

The Feds Are Coming!

Marilyn Allen, Editor at Large

As January 2009 makes its debut, it reminds us that another year has passed and many new challenges face the Oriental medicine profession in the United States during this coming year. One of the more important issues facing the profession is that of the Good Manufacturing Procedures (known as GMP) and the new requirements by the Food and Drug Administration (FDA).

The guidelines state in their summary: "The Food and Drug Administration (FDA) is issuing a final rule regarding current good manufacturing practice (CGMP) for dietary supplements. The final rule establishes the minimum CGMPs necessary for activities related to manufacturing, packaging, labeling, or holding dietary supplements to ensure the quality of the dietary supplement. The final rule is one of many actions related to dietary supplements that we are taking to promote and protect the public health."

This year is particularly important in terms of the CGMP due to the compliance dates: "The compliance date is June 25, 2008; except that for businesses employing fewer than 500, but 20 or more full-time equivalent employees, the compliance date is June 25, 2009; and except that for businesses that employ fewer than 20 full-time equivalent employees, the compliance date is June 25, 2010."

So, whether or not we like it, the feds indeed seem to be coming.

There seems to be some discussion within the profession as to how these regulations will affect the profession. These discussions remind me of the issues surrounding HIPAA regulations a number of years ago as to who was a covered entity, and the varying opinions on the subject. I hope the FDA, GMP regulators and the profession can reach an agreement that can be disseminated to all the OM practitioners.

The major groups and leadership associations have agreed that something must be done to produce guidelines for dispensaries. The Council of Colleges of Acupuncture & Oriental Medicine has the major responsibility to the Oriental medicine schools. The council has worked with consultants and is preparing information for schools and clinic directions. They are hosting a panel discussion and the AAAOM conference in Sacramento, Calif., to be held April 23-26, 2009. They have graciously invited the public, members of the profession and the participants of the conference to attend the panel discussion.

The American Association of Acupuncture and Oriental Medicine has been working with the herbal vendors to create an adverse-events/reactions database. This database would record and calculate information regarding herbal formulas, numbers of bottles dispensed and other data regarding herbs. The National Certification Commission of Acupuncture & Oriental Medicine has agreed to participate in this process.

The proposal is to formulate guidelines for dispensaries, private practices and herbal formulations that can be standardized, taught to the profession and ultimately presented to the FDA. The

feasibility of this project could take 12 to 18 months. The classes would include GMP information on dispensary guidelines, food handling, adverse events, how to access and report to the database, and an exam which will provide a certificate upon completion. This would give the profession the offensive edge, as opposed to being in the defensive position.

This general format of a similar program with the FDA has been designed and used before, in an unrelated field. The FDA was very pleased with the concept and the guidelines. The classes would be taught in numerous locations throughout the United States so practitioners do not have to travel. There will also be CEUs given for the class.

The design of this plan has several benefits for the practitioner:

- It demonstrates knowledge and compliance with regulations.
- The certificate, hanging on the walls of Oriental medicine offices, creates credibility for the practitioner in the eyes of patients and the public.
- It puts the profession in a strong position of self-regulation.
- It demonstrates the profession's concern for public health and welfare.
- It will create some funds for research, public education and legislation.
- It will create a standard of care in the profession by using a standardized test produced by the NCCAOM.

This is somewhat of an enormous project. Many people will be involved in this endeavor. We are looking forward to seeing you in a class this coming year. I hope you plan to attend a class near you in 2009-2010. Please watch for further details and contact the editor if you have any information or any ideas.

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