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FDA Regulation of Imported Non-Compliant Chinese Herbal Remedies

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Introduction

“

I've seen the past and it works!”¹ So wrote James Reston, a New York Times reporter, after being treated with acupuncture on the occasion of the removal of his appendix in Beijing in the early 70's. At that point, arguably, Traditional Chinese Medicine (TCM) entered mainstream American Consciousness.² Today in the United States, the use of TCM, of which Chinese herbal medicines are a part, is quite widespread. In spite of this growth, the Food and Drug Administration (FDA) does not have a consistent policy of regulating Chinese herbal medicines.³ The purpose of this paper is to investigate why a policy of regulating Chinese herbal medicines is lacking, and to suggest some possible solutions to the dilemma. To achieve this goal, the paper will be divided into three parts. Part one will briefly examine the history of Chinese herbal medicines, and will specifically define the type of herbal medicines that are the focus of this paper. This part will also contain a description of some of the problems that may arise when some Chinese herbal medicines are ingested, as well as a description of the degree to which alternative medical practices, including herbal remedies have permeated American society. The landscape having been set, in part two I will examine the FDA's response to the issues raised by unregulated

¹James Reston, New York Times journalist, quoted in Harriet Beinfield & Efrem Korngold, Between Heaven and Earth: A Guide to Chinese Medicine xiii (1991).

²Id. at xiii.

³Herbal remedies in general are regulated under the Dietary Supplement Health and Education Act of 1994 (DSHEA). Under the Act, such remedies do not have to undergo rigorous testing and manufacturers may make limited claims for their product as long as they do not claim to diagnose, prevent, treat or cure a specific illness. Some Chinese herbal medicines clearly contravene even these relaxed standards of the DSHEA, yet I have found no evidence of the FDA seeking enforcement under the Act.

non-compliant Chinese herbal medicines. Finally, in part three, I shall present some suggestions for the best approach to the regulation of these remedies.

Part I

A. History & Definition

The Chinese characters for various diseases, inscribed on oracle bones and used for prophesying were the first written documents on the Chinese art of healing.⁴ These inscriptions dated back to the fourteenth century B.C., but it was not until 3,494 B.C. that a legendary Emperor named Shen Nong listed, in encyclopedic form, all the names of the herbal medicaments known at that time, and their various uses.⁵ Knowledge of medicinal herbs and medicaments continued to be based on popular experience and passed down by word of mouth, until over the course of time, these medical traditions were collected in large encyclopedias and lexicons, as well as in literary documents which dealt with specific illnesses and gave accounts of the lives of doctors.⁶ Examples of these include *The Yellow Emperor's Classic of Internal Medicine* dating from 26 A.D. and Li Shih-Chen's *Pharmacopoeia*, produced in 1587.⁷

By the late middle ages, TCM found its way into foreign countries.⁸

By 1605, German physicians were referring to Li Shih-Chen's text, and in 1810 a

⁴Stephan Palos, The Chinese Art of Healing xiii (1971).

⁵Id. at 7.

⁶Id. at 5.

⁷Id. at 9.

⁸Harriet Beinfield & Efrem Korngold, Between Heaven and Earth: A Guide to Chinese Medicine 11 (1991).

French physician reported successfully treating neurogenic diseases with acupuncture.⁹ In the mid 1800s, Chinese immigrants building railroads and mining gold in the United States brought their methods of treatment and their medicines with them.¹⁰ One of the more modern developments in TCM is the production of prepackaged Chinese remedies refined from extracts of crude herbs.¹¹

B. Definitions

TCM is the general name given to a health care system which consists of acupuncture,¹² moxibustion,¹³ Tui Na,¹⁴ Tai Chi, Qui gong,¹⁵ and herbal medicine.¹⁶ Chinese herbal medicines can be obtained in three forms: i) some herbs are available in local Chinese markets. These are used for simple herbal remedies obtained from an informal network of families and friends; ii) more complex formulas can be obtained at a herbal store or pharmacy.¹⁷ In such cases, a specific herbal prescription based on an individual diagnosis is obtained from a herbal practitioner. The pharmacist in the herbal store then weighs each of the herbs according to the prescription. In some of these stores there is also a pharmacist on sight who can prescribe and dispense a remedy.¹⁸ iii) The

⁹Harriet Beinfield & Efreim Korngold, Between Heaven and Earth: A Guide to Chinese Medicine 11 (1991).

¹⁰Id. at 11.

¹¹Daniel P. Reid, Chinese Herbal Medicine 68 (1978).

¹²Acupuncture is the practice of placing metal needles at points in the body to alleviate pain and normalize the body's physiologic function.

¹³Moxibustion is the treatment of points or areas with heat generated by burning the herb mugwort near various points. It is often used in conjunction with acupuncture.

¹⁴Tui Na (also called therapeutic manipulation) is a highly specialized type of massage used to treat muscle injuries.

¹⁵Tai Chi and Qi gong are types of exercise which apply principles of traditional Chinese philosophy to the function of the body in order to build up the body's energy.

¹⁶The preceding descriptions were taken from a bulletin placed on the homepage of the American College of Traditional Medicine.

¹⁷Linda Barnes, Alternative Pursuits: A History of Chinese Healing Practices in the Context of American Religions and Medicine 428 (1995) (Unpublished Ph.D. dissertation, Harvard University).

¹⁸Id. at 429.

third method in which Chinese herbal medicines can be obtained is through the purchase of imported prepackaged herbal medicines (also called Chinese patent medicines) which are sold in Chinese herbal stores in pill, capsule or tonic form.¹⁹ These prepackaged herbal remedies are imported from China, Hong Kong or Taiwan, and they claim to remedy various ailments ranging from the common cold to more serious conditions linked to the brain and heart. Following is a report of some of the types of imported Chinese herbal medicines that are available. These particular medicines were observed in Nam Buk Hong, a Chinese herbal store in Boston's Chinatown.²⁰

C. Examples of Imported Chinese Herbal Medicines

On one side of the Nam Buk Hong pharmacy there was a wall of wooden drawers containing dried herbs for prescription purposes. On the other side of the pharmacy were shelves containing imported prepackaged herbal medicines. There were cough mixtures, tablets for general weakness, fatigue and "feminine weakness." Some of the medicines made specific claims for the cure of ailments such as hypertension, respiratory tract infection, clearing of the lungs, influenza prevention, pneumonia and dizziness. Some of the medicines were labeled only in Chinese while others were labeled in both Chinese and English. Most of the products were made in China, Taiwan or Hong Kong, although a minority were manufactured in the United States. The medicines manufactured in the United States did not tend to have specific health claims. All of the medicines were in brightly colored boxes, and the prices ranged from 60 cents to approximately

¹⁹*Id.* at 429.

