



Participants in the Traditional Medicines Congress, held in Washington, D.C. in October 2005. From left: Michael McGuffin, Paul Werder, Connie Axelrod, Kevin V. Ergil, Jean Giblette,

BILLING / FEES / INSURANCE

Traditional Medicines Congress Calls for Comments on "Ideal Regulatory Model"

Editorial Staff

Nine national organizations working together as the Traditional Medicines Congress¹ have released the first draft of *A Proposed Regulatory Model for Traditional Medicines: Guiding Assumptions and Key Components*. This comprehensive document presents ideas for a new model for the regulation of traditional medicines in the United States, and will be subject to an open review process by interested individuals and organizations.

The nine organizations, representing acupuncturists, herbalists, Oriental medicine practitioners, naturopathic physicians, ayurvedic practitioners, and manufacturers of traditional products joined together in 2004 to exchange ideas about the future of traditional medicines in the U.S. The result of these discussions was the formation of the Traditional Medicines Congress. In seeking to emphasize both the value of traditional medicines and the responsibilities associated with their use, the following statement was agreed upon:

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.



Participants in the Traditional Medicines Congress, held in Washington, D.C. in October 2005. From left: Michael McGuffin, Paul Werder, Connie Axelrod, Kevin V. Ergil, Jean Giblette, Cynthia Copple, David Molony, Claudette Baker, Mercy Yule, and Bryn Clark.

The acupuncture and Oriental medicine community is well-represented in the Congress by Corinne Axelrod and Mercy Yule (of the Acupuncture and Oriental Medicine Alliance), Claudette Baker and David Molony (of the American Association of Oriental Medicine), Kevin Ergil (of the Council of Colleges of Acupuncture and Oriental Medicine), and Bryn Clark (of the National Certification Commission for Acupuncture and Oriental Medicine). This occasion marks the first time these groups have worked together with national organizations of related professions to address one of the most critical issues facing practitioners and consumers today.

Traditional Medicine Congress: Guiding Assumptions

For brevity's sake, the "Guiding Assumptions" portion of *A Proposed Regulatory Model for Traditional Medicines* is included below for review. The entire document is available online at the address below.

... remembering the agreed upon Purpose of this Congress: *To benefit public health by ensuring access to traditional medicines in a manner that provides a reasonable expectation of public safety*

Assumptions Re: Reasons to Act

- There is value in preserving access to a full range of traditional medicines.
- Current regulations in the United States do not adequately assure continued access to and safety of traditional medicines.

Assumptions Re: Reasons to Create a Traditional Medicine Category

- The current definitions of "food" and "drug" under the Federal Food, Drug and Cosmetic Act (FFDCA) do not provide an adequate regulatory category for traditional medicines.
- The Dietary Supplement Health and Education Act (DSHEA) provides a regulatory framework for dietary supplements, which may not be marketed as medicines. Thus, DSHEA does not provide a regulatory framework for traditional medicines.
- A traditional medicine category will preserve access by professionals to traditional medicines that state or federal regulatory agencies have withdrawn, or may withdraw, from the market under current regulatory frameworks.
- A traditional medicine category will support the use of traditional medicines, by both health professionals and consumers.
- A traditional medicine category will ensure the public's access to traditional medicines and to truthful information about them.
- A traditional medicine category will ensure practitioner access to traditional medicines that, for safety reasons, should not be directly accessible to the public.
- Accurate information about traditional uses and indications for traditional medicines will improve public safety.
- Distribution of restricted traditional medicines by qualified professionals will improve public safety.
- A traditional medicine category will provide a contribution to repair the U.S. health care crisis.
- Creation of a traditional medicine category in the U.S. will be harmonious with international models.

Assumptions Re: An Ideal Regulatory Model

- Establishment of a new regulatory structure for traditional medicines may require amending the Federal Food, Drug and Cosmetic Act (FFDCA).
- This TM Congress does not intend to propose amendments to the Dietary Supplement Health and Education Act (DSHEA).
- The focus for development of the envisioned ideal regulatory model is limited to the United States.
- Most traditional medicine ingredients and products will remain directly accessible to the public.
- Some traditional medicine ingredients and products will be accessible to practitioners only (and so not accessible to the public without practitioner supervision).
- Many ingredients and products that fall into a new traditional medicine regulatory category will also be able to be marketed as dietary supplements under DSHEA.
- Any regulatory structure must address safety, efficacy and product quality.

Assumptions Re: The Long-Term Process

- This may not be a short-term process; it may take several years to pass legislation and to implement regulations.
- Additional losses to traditional medicine *materia medica* may be incurred in the time that it takes to create a traditional medicine category.
- Recognizing that professional practice of medicine is regulated at the state level, this TM Congress intends to maintain awareness of the potential impact on all stakeholders at state levels.
- This Congress will subject its work product to significant review by broad communities of interested persons.
- This Congress will invite and welcome significant input from sectors of the industry and professional practitioner communities.
- Some current trends in national politics create a window of opportunity favorable to creation of a traditional medicine category.

Your Comments Wanted

Anyone with an interest in traditional medicines is invited to review the draft document the Traditional Medicines Congress has developed. A PDF version of *A Proposed Regulatory Model for Traditional Medicines*, including both "Guiding Assumptions" and "Key Components," is available online at www.acupuncturetoday.com/online/tmcongress.pdf. Comments regarding the document can be e-mailed to tmcongressfeedback@pobox.com. The deadline for comments is March 30, 2006.

Reference

1. The nine national organizations of the TM Congress are the Acupuncture and Oriental Medicine Alliance, the American Association of Naturopathic Physicians, the American Association of Oriental Medicine, the American Herbalists Guild, the American Herbal Products Association, the Council of Colleges of Acupuncture and Oriental Medicine, the Medicinal Herb Consortium, the National Ayurvedic Medical Association, and the National Certification Commission for Acupuncture and Oriental Medicine.

JANUARY 2006