The Impact of FDA Enforcement of DSHEA on the Practice of Traditional Asian Herbal Medicine

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Background

The Dietary Supplement Health and Education Act (DSHEA), implemented in 1994, provided continued consumer access to vitamins, minerals and herbal remedies as dietary supplements, clarified that dietary supplements are classified under foods rather than drugs, and provided parameters under which a dietary supplement is not considered a drug. Prior to the passage of DSHEA in 1994, Americans spent $1.5 billion annually on herbal remedies.¹ After DSHEA, this more than doubled: In 1997, $27 billion was spent on alternative medicine,² with $3.24 billion spent on herbs.³

As a result of DSHEA, herbal remedies fall under dietary supplements and must be labeled as such when sold to the general public, as well as meeting other requirements.⁴ DSHEA created a more defined regulatory framework and provided the Food and Drug Administration (FDA) with additional legal authority to properly protect the public and the option of removing incorrectly labeled products or unsafe products from the marketplace.⁵ However, there are no specific regulations which require that traditional Asian remedies be sold only by fully trained and licensed practitioners of traditional Asian medicine, or by seasoned manufacturers of traditional Asian herbal medicine. Practitioners of Chinese medicine, for example, are required in some states to pass the National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM) herbal medicine exam prior to licensure,⁶,⁷ thereby providing assurance to the consumer that they possess...
appropriate qualifications to sell or recommend herbal remedies. Conversely, some companies’ web sites offer no information to indicate that their claims are supported by appropriate training in traditional Asian herbs and in some cases the claims are contraindicated in traditional use.8

Traditional Asian herbal medicines are not regulated as they fall under DSHEA: herbs and drugs are not regulated in the same way. Herbs under DSHEA do not require premarket approval by the FDA as is required for pharmaceuticals.9 Traditional Asian medicines have received media attention suggesting that some herbs are dangerous.10 The FDA has had fewer reports of adverse events due to herb use compared with pharmaceuticals. Any adverse events reported have been due to inappropriate use by supplement companies advertising the product for non-traditional uses: One example of this is ephedra, or ma huang; ma huang has been used for thousands of years in Chinese medicine and was first mentioned approximately 3,000 years ago in The Divine Farmer’s Materia Medica.11 It is used for certain lung conditions, or “wind-cold” with “lungs and kidneys not communicating” (similar to asthma), as defined by traditional Chinese medicine.12 In Chinese medicine, ma huang is not traditionally used to increase energy levels or for weight loss.13 Some companies in recent years have produced and advertised ephedra products to be used as a weight loss or energy stimulant rather than its traditional use.14 Several well-publicized adverse events occurred as a result of this incorrect advertising and the resulting misuse by the public.15 There have been no reported adverse events when ma huang has been appropriately used by fully trained, licensed health care practitioners. As a result of multiple adverse events relative to misuse of ma huang, ephedra was removed by the FDA from the market when the FDA issued a “Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk”.16 Recognizing that ma huang has been used for thousands of years in the context of traditional Asian medicine, the ruling indicated that “Several Ephedra species (including those known as ma huang) have a long history of use in traditional Asian medicine. These products are beyond the scope of this rule because they are not marketed as dietary supplements… This final rule does not affect the use of Ephedra preparations in traditional Asian medicine.”17 In the U.S., herbal products must be labeled as supplements. However, ma huang cannot be sold as a supplement per the FDA ruling; thus it must be marked “for professional use only” when sold by practitioners of traditional Asian medicine.

Under DSHEA, herbs fall under supplements. Supplement labels may not contain ‘drug claims’;18 For example, a headache is considered a ‘drug claim’ which may create challenges for manufacturers to indicate on the label what the product does such that a consumer can understand. If drug claims are placed on labels of herbal products or supplements, the product is then considered a drug and requires an Investigational New Drug (IND) designation by the FDA,19 incurring additional cost and resources prior to marketing. Other countries have different methods of regulating and labeling herbal medicine: for example, Canada’s Natural Health Products (NHPs) must state on the label a complete list of medicinal and non-medicinal ingredients as well as recommended use.20 When applying for a product license, the manufacturer is required to provide substantiation supporting the reasoning for the indications on the label.

**Method**

**Content Development/Study Design**

In addressing whether DSHEA has impacted the practice of Traditional Asian herbal medicine, a survey was developed and administered to reflect the experiences of professionals in the field of traditional Asian medicine relative to DSHEA and perceived impact on professionals and consumers.

**Data Collections and Analysis**

A search conducted on the FDA Warning Letter database for warnings related to traditional Asian herbs, and for seizures and detentions of traditional Asian herbs by FDA and/or U.S. Customs officials. The total number of seizures and detentions were calculated based on whether seizures or detentions occurred at companies advertising traditional Asian herbs or remedies containing traditional Asian herbs, and at companies which advertised the herbs for use in a traditional or a non-traditional manner. A set of 30 interviews was then conducted of traditional Chinese medicine practitioners asking about any impact of DSHEA on their practice. Surveys were distributed from an anonymous source to U.S. practitioners of traditional Asian medicine. A set of three personal interviews was conducted with three CEOs of traditional Asian medicine manufacturing companies in the United States. Questions asked of CEOs:

- Has your business been impacted
by the passage of DSHEA? Do you think FDA enforcement of the Dietary Supplement Health and Education Act (DSHEA) has impacted the practice of traditional Asian herbal medicine and if so, how?

