



EDUCATION & SEMINARS

The Time Has Come

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It has been two years since the [FDA's Current Good Manufacturing Practices \(cGMP\)](#) requirements became regulations. These are those guidelines that are going to update and change some of the methods practiced in the schools and offices of Oriental medicine practitioners. Yes, these are the ones in relation to herbs, herbal compounds and herbal formulas that are prescribed and/or suggested for patients. The regulations themselves are more than 800 pages of legalese. It is a daunting task, at best, to read through the information. I know of one herbal company that has been working on the compliance process for almost five years.

This FDA process of regulation reminds me of the time when the [HIPAA regulations](#) were about to have mandatory compliance. There was much discussion about whether or not the acupuncture and Oriental medicine profession was a covered entity. The current FDA cGMP is undergoing somewhat the same discussion. Are herbs and herbal formulas exempt, or are they in a category by themselves? Are they or are they not subject to regulation?

Well the time is here. There are approximately four months until the schools of Oriental medicine must meet these challenging requirements, and about 16 months before the private practitioners must comply. These rules and regulations will affect the way you do business, just as HIPAA affected the policies and procedures in individual offices regarding patient information. So what does this mean, and how can we prepare so the FDA's discretionary enforcement does not create too many problems?

According to the *New York Times*, the FDA regulates [more than \\$1 trillion](#) worth of consumer goods. That amounts to about 25 cents of every consumer dollar spent in this country. That is a great deal of "buying" power. It seems to me that, as a profession, we should form strategies and prepare to go on an educational offense, increase the FDA's knowledge of what these herbs and formulations do and don't do.

POLITICS: GOVERNMENT



To that end, the [American Association of Acupuncture and Oriental Medicine](#) (AAAOM) is considering the construction of a database for reporting adverse reactions to herbs and herbal formulas in conjunction with the various herbal vendors,. Along similar lines, the [Council of Colleges of Acupuncture and Oriental Medicine](#) (CCAOM) is working to steer the schools through the compliance process by using consultants to help with guidelines and procedures.

The [American Acupuncture Council](#) along with the AAAOM, the [National Certification Commission for Acupuncture and Oriental Medicine](#) (NCCAOM) and the Consortium for Oriental Medicine Research and Education (COMRE) are working to draft a certification workshop that will inform, educate and certify the individual practitioners in FDA cGMP, before the compliance deadline of July 2010. These workshops will give CEU credits and a certificate, suitable for framing, for Oriental medicine practitioners to display in their office, letting patients and the general public know that the practitioner is knowledgeable about the regulations and the office is in compliance. This indeed could create a positive public-relations impression, both for the practitioners and for herbal therapy. These workshops will be presented across the country beginning this summer. That gives the profession just one short year to be trained.

The Consortium for Oriental Medicine Research and Education is a nonprofit foundation, designed to help fund research. Research is a necessary piece in order for this profession to grow and take its rightful place in the health care system. One of my goals is to create some funding for research. Money from these workshops is going to be directed into Consortium for Oriental Medicine Research and Education. Some of the money will go to the AAAOM for their political agenda, to ensure the rights of

practitioners, and to protect this medicine for future generations and our patients' right to choose this medicine as a viable form of treatment. I hope you will join me in this monumental task, and I will see you in class.

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