²⁰Visit to Nam Buk Hong, 75 Harrison Avenue, Boston. Saturday January 18, 1997.

§8. The following five examples serve as a representative sample of the kinds of medicines observed. The labeling, indication and ingredient information is reproduced here as they appear on the box.

1. Fritillaria Verticellata & Loquat

Recommended in Dry or Spasmodic Cough. Dose: Half to One Table-spoonful.

Price: \$2.50. Made in Honk Kong.

These were the only words in English on the box of this fairly common cough syrup.

Similarly, the insert was printed only in Chinese.

2. Ganmaoling Tablets

Made in Qixing Pharmaceutical Factory, Guangzhou, China. Man-ufacture supervised by the Guandong Medicines & Health Products Import & Export Corporation. Price: 60 cents.

Actions and Indications: Antipyretic, antiphlogistic and antidotal. Applicable to common cold and prevention of influenza, epidemic ei-cephalitis.

Direction and Dosage: For adult, four tablets each, three times daily. Double dosage in severe cases, Children decreased accordingly.

Prevention: Two tablets each, two times daily, to be taken continu-ously 3 days.

Ingredients: Flos Lonicerae: 4.85%; Flos Chrysanthem Indici: 13.03%; Folium Et Ramulus Evediae Leptae: 21.72%; Radix Licis Asperallae: 34.33%; Mentholum: 0.01%.

The insert was written in both Chinese and English, and stated the following:

Ganmaoling a most effective preparation for the treatment of com-mon cold and influenza, is extracted from selected Chinese medicinal herbs by means of scientific method. The chief actions of these medic-inal ingredients of Ganmaoling are antipyretic, antidotal and antiphlo-gistic. the antipyretic efficiencies is affording instantaneous relief with effects remarkably marvelous. Clinical observation has proved that Ganmaoling is excellent in cure and prevention of common cold and influenza. It is particularly valuable in the treatment of influenza with fever of different degrees during the onset of the disease. Usually a dosage of four tablets can effectively put under control all of symptoms. Owing to its quick action and absence of undesirable side effects, both doctors and patients prefer to use this remedy.

The actions and indications, directions, dosage and prevention statements were repeated

in the insert. The bottle contained 36 bright yellow coated tablets.

3. Fare-You (Vitamin U Complex)

Made in Qiaoquang Pharmaceutical Factory, Guangzhou, China.

The latest and most effective remedy for various sorts of gastric pains,

and ulcer and duodenal ulcers. Price: \$2.20.

Indication: Treatment of peptic ulcers: as gastric duodenal ulcers, achylia gastrica, hyperacidity, chronic gastritis, regurgitativa and lesions in the coats of the stomach.

Dosage: 1 - 2 tablets each time, Thrice a day.

The insert was in Chinese and English and stated the following:

The preparation of Fare-you (Vitamin U Complex) is a new special remedy. They are made from the best quality of vitamin U and other ingredients. These tablets are reputed to be the latest and most effective medicine for gastric duodenal ulcers, chronic gastritis and various types of gastropathies.

The diseases mentioned above generally are due to the functional irritation of the gaster or lesions in the coats of the stomach. But nothing can resolve the difficulties of the problem. It is only after the discovery of Vitamin U Composita tablets of our laboratory, that a cure is possible for the purpose.

This medicine is a specialty for gastrophies: It provides for the organism with more proliferative methyl to promote the ulcerated part of gastro-intestinal tissue to accelerate healing. We strongly recommend to use our products "TABLETS FARE-YOU COMPOSITA." Those who are effected with this kind of disease will be cured quickly, and the disease will soon be eradicated.

The dosage and indication were repeated in the insert. The bottle contained 50 bright yellow coated tablets that looked identical to the Ganmaoling tablets.

There was no ingredient list in English.

4. Sumalin

Made in Ming Xing Pharmaceutical Factory, Guangzhou, China. Sugar-coated tablets. 100 tablets.

Actions and Uses: Sumalin is remedy for prevention and treatment of coronary heart disease. It reduces elevated plasma cholesterol, triglyceride and B-lipoprotein levels and dilates coronary artery. It is used in artherosclerosis and other conditions characterized by high blood cholesterol level, such as angina pectoris, myocardial infarction, heart failure, hypertension, dizziness, headache, palpitation and breathlessness etc.

Dosage and Administration: 3 times daily 2 or 3 tablets each time after meal, or prescribe by doctor.

Storage: Preserve in dried place in well closed container.

There was no ingredient list in English and the package insert was in Chinese only.

5. Naolutong Capsule

Made in China by the United Pharmaceutical Manufactory, Kwang-

chow. Price: \$5.50.

Use: Naolutong is a new product for treatment of cerebral apoplexy and meningitis, cerebral palsy, spastic myeloplegia, amyotrophic lateral sclerosis.

Dosage: 1 - 2 capsules each time, 3 times daily.

Everything else on the box and the bottle was in Chinese. The insert was also in Chinese, but repeated the use and dosage information in English. There was no ingredient list in English, although there appeared to be one in Chinese. The bottle contained 30 beige and burgundy capsules.

It is evident from the preceding descriptions that these imported Chinese herbal medicines do not conform either to the DSHEA or to the statutory provisions mandated by the Food, Drug and Cosmetic Act (FDCA) for the approval of new drugs. Yet they are easily available in herbal stores and pharmacies in Chinatown (indeed, this law student was able to purchase a variety of these medicines without making a dent in an otherwise limited budget). It is unclear what is in these herbal medicines: as we have seen, some of the medicines have no ingredient lists, and even if they do, it is not certain that the medicines contain what they say they do. The range of ailments supposedly cured by these medicines is unfathomable – it is difficult to imagine a cure for cerebral palsy or coronary heart disease coming in the shape of these medicines. Clearly some of these imported Chinese herbal medicines present a perfect opportunity for the FDA to “protect the unthinking from the unscrupulous.”

