

Frequently asked questions about the work of the Traditional Medicines Congress

What is a traditional medicine?

A traditional medicine is a botanical, animal, or mineral substance or formulation thereof that is generally recognized as being used in traditional health care practices to maintain health or to treat or prevent illness.

What is the Traditional Medicines Congress?

The TM Congress is a forum for meetings and communications between various U.S.-based organizations with a common interest in preserving access to traditional medicines and improving the free flow of information about the traditional uses of these medicines.

How did the TM Congress come about?

In the spring of 2004 a diverse group of organizations met to initiate a cooperative process to exchange ideas about the future of traditional medicines in the United States. The result was the convening of the Traditional Medicines Congress, now sponsored by nine national organizations.

Who are the sponsors of the TM Congress?

The Traditional Medicines Congress is sponsored by:

- [Acupuncture and Oriental Medicine Alliance \(AOMA\)](#)
- [American Association of Naturopathic Physicians \(AANP\)](#)
- [American Association of Oriental Medicine \(AAOM\)](#)
- [American Herbalist Guild \(AHG\)](#)
- [American Herbal Products Association \(AHPA\)](#)
- [Council of Colleges of Acupuncture and Oriental Medicine \(CCAOM\)](#)
- Medicinal Herb Consortium (MHC)
- [National Ayurvedic Medical Association \(NAMA\)](#)
- [National Certification Commission for Acupuncture and Oriental Medicine \(NCCAOM\)](#)

Each of these organizations either represents or is engaged in standards setting, certification or accreditation for health care practitioners who include traditional medicines in their scope of practice; for educational institutions that provide training in traditional medicine; for manufacturers of traditional medicines; or for growers and producers of traditional medicine ingredients. Each of these organizations is also committed to providing an equitable portion of the financial resources required for the functioning of the TM Congress and to providing representative(s) to advance the purpose of the Congress.

Can other organizations also participate in the TM Congress?

Yes. Other national organizations that meet the criteria above are welcome to be sponsors of the TM Congress. Any interested organization should contact one of the current sponsors for further information.

What is the purpose of the TM Congress?

The goal of the Traditional Medicines Congress is to benefit public health by ensuring access to traditional medicines in a manner that provides a reasonable expectation of public safety.

The sponsors of the TM Congress have worked together to create a Draft Proposed Regulatory Model for Traditional Medicines, and believe this initiative will provide a rational framework for truthfully representing the value of traditional medicines and for assuring widespread consumer access to herbal products. This draft proposal consists of “guiding assumptions” and ideas for “key components” that are essential in a regulatory framework that would clearly define traditional medicines and ensure access to these while addressing safety, in the retail marketplace and in clinical settings.

What’s wrong with the current regulation of traditional medicines in the U.S.?

The current regulatory system in the United States does not adequately allow the free dissemination of information about the therapeutic use of traditional medicines. For instance, product labels can make only ambiguous statements such as, “Garlic supports cholesterol levels already within its normal range,” but not a more direct cholesterol lowering claim. Conversely, herbal products in many other nations are able to display truthful information about herbal products such as “Valerian has traditionally been used for insomnia.” If such a statement were made for a valerian product sold in the United States it would be considered by the U.S. Food and Drug Administration (FDA) to constitute an unapproved drug claim.

Also, current dietary supplement regulations do not adequately protect access to herbal products. The most significant recent example of this fact was the banning of all ephedra products except those containing pharmaceutical ephedrine. This occurred in the wake of a number of reports of harm related to misuse of products advertised for weight loss and athletic performance, which are not traditional uses of this herb.

Is the traditional medicines concept new?

No. A traditional medicines regulatory model is used in many countries. Such models exist in the European Union, China, Japan, Taiwan, and parts of Africa. Canada has a similar model, and regulates “Natural Health Products” in a manner that allows traditional medicinal uses to be declared.

Would the regulatory model proposed by the TM Congress affect the regulation of herbal products that are now sold as “dietary supplements”?

No. The creation of a traditional medicine category would represent an option for certain herbal products, not a replacement for the dietary supplement category. One of the guiding principles expressed in the draft proposal is that “Many ingredients and products that fall into a new traditional medicine regulatory category will also be able to be marketed as dietary supplements.” Another is that the TM Congress “does not intend to propose amendments to the Dietary Supplement Health and Education Act (DSHEA).” In other words, the current dietary supplement category is to be preserved completely.

Does this proposal restrict access to any botanicals?

The proposal would not change the status of any ingredient currently available as a dietary supplement. Almost all of the natural ingredients that are commonly used in traditional medicines have a remarkable history of safety. Some traditionally used ingredients, however, are potentially harmful unless used by someone with sufficient training and knowledge. The draft proposal therefore includes a requirement for products that contain such ingredients to be singled out for special labeling that would require supervised use and, if needed, prohibition from retail sale.

What information would the traditional medicines proposal allow that differs from current dietary supplement information?

Under current law, it is illegal to disclose on the label of an herbal or other natural product any information about use of the product to treat, cure or prevent any disease – even if the information is true. This proposed model would allow these products to be identified as traditional medicines and to bear truthful information regarding their appropriate use, including therapeutic uses that are currently prohibited.

Would the requirements for marketers of traditional medicines be any different than those for dietary supplement companies?

Yes. The proposed model would impose new requirements on companies that market traditional medicines for retail sale. For example, marketers of these products would be required to inform FDA if they receive any reports of serious adverse events associated with their products. In addition, marketers of traditional medicines would need to describe a recommended traditional purpose or use on product labeling, while this kind of label statement is optional for dietary supplements. And since notice of such label claims for traditional medicines would be required to be sent to FDA (as is also true for supplement claims) the result would be that all traditional medicines would be identified to the federal health authorities.

Would this model affect the regulation of natural medicine practitioners?

No. This proposal is presented as a federal regulatory concept for traditional medicine products. It has nothing to do with the practice of medicine. Licensing and scope of practice regulation are issues that are addressed at the state level. The proposed model is exclusively designed to allow for consumers and natural medicine practitioners to utilize traditional medicines with full disclosure of their benefits, a right denied by current federal regulatory restrictions.

Would this model apply to practitioners who prepare and sell herbal formulas for their patients?

No. The draft proposal differentiates between products offered for retail sale, which would be subject to the proposed regulatory model, and traditional medicines provided directly through a practitioner. This last category is addressed in the draft to ensure that such products are not subject to the same regulation and to encourage good practices.

Is the proposed model restricted to orally consumed products?

No. Non-oral traditional medicines have been used for centuries. This proposal therefore includes product forms such as salves, ointments, suppositories, and poultices.

Can I read the proposal and provide guidance, feedback, and comments?

Yes. The full text of the current and evolving Draft Proposed Regulatory Model for Traditional Medicines is available at http://www.ahpa.org/trad_med_congress.htm. The sponsors of the Traditional Medicine Congress hope that everyone with an interest in traditional medicines will educate themselves about this important issue and provide constructive feedback regarding its development. Comments will be accepted until June 30, 2006.