese herbal medicine practice in the US

According the current situation and status in

the United States, the author proposed a CLAP action plan to advance and promote Chinese herbal medicine practices.

**Compliance.** It is very important to make sure that practices are in compliance with the federal, state and local laws and regulations. Especially for Chinese herbal medicine practices, we should try every effort to avoid any violation of laws. All the advertisement, online or printed documents, clinic forms, and labels, if have, are legitimate. Since Chinese herbal products are considered as dietary supplements, we have to not use terms like "cure, treat, or prevent diseases which are biomedical terms". Since the practice scope for licensed acupuncturists is limited and the boundary for Chinese herbal medicine is even more restricted, we have to protect ourselves and abide by all laws and regulations.

**Legislation.** The practitioners and professional associations should unit together to lobbying the lawmakers for provocation of Chinese herbal medicine by introducing more bills in favor Chinese herbal medicine. Chinese herbal medicine practices should get a fair treat. So national organizations need to work on strategies and the optimal goal is to persuade the Congress to establish a new category as an herbal product. The therapeutic effect of herbal products should be appreciated and recognized so those products should be applied clinically which are far more than just as dietary supplements. It is a medicine so it should be considered as being an important composition of integrative medicine in the healthcare system.

**Adaptation.** Chinese herbal medicine should adapt itself to modern medical practices. The unique theories and rich experiences are invaluable but this practice should be able to communicate with allied healthcare providers. Integrative medicine is a trend in the United States so it is critical to incorporate Chinese herbal medicine practice in the mainstream healthcare system. The good news is that one of top medical centers, Cleveland Clinic has begun using Chinese herbal medicine since 2014<sup>[27]</sup>. Safety is the number one concern for Chinese herbal medicine

applications so the herbal product industry should ensure the quality of those herbal products which are not being polluted and not containing pesticide residue, heavy metal, and aristolochic acid, etc. The herbal-drug interaction is an important project which is demanding in the medical field so corresponding research should be approached as soon as possible. The format of herbal products should also be in a convenient way, like concentrated granules. The old fashion of oral administration of herbal decoction is almost impossible to be applied in America. The advancement of Chinese herbal medicine should be assisted with new technology to make this ancient healing art in a modernized platform.

**Promotion.** Having accumulated over thousands of year experiences, Chinese herbal medicine has been used in treating numerous diseases worldwide and the effect is confirmed, credible, and trustworthy. In modern time, evidence-based practice is a golden standard. High quality clinical trials for Chinese herbal medicine are so important but it is unfortunately that they are not as popular as such trials in acupuncture in the United States. Although we cannot use terms like "cure", "treat", or "prevent COVID-19", Chinese herbal medicine still can play an important role in symptom management for patients and even more importantly to those COVID-19 "long haulers". Those patients will be beneficial and successful practice in this special time period can be a point of big promotion of Chinese herbal medicine in the United States.

## 5 Conclusion

Chinese herbal medicine practice has a limited scope but a huge boundary in the United States and is facing big challenges during COVID-19 pandemic since herbal products are categorized as dietary supplements. This status won't be changed in the short term but we still have different ways to advance and promote Chinese herbal medicine, even if it is extremely difficult, and will need more endeavors to be made through several generations. We will never lose our hope.



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