It is worth noting that there is a strong contrast with this picture when one asks for Chinese herbal remedies in a general healthfood store. For example

in the Cambridge Natural Foodstore²¹ two or three shelves of Chinese herbal medicines consisted of medicines manufactured in the United States which made no health claims but did list the ingredients. The contrast between the two sets of herbal medicines put in sharp relief the difference between compliant and completely non-compliant unregulated medications.

D. The Dangers of Imported Chinese Herbal Medicines

There are a lot of thing I don't believe work. The worst are the prepackaged medicines from China. There is no quality control, no FDA. Anyone can open a company. There is no need to tell the side effects, like with arthritis medicine. This is the most notorious case. It is a medicine with a steroid-related compound, which can cause serious illness. If I were given the choice between prepackaged medicines and loose herbs, I would take herbs.²²

This quotation highlights the basic concern about imported Chinese herbal medicines. Many of the medications remain largely untested (as do the majority of herbal preparations), nor do they list information about side effects or contraindications.²³ In addition, batch-to-batch variability is a serious problem with herbal preparations, and the companies producing these preparations do not employ rigid quality-control standards; neither do they evaluate their products for purity and reliability.²⁴ For example, an analysis of 24 herbal preparations of ginseng revealed the absence of ginsenosides, the active pharmacological constituent of ginseng.²⁵ Further analysis of the ginseng preparations indicated

²¹Visit to Cambridge Natural Foods, 1670 Massachusetts Avenue, Cambridge. Saturday January 18, 1997.

²²Paul Kwan, Research Assistant Professor in the Department of Pathology at Tufts Medical School, and long-time student of Martial Arts. Quoted in Linda Barnes, Alternative Pursuits 429 (1995) (Unpublished Ph.D. dissertation, Harvard University).

²³Jacqueline Gazzera & John Pinto, *Herbs: Use and Abuse* Current Concepts and Perspectives in Nutrition, Vol. 6, July 1987.

²⁴Id.

²⁵Jacqueline Gazzera & John Pinto, *Herbs: Use and Abuse* Current Concepts and Perspectives in Nutrition, Vol. 6, July 1987.

the inclusion of incorrect species, altered mixtures of species, underweight products and improper product labeling.²⁶ Because herbal preparations (including Chinese herbal medicines) are not usually evaluated for purity and consistency of active components, they can contain contaminants.²⁷ Lead poisoning caused by the ingestion of prepackaged Chinese herbal medicines has been reported in China, although it was unclear whether the lead was an ingredient or a contaminant.²⁸ In the United States, the FDA has found that imported Chinese herbal medicines that listed only herbal ingredients on the labels contained several compounds, in addition to arsenic, mercury, tin, zinc and lead.²⁹

High levels of toxicity are another problem found in imported Chinese herbal medicines. These medications can be toxic on their own, or they can become toxic when they are taken in conjunction with other drugs.³⁰ In 1994, the Journal of the American Medical Society reported cases of toxicity in three adults after they had taken Jin Bu Huan (JBH), a Chinese herbal product which was prepackaged in tablet form for use as a sedative and analgesic.³¹ All three patients were diagnosed with acute hepatitis after taking the medication, and their cases were later linked to three cases in Colorado, this time involving children who had taken unintentional doses of JBH that caused a depression of the central nervous and respiratory systems, as well as the rapid onset of an extremely slow heartbeat.³² On further analysis it was discovered that the plant

²⁶Id.

²⁷Id.

²⁸Id.

²⁹Id.

³⁰Id.

³¹G.M. Woolf et al., *Jin Bu Huan Toxicity in Adults - Los Angeles 1993*, 271 JAMA 423 (1994).

³²Id. at 423.

source and the percentage of active ingredient indicated on the JBH labels were incorrect.³³

During the past twenty years, the FDA has identified several deaths and many hospitalizations linked to imported herbal medicines from China.³⁴ An example is the reported case of a chemist in the FDA's Seattle office who analyzed ten samples of confiscated Chinese Rhino Horn Tea Balls – a mixture of ground up rhino horns and herbs commonly used to help people who have a very high fever, or have suffered a stroke.³⁵ Although no trace of rhino horn was found, dangerously high levels of lead, mercury and arsenic were.³⁶ In New York, after a Chinese child was exhibiting strange behavior, his mother admitted to feeding him imported Chinese herbal medicine. Subsequent tests showed that the child was suffering from mercury poisoning.³⁷ Other imported Chinese medicines have been found to contain various Western medicines, including barbiturates, non steroidal anti-inflammatory agents, antibiotics, diuretics and narcotic pain relievers.³⁸

All of the dangers listed above are exacerbated by the fact that people who take these herbal medications are often treating themselves and do not recognize the danger. Neither do they realize that they may be ingesting dangerous levels of toxic substances or products that are improperly mixed or labeled.³⁹

³³Id. at 424.

³⁴Evelyn Iritani, *A Warning on Imported Herbal Medicine: Lethal Toxins in Some Formulas*, Seattle Post-Intelligencer, Nov. 9, 1994 at C1.

³⁵Id.

³⁶Id.

³⁷Id.

³⁸Elaine Kang-Yum, *Cross-cultural Miscommunication*, 26 Hastings Center Report, May 15, 1996.

³⁹Evelyn Iritani, *A Warning on Imported Herbal Medicine: Lethal Toxins in Some Formulas*, Seattle Post-Intelligencer, Nov. 9, 1994 at C1.

Additionally, people who tend to use medicinal herbs rarely consult with their doctors, Asian or Western, so they might well be unaware of the potential interactions between different drugs.⁴⁰ There is additional cause for concern when part of the population targeted by manufacturers of imported Chinese herbal medicines are a specific immigrant group such as Asians. Immigrants might not only be unaware of the danger, but once they do find out, they might be uncomfortable reporting ill-effects or making claims. Underpinning all of these factors, and indicating the importance of the issue, is the increasing knowledge and use of herbal medicines and alternative medical practices among all facets of the American population.