**Results**

According to the FDA public data base, 1000 warning letters were issued since 1996 to companies promoting pharmaceuticals. Comparatively, in a search of the 122 letters pertaining to herbs, a total of 11 warning letters were sent relative to companies regarding herbs used in traditional Asian Medicine herb formulas. One seizure of raw materials is indicated in the FDA data base; this seizure occurred at a company not affiliated with or promoting traditional Asian Medicine.

In the survey of practitioners, one hundred percent of practitioners indicated that the implementation of DSHEA had positively impacted their practice with respect to patient access to herbs. Additionally, 96.7% of practitioners advocated for a separate regulatory category (which is not drugs and not food/supplements) for Chinese herbs which would help to protect patient access to herbs.

All CEOs interviewed indicated that DSHEA had had a positive effect on their businesses. Because ma huang is sometimes illegally used to produce methamphetamines, CEOs expressed that there has been some disconnect with FDA enforcement agents believing that traditional Asian herbs are illegal to possess in all cases. Additionally, two barriers exist to providing ma huang to consumers even while the company is in possession of the product: 1) product liability insurance in many cases will not cover ma huang, and 2) U.S.-based herb companies are having difficulty getting ma huang through customs; As not all U.S. border agents are familiar with traditional Asian herbs, herb company orders are often refused, or temporarily or permanently detained at U.S. borders.

Current FDA regulations requiring that herb companies refrain from placing *drug claims* on the labels of herbal preparations was listed as an obstacle for CEOs. Labeling is also challenging because some traditional Asian medicine diagnoses do not translate well into typical English symptoms or disease classes as expressed using Western medical terminology and would not be easily understood by consumers: CEOs indicated that new or revised labeling is needed. Agents have turned away herbs at U.S. borders as they may not recognize an herb based on its Chinese translation; for example, shen qu is directly translated as “medicated leaven”, even though shen qu is an herb processed with wheat and does not contain drugs.

Finally, CEOs reported that one of their greatest challenges is that herb companies are required to declare on U.S. import forms that the items being imported are either foods, drugs, or supplements. As ma huang is not a food, is not approved as a supplement (only exempted under ephedra ruling for practitioners of traditional Asian medicine), and cannot be claimed as a drug by an herbal company, there is no option on the form to claim the product. Companies have been required to permanently change their herbal formulas, as they are unable to rely on the arrival of required herbal ingredients through U.S. borders for their products.

**Conclusion and Comments**

Since the implementation of DSHEA, herb companies have been able to offer traditional Asian medicines to practitioners and thus consumers more easily, as herbs are now considered supplements instead of food additives, and FDA approval of herbs for marketing as a result is less cost-prohibitive. Challenges remain, however, to herbal companies and practitioners in successfully attaining and selling some herbs, which inhibits consumer access. Communications regarding content of herbs and labeling of herbs such that they are not detained at U.S. borders remains an obstacle to be overcome. Labels on herb products arriving from China stating “supplement” may need to be addressed with both U.S. border agents and the FDA office in China, since some herbs can be sold by licensed practitioners but not as “supplements”. Some herbs should be labeled “for professional use only” as they should be combined with complimentary herbs, and consumption of such herbs by consumers should be overseen by a qualified, licensed practitioner of traditional Asian medicine.

A solution may be to implement an advisory committee under U.S. Health and Human Services, comprised of representatives for consultation from all traditional medicine backgrounds. This could assist the FDA in sharing information with its U.S. customs agents in translating materials and creating more appropriate import forms for manufacturers and distributors. Health Canada has moved forward with this approach, and has advisors from traditional medicines community on its staff. Another benefit offered by this approach would be in having advisors who could easily identify web sites or companies which list non-traditional uses for products which might endanger consumer health. An advisory committee could also assist in rewriting some of the Code of Federal Regulations as
2. THE PROGRESS OF CHINESE MEDICINE IN THE UNITED STATES; Ka Kit Hui, MD, FACP; Jun Liang Yu, MD (China), LAc; Lidia Zylowska, MD; University of California, Los Angeles, School of Medicine, Center for East-West Medicine, USA; http://www.cewm.med.ucla.edu/sources/progress.pdf
18. U.S. Food and Drug Administration; Claims That Can Be Made for Conventional Foods and Dietary Supplements; September 2003; http://www.fda.gov/food/labelingnutrition/labelclaims/ucm111447.htm
20. Health Canada; Natural Health Products; What are Natural Health Products?; http://hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php
21. Additional resources