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HERBAL MEDICINE

Chinese Herbal Medicine Passes FDA Phase II Clinical Trials

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There's a new trend emerging in the field of traditional Chinese medicine; an increasing focus on legitimizing herbs as healthier alternatives to the synthetic chemicals normally used as pharmaceutical drugs. Several producers of herbal medicines are pursuing FDA clinical trials to market their products as drugs to U.S. and European markets. One compound, Danshen Dripping Pill, formulated by Tasly (based in Tianjin, China) has passed Phase II clinical trials this past July. The intent of Phase II trials is to initially measure the effectiveness and risks of the drug. This particular formulation treats angina and coronary heart disease and is due to be on the market by 2013. Canada, Russia, South Korea, Vietnam, Singapore, and a few African countries have already approved the product. Tasly plans on building 50-70 trial centers worldwide over the next 18 months for its Phase III trials, which will be more involved.

In a search using the key words "Traditional Chinese Medicine" on the National Institutes of Health "clinicaltrials.gov" Web site spanning 174 countries and more than 95,000 trials, 148 studies come up, with status varying from "not yet recruiting" to "completed." This doesn't mean that all of the studies are focused on FDA-approved drug development, but it demonstrates that more of our medicine is undergoing serious study.

Using naturally occurring substances for pharmaceutical drug application is far from a new concept. Many of the pharmaceuticals available to physicians, such as quinine, opium, aspirin, digitalis and cocoa, have herbal origins. According to a study published in the March 2007 issue of the *Journal of Natural Products*, 70 percent of all new drugs introduced to the U.S. market within the past 25 years have been derived from natural products.[3] In fact, say the authors, "Half of all anti-cancer drugs introduced since the 1940s are either natural products or medicines derived directly from natural products." Co-author Dr. Gordon Cragg, notes for example that Taxol, derived from the bark of the Pacific Yew tree, is one of the strongest cancer drugs on the market.

Medicinal herbs are proving to be increasingly valuable as a reservoir of compounds and extracts with substantial medicinal merit. Through the rigorous process of natural selection, plant species have been perfecting various chemical defenses to ensure survival over millions of years of evolution, and are proving to be an increasingly valuable reservoir of compounds and extracts of substantial medicinal merit. These plants have synthesized compounds to protect against parasites, infections and herbivores, creating acutely powerful chemical templates with which

pharmacologists can create new drugs.[1] The beauty of nature is that plants contain not only the active ingredients to produce a positive clinical effect on a particular disease process, but also compounds to counteract any possible ill effects. In contrast, when pharmacologists successfully isolate or synthesize a naturally occurring compound for use in a drug, they lose the *yin* that balances the *yang* action of the substance, resulting in potentially deadly side effects.

It's clear that traditional Chinese herbal medicine will reach a far greater patient-base if it is FDA-certified as a drug and thereby dispensed by MDs, with the implications being far-reaching if the trend continues. On the positive side, our profession can view this as a strong indication of the legitimacy of our medicine. However, it would change the character of how natural medicine is practiced, not necessarily all for the better.

We don't diagnose illness/disease states the same way as Western medicine, and do not prescribe our herbs with the "one size fits all" mentality that dominates allopathic medicine. In order to

guarantee the safety and benefit to the patient, Chinese herbal medicine should be prescribed by a properly trained herbal practitioner. If herbal medicines do become FDA-approved drugs, physicians will take over all of our herbal medicine since it is outside our scope of practice to prescribe drugs. However, if the Danshen Dripping pill goes public as a drug after completing the necessary FDA trials, AOM practitioners may still prescribe *dan shen* and *san qi* (the two main ingredients in the formulation) freely to their patients.

In April 2004, in response to importation difficulties of Chinese herbs at American borders, the AAOM (now the AAAOM) met with the Department of Health and Human Services (HHS) to educate the HHS on Chinese medicinal herbs. The American Herbal Products Association (AHPA) sent their attorney to a separate meeting as well. Shortly thereafter, the Traditional Medicines Congress was formed, with stakeholders including not only Chinese medicine but also Western herbal medicine, Ayurveda, and others. The intent was to create an optional product category in the U.S. for herbs traditionally used as medicines, while maintaining the current dietary supplement option, and without in any manner affecting practice. The group successfully drafted a regulatory model, but failed to hold a coalition together due to disagreements on bill content, and the model was never submitted.

So where does this leave Chinese herbs now, in light of this new FDA development? Should our profession continue to try to create a separate category legislatively, this time with a bill focusing solely on Chinese herbs? Should we take a passive stance and transfer the responsibility and liability for dispensing Chinese herbs to MDs?

The FDA imposes less stringent standards on botanicals vs. their synthetic, semi-synthetic or chemically modified drug counterparts. The agency states that applicants for botanical drugs "may submit reduced documentation of nonclinical (preclinical) safety and of chemistry, manufacturing, and controls (SMS) to support an investigational new drug application for initial clinical studies of botanicals that have been legally marketed in the United States and/or a foreign country as dietary supplements without any known safety concerns."[2]

The devil is always in the details. Difficulties arise when collecting, sampling, standardizing, processing and analyzing the botanicals to meet predetermined criteria within a narrow margin of error, and predicting the shelf-life based on the "weakest link" (the herb that loses its potency most rapidly in the formulation.) Additionally, the FDA requires every pill to be identical, which obviously would be quite a feat. This is a complex issue and one that will be getting its share of attention as our profession matures and gains recognition in America.

References

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