E. The Increasing Popularity of Alternative Medicine, including Herbal Medicines, in the United States.

Perhaps the most obvious indication of the widespread use of herbal remedies in the United States is the amount of money spent on such remedies. A study published by the New England Journal of Medicine found that the total projected out-of-pocket expenditure for unconventional therapy plus supplements was \$10.3 billion in 1990.⁴¹ This compares quite favorably with the out-of-pocket expenditure for all hospital care in the United States which was \$12.8 billion in 1990, and the amount spent out of pocket for all physicians' services in the same year – a total of \$23.5 billion.⁴² Although these figures cover all methods of alternative medicine, the figures for herbal product sales alone have

⁴⁰Elaine Kang-Yum, *Cross-cultural Miscommunication*, Hastings Center Report, May 15, 1996.

⁴¹David Eisenberg et al., *Unconventional Medicine in the United States – Prevalence, Costs, and Patterns of Use*, 328 *New Eng. J. Med.* 246 - 252 (1993).

⁴²Id.

increased from \$167 million in 1980⁴³ to \$2 billion in 1995.⁴⁴ It is of course difficult to ascertain how much of these figures is spent on imported Chinese herbal medicines. The importance of the figures however, is that they indicate the degree to which herbal products have gained in popularity, and with that comes the recognition that Chinese herbal medicines may indeed be considered a viable part of an alternative regimen and may take their place firmly within the cadre of alternative medical practices.

There are other indications of the extent to which alternative remedies have permeated American culture. The New England Journal of Medicine study which has already been quoted, concluded that unconventional medicine had an important presence in the American healthcare system.⁴⁵ One in three respondents used unconventional therapy in 1990, and the estimated number of visits made in 1990 to providers of unconventional therapy was greater than the number of visits to all primary care physicians nationwide.⁴⁶ The study also found that approximately one in four Americans who see their physicians for a serious health problem, may be using unconventional therapy in addition to conventional medicine for that problem, and 7 out of 10 of the latter encounters take place without patients telling their physicians that they use unconventional therapy.⁴⁷ The study did find that unconventional therapy was used as an ad-

⁴³Jacqueline Gazzera & John Pinto, *Herbs: Use and Abuse* Current Concepts and Perspectives in Nutrition, Vol. 6, July 1987.

⁴⁴Lauren Picker & Joshua McHugh, *Herbal Medicine Goes Mainstream*, Am. Health, May 1, 1996.

⁴⁵David Eisenberg et al., *Unconventional Medicine in the United States – Prevalence, Costs, and Patterns of Use*, 328 New Eng. J. Med. 246 - 252 (1993). The study investigated the use of unconventional therapies such as acupuncture and massage therapy among English speaking respondents over the age of 18.

⁴⁶Id.

⁴⁷David Eisenberg et al., *Unconventional Medicine in the United States – Prevalence, Costs,*

junct to conventional medicine, but that half of those who did use unconventional therapy for their principal medical conditions have no supervision of such treatment by either a medical doctor or a provider of unconventional therapy. According to the study, approximately 20 million Americans fall into the latter, unsupervised category.⁴⁸ Again, these findings do not apply specifically to the use of imported Chinese herbal medicines, however they show a willingness, on the part of a significant portion of Americans to try alternative medicines. As many consumers grow disillusioned with harried, impersonal doctors and potent drugs, trade publications report that such consumers are turning to herbal teas, pills, extracts and salves to treat everything from high cholesterol and migraine headaches to the common cold.⁴⁹ It is not inconceivable that some of these consumers might seek to add Chinese herbal medicine to their other methods of alternative healing.

The widespread use of alternative medicines in American society has been recognized at Federal and State levels. For example, an Office of Alternative Medicine (OAM) was created in 1992 within the National Institutes of Health, with an \$8 million budget to investigate, among other things, the use of traditional Chinese herbs in treating a variety of medical conditions.⁵⁰ For example, a center funded by the OAM at the University of Texas plans to investigate the effects of herbs and natural products on cancers.⁵¹ Of the

and Patterns of Use, 328 *New Eng. J. Med.* 246 - 252 (1993).

⁴⁸Id.

⁴⁹Lauren Picker & Joshua McHugh, *Herbal Medicine Goes Mainstream*, *Am. Health*, May 1, 1996.

⁵⁰Joy McIntyre, *OAM Commences \$8 million Investigation into Alternative Therapies*, *The Scientist*, Jan. 22, 1996 at 6.

⁵¹Id.

40 different research projects funded by the OAM between 1993 and 1995, five were in Chinese herbal medicine.⁵² In addition, the 1994 Dietary Supplement and Health Education Act exempts herbs and vitamins from the FDA's rigorous drug approval process. In the "findings" section, the Act acknowledges that more consumers are relying on non traditional health care, and that "50% of 260,000,000 American regularly consume dietary supplements of vitamins, minerals, or herbs, as a means of improving their nutrition."⁵³ Other pertinent pending federal legislation includes the Access to Medical Treatment Act proposed in July 1995 by Senator Tom Daschle. The Act provides for an individual to choose any medical treatment offered by a health care practitioner (including medical treatment that has not been approved, certified or licensed by the Secretary of Health and Human Services), as long as the individual is informed of the approval status of such treatment.⁵⁴ This bill has not yet been enacted.

On the state level, New York has amended its Public Health Act to enable unconventional therapies to be used, and to provide for a Board for Professional Medical conduct with two physicians who dedicate a significant portion of their practice to the use of non-conventional medicines.⁵⁵ In 1996 Washington State passed its first law requiring every insurer to cover all licensed healers including alternative practitioners such as acupuncturists, naturopaths, massage therapists and midwives; and the King County Council, which governs the greater Seattle area, has unanimously voted to establish a naturopathic health

⁵²Corinna Wu, *Yin and Yang, Western Science makes Room for Chinese Herbal Medicine*, Science News, Sept. 9, 1995 at 172.

