Introduction

Resurgence in the popularity of herbal products in the United States has spawned major headaches in Washington and the medical community. Even with the recent guidelines from the Federal Trade Commission (8). requiring truthfulness and accuracy in the advertising of herbal medications, rampant marketing abuse for unscrupulous purposes has defrauded millions of honest American consumers (7). Many of the herbal medication advertised promises miracles for its followers, while omitting toxicity information that can result from its overuse or combined use with other medications (7). The accurate reporting of dosage, and quality are all left to the manufacturers' conscience. These complications with toxicity have already led to numerous deaths, deaths, which are projected to increase exponentially if regulations and restrictions on herbal medications are not imposed in the immediate future.

Toxicity and other dangers associated with herbal products is not a new problem. Far Eastern Asian countries have already had thousands of years of coping to diminish and regulate toxic effects of their therapeutic drugs through variety of means. The source of the herbs, the quality, and the time it was harvested is taken into consideration even before it becomes set apart for medicinal purposes (1,9). In addition, these herbal medications are limited in their availability, being dispensed only as prescriptions and that with specific set of instructions.

Such systematic regulations and restrictions placed on these herbal medications are largely absent in the United States. The ease with which one can obtain these herbal medications via the Internet or on the shelves of a local nutrition supplement retailer presents a major public health hazard. Furthermore, herbal medications are deceptively called "herbal supplements" lulling the American public to think of them as benign (7). Hence, it is of crucial importance to implement a systemized regulation on herbal medications and raise the public awareness of its' potential adverse effects.

Traditional Chinese Medicine 101-A Background

Recognized traditional Chinese Medicine totals to almost 70,000 items, of which 1,500 are regularly prescribed (3). Most remedies obtained come from the wild as medicinal plants grown in gardens or fields are considered inferior and not to have the comparative therapeutic effect (9). The herbs collected from the wild were thought to absorb the chi (force) of nature enhancing its' healing properties. The location of the herb is also important, as some areas are known to produce higher quality herbs than others (9). In collecting the herbs, the time of collection can be an important issue since some plants are considered to have their full therapeutic effect only if they are collected early in the morning or during a certain season (9).

Patients in traditional Chinese medicine are treated on an individual basis. The practitioner feels the pulse and discovers the irregularities in the flow of chi of the body. The herbal concoction ascribed changes depending upon the age, sex, health, and other physical manifestations ascertained through history and pulse (1). Hence a mixture of herbs given to one patient may be different from another suffering from the same disease.

Considering the incredible number of potential remedies available, tremendous variations exists in how each herbal product is prepared. To name a few, medications can be grinded to powder or

prepared as a collection of dried roots and leaves (9). Other herbs are thought to retain their therapeutic effect only if obtained fresh. Many herbs are then subjected to the process of steaming or boiling to reduce the toxicity before being given to the patients. These methods of preparation reflect the depth of Chinese medicine established from centuries of empirical usage. Most of the traditional Chinese herbal medications given to patients have a high therapeutic index and are unlikely to cause toxicity even if used in considerable excess (1,4). The combinatorial use of herbal raw materials is thought to allow the use of smaller doses of herbs with synergistic beneficial effects, perhaps with some items counteracting the potential toxicity of others (1). However, although this apparent lack of side effects compared with the drug therapies used in allopathic medicine has become of the main attractions of Chinese traditional medicine, there are still few materials with well-recognized toxicity that are still in common usage.

Current Concerns on Medicinal Herbs

Medicinal Herbs cannot be assumed safe because they are natural. A number of potentially toxic herbs with low therapeutic levels are still used in Chinese Traditional Medicine and other systems of herbal medicine (2). Herbs such as Aconitum carmichaeli and A. kusnezoffii contain C19-diterpenoid esters, aconitine, and derivatives, which activate sodium channels, resulting in neurological and cardiac toxicity (1). Although most problem cases arose from excessive doses, other factors such as the differences in the amount of alkaloids present in the plant at the time of harvest and the use of inappropriate combinations with other herbs have caused numerous unnecessary deaths.