⁵³21 U.S.C. § 321(9) (1994) (new section 201(9) of the FDCA).

⁵⁴S.1035, 104th Cong., 2d Sess. (1995).

⁵⁵N.Y. Public Health Law §230 (McKinney 1992).

clinic.⁵⁶

Research by biotechnology firms and pharmaceutical companies which is based on the pharmacopoeia of Chinese herbal medicine is not uncommon.⁵⁷ For example, the biotech firm Pharmagenesis is investigating compounds from Chinese herbs in its attempt to develop therapeutics that augment or suppress the immune response, or that stimulate red blood cell production.⁵⁸ Similarly Pfizer Incorporated is studying traditional Chinese herbs as potential sources of new medicines under an agreement with the China Academy of Traditional Medicine in Beijing.⁵⁹ Such developments acknowledge the importance of Chinese herbal medicine, and inevitably lend credence to alternative medicines such as imported Chinese herbal medicines.

There are many other less formal indications of the permeation of the notion of alternative healthcare in the United States. Some mainstream physicians are prescribing herbal remedies along with standard drugs, and some insurance companies, HMOs and other health plans have begun to cover their costs when prescribed by health care professionals.⁶⁰ In addition, a new generation of Asian herbal companies operating in the U.S. are popping up, mostly on the West Coast.⁶¹ The result of all of this type of activity is bound to be the increased awareness of the availability of Chinese herbal medicines.

⁵⁶Timothy Egan, *Seattle Area Giving Natural Medicine a Chance to Come in from the Fringe*, N.Y. Times, Jan. 3, 1996, at A10.

⁵⁷Alison Mack, *Biotechnology Turns to Ancient Remedies In Quest for Sources of New Therapies*, The Scientist, Jan. 6, 1997 at 1, 8.

⁵⁸Id.

⁵⁹Id.

⁶⁰Lauren Picker & Joshua McHugh, *Herbal Medicine Goes Mainstream*, Am. Health, May 1, 1996.

⁶¹*Biostrategies in the Pacific Rim*, Genetic Engineering News, June 15, 1996.

Also to be considered in these developments is the growth of information output from various media. Newspapers and magazines like the New York Time, The Boston Globe, Times, Newsweek and Forbes often present articles concerning alternative medical practices.⁶² Not to be outdone, supermarket tabloids contain a preponderance of advertisements for Chinese herbal medicines, most commonly Chinese weight loss formulas. The National Enquirer even printed a front page story on how acupuncture and Chinese herbal medicines helped Vanna White become pregnant (“I wish I could tell you what the herbs are. I’ve got the bottles but I can’t pronounce the names!”)⁶³ On television, Bill Moyers has hosted a series of programs on PBS on the subject of alternative healing practices entitled *Healing and the Mind*.⁶⁴ The first show which was co-hosted by Dr. Eisenberg covered the use of acupuncture, herbs and Qigong in China.⁶⁵ The program was covered positively in national newspapers, and the book accompanying the series reached number four on the Bestseller list of the New York Times Book Review.⁶⁶ There are also advertisements for TCM in sources as diverse as the telephone directory and new age newspapers. And there is a profusion of information on the subject on the world wide web. One such information page, put up by a certified acupuncturist and degreed Chinese herbalist, asserted that “Chinese patent medicines offer a safe, easy and cost-effective means of dealing with a wide variety of ailments.”⁶⁷ In

⁶²Linda Barnes, *Alternative Pursuits: A History of Chinese Healing Practices in the Context of American Religions and M* 436 (1995) (Unpublished Ph.D. dissertation, Harvard University).

⁶³*Id.* at 437.

⁶⁴*Id.* at 437.

⁶⁵*Id.* at 437.

⁶⁶*Id.* at 437.

⁶⁷Randy Bimestefer, Dipl.Ac. Web page entitled *Taking the Mystery Out of Chinese Patent*

addition to all of this information, there are twenty-seven colleges accredited in acupuncture and Chinese herbal medicine across the United States,⁶⁸ and some medical schools are beginning to add training in alternative therapies to their curricula.⁶⁹

Chinese herbal stores are themselves reaching out to a wider audience. One indication of this is that in 1992 the city of Boston yellow pages listed only 3 herbal stores; by 1995, 8 stores and 5 practitioners were listed.⁷⁰ In 1996 the listings had grown to include 11 Chinese herbal stores. This number is still small compared to San Francisco's 1992 listings which included 54 herbal stores, herbal import companies and private label practitioners.⁷¹

Evidently information about alternative medical practices including imported Chinese herbal medicines is reaching Americans at several different levels. There is a wide range of information to choose from, and it is not inconceivable that stories about Americans turning to Chinese herbal medicines may encourage others to follow, perhaps not always having the best tools to distinguish between what is safe and effective and what is not. Consumers may well go to Chinatown to check out the reasonably priced herbal remedies, without any idea that they are potentially ingesting non-compliant and in some cases

Medicine. The article described the "brightly colored boxes that allow for easy display and customer recognition" to be found in Chinese herbal stores. It then described the types of remedies available, listing common colds, digestion and topical solutions, but declining to mention the type of medicines described earlier in this paper, with their extreme claims to cure heart or brain diseases.

⁶⁸Web page of the American College of Traditional Medicine, 455 Arkansas Street, San Francisco, CA 94107.

⁶⁹Marlene Cimons, *New Life for Old Remedies: No Longer Dismissed as Fringe Ideas, such "Traditional" Therapies as Acupuncture and Herbs Are Going Mainstream*, L.A. Times, Jan. 1, 1996 at A.

⁷⁰Linda Barnes, *Alternative Pursuits: A History of Chinese Healing Practices in the Context of American Religions and Medicine* (1995) (Unpublished Ph.D. dissertation, Harvard University).

⁷¹Id. at 440.

dangerous herbal remedies.

Part II

A. FDA Regulation of Imported Chinese Herbal Medicines

The FDA does not appear to have a specific, coherent policy when it comes to regulating non-compliant imported Chinese herbal medicines. The agency's response to the problems posed by this trade runs the gamut from articles in the FDA consumer on subjects such as how to avoid fraud, how to detect quackery, and whether herbs can really heal⁷² to enforcement of a ban on certain herbal medicines after a crisis has occurred, or in response to claims that people have made. The limited resources of the Agency undoubtedly contribute to this approach. Dr. Lori Love, a physician in the FDA's Center for Food Safety and Applied Nutrition, has said that the FDA focuses its limited resources on investigating the most serious complaints.⁷³ This view was underscored by Mr. William Goodrich, Chief Counsel of the FDA from 1939 to 1971.⁷⁴ Mr. Goodrich explained that the FDA attitude toward imported Chinese herbal medicines during his tenure was that if the medications did not

⁷²See e.g. Isadora B. Stehlin, *An FDA Guide to Choosing Medical Treatments* from the FDA homepage on the world wide web: <http://www.fda.gov>. ; *The FDA's List of Top Health Frauds*, also available from the FDA homepage; Roger W. Miller, *Can Herbs Really Heal?*, FDA Consumer June 1987 at 32. It is not clear how widely such warnings are disseminated among the general public – it is almost certain that such warnings do not reach the Asian community.

⁷³Evelyn Iritani, *A Warning on Imported Herbal Medicine: Lethal Toxins in Some Formulas*, Seattle Post-Intelligencer, Nov. 9, 1994 at C1.

⁷⁴Telephone Interview with Mr. William Goodrich, former Chief Counsel, FDA (Jan. 14, 1997).

hurt anyone “except for those trying to fool with it,” then regulation of such drugs was not a priority. He explained by way of an example, that the FDA’s budget in 1951 was approximately \$51 million, and there were many pressing need that required the Agency’s scant resources, so if the imported Chinese medicines were not harming a lot of people, then they could not possibly be a priority. Mr. Goodrich also pointed out that, in any event, there were not many instances of claims of fraud that came to the attention of the FDA. He was of the opinion that the attitude he described probably persists in the Agency today. Indeed, Brad Stone, a representative of the FDA has stated that the FDA has no specific policy concerning any herbal product about which they have received no complaints.⁷⁵

Imported Chinese medicines that have elicited specific complaints or which contain herbs under investigation are not allowed to be imported. Mr. Sam Fine, a 44 year veteran of the Agency emphasized this method of regulation.⁷⁶ Mr. Fine remembered discussion at the FDA about the dangers of Chinese herbal medicines, particularly when mixed with American drugs. Mr. Fine stated that the FDA sought control of these imported Chinese medicines through collaboration with the Bureau of Customs, to stop any misbranded drugs or drugs with false and misleading claims from entering the country. The most common method was to issue import alerts. Mr. Fine also stressed that there were not very many claims made, and there were certainly no prosecu-

⁷⁵Quoted in Randy Bimestefer, *FDA On Chinese Patent Medicines* in Taking the Mystery Out of Chinese Patent Medicines on the world wide web.

⁷⁶Telephone Interview with Mr. Sam Fine, former Associate Commissioner for Compliance, FDA (Jan. 14, 1997).

tions. From Mr. Fine's perspective, the main method by which the FDA sought compliance was through border control. Mr. Fine said that he was not certain what the current attitude at the FDA on the issue might be.

Import alerts are still used, and during the research for this paper, one such alert was found, which had been revised in 1991, with the latest attachment dated December 18, 1996. Although the import alert may be effective in keeping targeted medications out of the country, the method encourages a regulatory scheme that is crisis oriented. An example of this is the Agency's response to the ephedrine controversy.⁷⁷ In August 1996, after receiving over 600 reports of injuries and the occurrence of 17 deaths associated with ephedrine supplements, the FDA contemplated stopping sales by those who advertise ephedrine as "herbal high" alternatives to illegal drugs.⁷⁸ In addition, an FDA advisory committee unanimously recommended that manufacturers be required to place warning labels on dietary supplements containing ephedrine or one of its derivatives.⁷⁹ As of December 1996, no one was quite sure what the final FDA action would be. I would argue that a coherent planned policy concerning herbal medicines would lead to more effective regulation, rather than an ad hoc approach which tends to leave manufacturers as well as consumers in the dark.

There are three additional ways in which the FDA responds to the problem of illegal imported Chinese medicines. One method is to carry out ac-

⁷⁷Ephedrine is not a prepackaged imported Chinese medicine, but rather is made in the United States from the Chinese herb Ma Huang. The example is useful for showing how the ad hoc approach works.

⁷⁸*U.S. May Move on "Natural High" Herbs: Ephedrine is at Issue in FDA Inquiry*, Boston Globe, Aug. 28, 1996 at A11.

⁷⁹Reed Johnson, *The Downside of New "Herbal Drugs"*, L.A. Daily News, Sept. 9, 1996 at L3.

tual enforcement against imported medicines that are already in the country. It appears that this happens rarely, although in 1991 the FDA worked in partnership with the FTC to stop a New York firm's false labeling and false advertising in Chinese.⁸⁰ A second method of response is for the FDA to join with other institutions or agencies for research purposes. A recent Hastings Center Report indicated that due to an increase in reported cases of severe and fatal poisonings from Chinese herbal medicines, the FDA, the California Health Department and the Hudson Valley Regional Poison Control Center have begun gathering data on the adverse effects, contraindications and other potential problems raised by using these medications. The aim of the joint activity is to make the public and the medical community more aware of the potential health hazards and eventually to provide the medical community with more data.⁸¹

The third way in which the FDA has responded to Chinese herbal medicines is by granting approval to the Chinese manufacturers of certain herbal medicines. For example, the Agency has granted approval of Hainan Hengxin Pharmaceutical Company's Ginseng Pills to enter the U.S. market.⁸² In 1991 the FDA granted a Tokyo based company specializing in Chinese herbal medicines approval to run phase II clinical trials of a Chinese herbal medicine for treating

⁸⁰Igor Cerny et al., *Reports from the Field*, FDA Consumer, April, 1991 at 43. Both the FDA and the FTC received complaints about the extravagant claims made by two imported Chinese medicines which included cures for breast cancer and heart disease, as well as arteriosclerosis. The FDA in this case, warned the importer that because of the health claims, the products were considered drugs, and that the company either had to stop making such claims, or provide scientific evidence to support them

⁸¹Elaine Kang-Yum, *Cross-cultural Miscommunication*, Hastings Center Report, May 15, 1996.