Other concerns regarding the use of medicinal herbs include the possibility of herb/herb or herb/drug interactions and allergic reactions (7). Any pharmacologically active agent has the potential to result in synergistic or antagonistic interaction when consumed with other pharmacologically active compound. This is no less the case for medicinal herbs. Warfarin, for example, is administered to delay blood clot formation and could be potentiated by co-administration of feverfew, garlic, ginkgo, ginger, or ginseng, which have similar actions (10). Taken together, warfarin and one or more of these herbs might cause the patient to hemorrhage.

Substitution or adulteration with more toxic herbs is also not an uncommon occurrence (1,5)). Herbs may be incorrectly identified or in some cases deliberately substituted with cheaper remedies (5). Such was the case in Belgium when an epidemic of rapidly progressive fibrosing interstitial nephritis were reported. The problem was attributed to the substitution of Aristolochia fangchi instead of the Chinese herb Stephania tetrandra (1). The story ended with the tragic development of irreversible end-stage renal failure or carcinoma in the urinary tract of many young women.

Contamination or adulteration of Chinese traditional medicine with heavy metals such as lead, mercury, cadmium, arsenic, or thalium has also recently been a major cause of concern (1). With dramatic increase in demand for herbs many of the herbal products are harvested on farms instead of being collected from the wild. Raising concerns as many farm soils are contaminated with heavy metal residues deposited from the neighboring factories. Studies on the prevalence of such contaminations reveal arsenic contamination in Chinese herbal medicine to be quite common. One study even reports of the potentially toxic degree of arsenic contamination in

many samples of Chinese patent medicines (6).

Even the herbs that are regarded as nontoxic can cause side effects when used inappropriately or in great excess (1). Ginseng for example, is considered a nontoxic herb. However it has been incriminated in some cases of toxicity, particularly in the "ginseng abuse syndrome' where its excessive usage has been implicated with nervousness and depression.

Herbal Chaos in the United States

-research needs-
Of primary concern is the absence of requirement for medicinal herbs to undergo extended pre-clinical and clinical testing to assure the safety of prescription drugs before they are released to the market (7). Such absence in the drive to support research has been blamed on the financial disincentive for the industry to support such study (7). As these products cannot be patented, research findings by one company could be used equally well by the competing companies. Other hindrances to research lie in the inherent mode of treatment of Chinese medicine. As aforementioned, the herbal mixtures prescribed to patients are determined case by case. With the products believed to achieve their beneficial effects through the combined actions of several ingredient chemicals, such differences in product composition makes it very difficult to analyze the active therapeutic agent.

-literature needs-
The lack of knowledge of the general public on the potential toxicity associated with the use of medicinal herbs has been attributed to the overwhelming domination in the amount of information provided by the marketers of the herbal products (7). Most of the available information, biased towards the therapeutic aspects of the remedies, includes very little discussion of the potential side effects. In many cases, the literature available largely exaggerates, or presents data that has yet to be confirmed through clinical trials.

-regulation needs-
Herbal medications available to the public, under the misnomer of herbal supplements, are full-fledged potent medicines. These medications, which are prescribed and under tight regulation in China, poses as a significant health hazard if they are lightly considered as supplements here. Most herbal medicines sold in the United States do not require package inserts that describe the potential drug/herb interactions (7). Nor is there a presence of adequate standardization or quality control. For these reasons, hasty governmental intervention in the matters of herbal medicines is mandatory.

Discussion

The need for some sort of regulation on herbal medications is not a contested issue. The potential dangers arising from herb/herb or herb/drug interaction is a public health peril that cannot be ignored. Additionally recent findings of substitution and contamination in some imported herbs dictate a more stringent regulation on foreign medicinal goods. New directives on herbal products as well as nonbiased consumer information updates regarding both beneficial and adverse effects should be prepared. Finally restricting many of the products already available

through a variety of retail outlets in the United States to be obtainable only as prescriptions may be the wisest path until further research data becomes available.

Addendum

Chinese immigrant first arrived on the American soil in the late nineteen hundreds. However, it is amusing to note how long it took traditional Chinese herbal medicine to take root in America. The current problems and chaos raging around traditional Chinese medicine is in part a cultural clash, a clash of two civilizations with their respective systematic and organized ideologies, customs and principles. Although harmony will be achieved in due time, it must not be forgotten that the ultimate goal of the medical community lies in the well being of the patients-to accept and adapt, to be open to new ideas and novel concepts.

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