⁸²*Hainan Herbal Medicine Wins Approval from the FDA*, Comline Daily News, January 6, 1997.

chronic rheumatoid arthritis.⁸³ The latter type of approval is extremely unusual as most manufacturers of herbal medicines cannot afford to pay for the lengthy Investigational New Drug and New Drug Application processes – particularly there is no certainty that the end result will be patentable.

The FDA's regulatory response to the dangers raised by the non-compliant sale of imported Chinese herbal medicines is quite varied. Yet there are statutory provisions which give the FDA full authority to act in this area.

B. Current Statutory Provisions Under Which Imported Chinese Herbal Medicines Can be Regulated.

1. The Dietary Supplement Health and Education Act of 1994. (DSHEA)

Illegal imported Chinese herbal medicines can undoubtedly be regulated under the DSHEA. However, it should be noted that because the Act limits the FDA's authority to regulate products regarded as herbal supplements, it is probably not the best instrument by which to reach Chinese herbal medicines. The specific health claims on many of these herbal medicines take them out of the DSHEA and place them squarely in the Food, Drug and Cosmetic Act (FDCA) provisions for regulating new drugs. Nevertheless, it worth examining the DSHEA to indicate the most potent provisions under which the FDA could regulate the non-compliant herbal medicines.

The DSHEA provides a broad definition of dietary supplement under which herbs are clearly included.⁸⁴ In terms of claims and labeling, section 403(r)(6) permits a dietary supplement to make a health claim only if the state-

⁸³*FDA Grants Tsumura Approval to Run Trials on Chinese Herbal Medicine*, Comline Daily News, December 17, 1991.

⁸⁴See 21 U.S.C. § 321 (ff)(1); (new section 201 (ff)(1) of the FDCA).

ment “describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans,” characterizes the “documented mechanism” by which it does so or describes “general well-being” resulting from their consumption.⁸⁵ To take advantage of this exemption, the supplement manufacturer must have substantiation that the claim is truthful and not misleading, must notify the FDA within 30 days of first marketing a supplement with such a statement and must include a statement to the effect that the product has not been evaluated by the FDA and is not intended to “diagnose, treat, cure or prevent a disease.”⁸⁶ Claims which meet the test for section 403(r)(6) are excluded from the drug definition under 201(g)(1)(c).⁸⁷ Under DSHEA, dietary supplements are required to list the name and quantity of each dietary ingredient.⁸⁸ A dietary supplement is misbranded if it contains a herb and the labeling fails to identify any part of the plant from which the ingredient is derived.⁸⁹

The DSHEA also contains new provisions for safety standards. The Act provides that a dietary supplement will be deemed to be adulterated if “it presents a significant or unreasonable risk of illness or injury.”⁹⁰ In addition, the Secretary of Health and Human Services may declare a dietary supplement to “pose an imminent hazard to public health or safety,” after which it becomes immediately illegal to market the product.⁹¹

⁸⁵21 U.S.C. § 343 (r)(6); (new section 403(r)(6) of the FDCA).

⁸⁶21 U.S.C. § 343 (r)(6)(C); (new section 403 (r)(6)(C) of the FDCA).

⁸⁷Covington & Burling Memo, *Dietary Supplement Health and Education Act of 1994*, Oct. 12, 1994 at 5.

⁸⁸21 U.S.C. § 343 (s)(2)(A); (new section 403 (s)(2)(A) of the FDCA).

⁸⁹21 U.S.C. § 343 (s)(2)(C); (new section 403 (s)(2)(C) of the FDCA).

⁹⁰21 U.S.C. § 342 (f)(1)(A); (new section 402 (f)(1)(A) of the FDCA). The Act specifies that the FDA has the burden of proving adulteration.

⁹¹21 U.S.C. § 342 (f)(1)(c); (new section 402 (f)(1)(C) of the FDCA).

I have recounted these provisions of the DSHEA at some length in order to show that, although imported Chinese herbal medicines do come within the purview of the Act, they potentially violate each provision relevant to them. Using the examples of illegal imported Chinese herbal remedies described in part one, it is clear that they do not comply with either the claim and labeling standard, or the safety standards within the Act. Presumably, the FDA could remove all such illicit medicines from the market under the Act, even if the Agency does have the burden of proof. However I have found no evidence of enforcement under the Act.

2. Regulation of Imported Chinese Herbal Remedies Under the Food, Drug and Cosmetic Act.

By making the rather extravagant health claims of the sort described in part one, illegal imported Chinese herbal remedies could be regulated as new drugs without an effective new drug application under section 355.⁹² These medications can, as we have seen, also be refused admission into the country under the import provisions of section 381(a)(3).⁹³ Finally, non-compliant imported Chinese herbal remedies can be regulated as misbranded drugs under section 352(a).⁹⁴

This statutory review would seem to indicate that the FDA has all the statutory authority it would need to police non-compliant imported Chinese herbal remedies. Yet a visit to many Chinese herbal stores or pharmacies indicate that the Agency is not using its power. In the final part of this paper I

⁹²21 U.S.C. § 505; (new section 355 of the FDCA).

⁹³21 U.S.C. § 801(a)(3); (new section 381(a)(3) of the FDCA).

⁹⁴21 U.S.C. § 502(a); (new section 352(a) of the FDCA).

will attempt to point out some of the negative effects of this lack of regulation and propose some methods in which the FDA could be more proactive in its approach while taking into account its limited resources.

Part III: Possible Solutions

A. Negative Effects of FDA's Lack of Enforcement

In the vast range of herbal remedies that are available, one can obtain anything from the purest quality of herbal extracts to the type of herbal remedies analyzed here and which are not in compliance with FDA requirements. Non-compliant Chinese imported herbal remedies are not the only potentially fraudulent medications on the market, but there are some important reasons why the Agency's attention should be focused on this issue. The fact that imported Chinese herbal remedies are mostly sold in the Chinatowns of various cities should not be a bar to regulation. Rather, it is precisely these immigrant populations that the FDA should be protecting. Although there are important cultural issues at stake, it is possible to protect a population without whittling away their cultural traditions. There is, I think, a world of difference between the Chinese herbalist who measures out prescribed dried herbs in his or her pharmacy, and the prepackaged imported herbal remedies on the shelves, heralding their fabulous cures for every conceivable sickness. If indeed, the FDA's goal is to protect the unthinking from the unscrupulous, the mantra should apply equally to everyone, including discrete immigrant groups. In any event, quite

apart from the implication of exclusionary regulation, the argument that fraudulent imported Chinese remedies only affect a few people, flies in the face of current trends in American society. As more people become disillusioned by the increasing costs of medical care as well as the impersonal nature of it, Americans are turning to alternative medical practices in large numbers. The population is obtaining a great deal of information from many different sources – not all of it with the same degree of trustworthiness. It is therefore in the best interests of public safety to prevent and police the incidence of non-compliant imported Chinese remedies. Some might press the argument that the FDA really does have more important things to do with its limited resources (regulating the race for a cure for Aids might be one example) than police something that affects so few people. It is a compelling argument, however the FDA has obligations to protect society as a whole – not just groups with the most effective lobbyists or with the highest profile diseases. This much is recognized in certain provisions of the FDCA which contains, for example, an orphan drug provision. Moreover, the costs of getting fraudulent Chinese medicines off the market or in compliance will probably be quite small in comparison with other expenditures that the FDA must make.

The FDA's method of waiting until there have been serious complaints before the Agency acts is also problematic. Resources can be wastefully spent by having to react on an ad hoc basis to a crisis situation. There can also be a lot of dithering, as in the case with the Ephedrine debate discussed earlier. It would probably be more efficient for the Agency to have a long term, organized

plan of action, as far as that is possible. In addition, when dealing with an immigrant community, there are concerns that members of that community will not feel comfortable making claims or bringing charges against fraudulent manufacturers and herb store owners. There may be particular reticence in the case where the owner of the herbal store also dispenses prescribed herbs and other treasured items from home. And as noted above, these issues are not limited to Chinese immigrants. There is a potential for disastrous results to occur every time a patient participates in unconventional medicine without informing their own doctor, and as indicated above, such behavior is not uncommon.

The FDA's publication of medical bulletins, advisories and public warnings are not guaranteed to produce satisfactory results in terms of either policing or prevention. It is not clear who reads these advisories – unless they get into the mainstream press there is little likelihood that they will have much of an impact. This is true, for example, of articles printed in the FDA Consumer. Even if the information does get into the mainstream press, it may not reach part of the intended audience in the Asian community.

B. Possible Solutions

There are two possible approaches to regulation of non-compliant Chinese herbal medicines: on the one hand, the FDA could attempt to look at the larger picture and institute a new method of regulating all herbal remedies. This may be necessary because herbal remedies and other dietary supplements in general receive little regulation, and may conceivably pose more quality and

safety problems that synthetic drugs.⁹⁵ In this regard, the FDA could learn from Germany where there are specific regulations for marketing medicinal herbs.⁹⁶ The German approach is to maintain the safety and efficacy standard, but to relax the degree to which such safety and efficacy must be proved. Instead of the absolute certainty required in synthetic drug trials, a standard of reasonable certainty is acceptable.⁹⁷ This reasonable standard is arrived at by taking into account the history of a product's safe use as well as clinical data.⁹⁸ To successfully emulate the German system, the FDA would have to devote resources to setting up a new bureau of experts to deal solely with medicinal herbals. New monographs would have to be created, and even if a standard of reasonable certainty was sufficient to determine safety and efficacy, there would still be a need for clinical trials to determine toxicity and to make risk assessments.⁹⁹ It is unlikely that the FDA would be willing or able to devote the necessary resources to such an undertaking. The Agency would probably point to the Office of Alternative Medicine and its different research centers as the best entities to oversee research in the area of herbal remedies. There are some more immediate alternatives, and ones that are more closely tied to the issue of non-compliant Chinese herbal remedies that I believe the FDA could successfully undertake.

Most immediately, the FDA could widely publicize the issue of non-compliant imported Chinese drugs. This objective could be achieved by the

⁹⁵Tiahah Xue, *Exploring Chinese Herbal Medicine Can Foster Discovery of Better Drugs*, *The Scientist*, Feb. 19, 1996 at 9.

⁹⁶See Edgar R. Cataxinos, Regulation of Herbal Medications in the United States: Germany Provides a Model for Reform, 1995 *Utah L. Rev.* 561.

⁹⁷Edgar R. Cataxinos, Regulation of Herbal Medications in the United States: Germany Provides a Model for Reform, 1995 *Utah L. Rev.* 561, 591.

⁹⁸*Id.* at 591.

⁹⁹*Id.* at 590.

orchestrated seizure (in small communities where herbal pharmacies are commonly situated the effect of seizure would be immediately felt) of offending herbal preparations from various herbal stores across the country. At the same time, the FDA should take advantage of any media attention that ensues to educate the public as fully as possible about the dangers of these medicines. Alternatively, the FDA could take a less aggressive approach, and mandate the licensing of herbalists nationwide (the Agency could consult with those most active in Chinese herbal remedies to ascertain a proper method of licensing, the logistics of which will be carried out at the state level), with the understanding that if herbalists sell non-compliant imported herbal medicines, they will lose their license.

Finally the FDA could engage in the even less direct method of encouraging medical and pharmacology schools to expand their curriculums to include herbology, so that doctors and healthcare professionals can be better informed about the risks that non-compliant Chinese herbal medicines potentially bear.

Conclusion

Any of the above proposals, or a combination of them would address the potential dangers that arise from the import of non-compliant Chinese herbal medicines. Perhaps it is most realistic to encourage the FDA to take short-term, cost-effective action such as publicity through seizure, or requiring licensing of

herbalists, and at the same time, encourage the agency to continue the steps already taken in increasing research on herbal remedies through institutions such as the Office of Alternative Medicine.