

US Pharmacopeia's Convention 2005



Roger L. Williams

At its 2005 Convention, USP passed 13 resolutions that will help define the organization's path for the next five years and represent the interests of its diverse constituency.

United States Pharmacopeia (USP) is a volunteer-based, nongovernmental standards-setting body that has convened at 10- or 5-year intervals since 1820 and whose compendia, the *United States Pharmacopeia* and the *National Formulary* (published jointly as the *USP-NF*), are enforceable by regulatory bodies such as the US Food and Drug Administration. *USP-NF* is the only fully nongovernmental pharmacopeia in the world, and it is believed to be the oldest continuously revised and published compendia. That it is the work of volunteer experts and a relatively small permanent staff adds to its uniqueness.

As an organization, USP began when physicians met in Washington, DC, in 1820 to write the nation's first pharmacopeia (which was recognized in the 1848 Federal Drug Import Act) and agreed to make no changes to the compendium until they reconvened 10 years later. As medicine and pharmacy progressed, more organizations joined the United States Pharmacopeial Convention; the American Medical Association, founded in 1847, and the American Pharmaceutical Association, founded in 1852, both joined in their early years.

This March, USP held its 23d convention, with 246 members or alternates in attendance. These members included representatives from US colleges and schools of medicine and pharmacy; national, state, and professional pharmacy associations; professional and consumer organizations; pharmaceutical manufacturers and trade organizations; foreign and international health organizations; and other pharmacopeias; along with officers, trustees, committee members, honorary members, other observers, and USP staff.

The mission. The essential work of the convention was to review the accomplishments of the previous five-year cycle; elect a new Board of Trustees, Officers, and Council of Experts; review and vote on proposed amendments to the USP constitution and bylaws; and review, discuss, and possibly amend a set of resolutions that support the work plan for USP during its 2005–2010 cycle.

USP's mission is to promote public health "by establishing and disseminating officially recognized standards of quality and authoritative information

for the use of medicines and other healthcare technologies by health professionals, patients, and consumers." This mission was movingly invoked by a trio of keynote speakers who opened the Convention on 9 March. Jack C. Chow, MD, assistant director-general for HIV/AIDS, Tuberculosis, and Malaria at the World Health Organization, noted that these three scourges are devastating societies in developing nations. In many cases, substandard or counterfeit drugs contribute to the emergence of drug-resistant strains. USP's Global Assistance Initiative and public standards-setting activities are helping to combat the problems, even though the magnitude of the problem in Africa and southwest Asia challenges our comprehension.

Lucian L. Leape, MD, adjunct professor of health policy at Harvard School of Public Health, spoke eloquently to advocate a new paradigm for teamwork in which specially trained collaborators coordinate in sophisticated groups to promote safe medication use and enhance patient safety. The information barriers among prescribers, dispensers, and patients, he argued, must be supplanted with new means that promote full understanding and interaction. Uwe E. Reinhardt, PhD, professor of economics and public affairs at the Woodrow Wilson School of Public and International Affairs, Princeton University, spoke in detail not only about the looming financial costs of Medicare and Medicaid, but also about the human toll of inequalities in the current healthcare delivery system in the United States and elsewhere.

Perhaps the greatest success of these brilliant presentations was the speakers' ability to move beyond the numbers to a clear and compelling depiction of the personal human tragedy arising from national and international gaps in healthcare delivery. During a dialogue with convention members, these speakers made it clear that the tasks of discovering new drugs, setting uniform standards, and ensuring the equitable availability of modern medicines are inextricably intertwined. None of this work is mundane or trivial for those in need of good-quality healthcare.

Constitution and bylaws. Convention members authorized a number of changes to USP's governance

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documents. Major changes included clarifying the duties and responsibilities of the executive vice-president-CEO and creating a "Council of the Convention." This new body will facilitate communications among convention members, perhaps through annual meetings, with a representative subset of the convention's membership. Other changes formalized the roles and activities of project teams and stakeholder forums,

which USP may convene from time to time, and clarified USP's conflict-of-interest rules.

Resolutions. Convention members passed 13 resolutions (see sidebar, "USP Resolutions for 2005–2010"). These resolutions help define USP's path going into the next five-year cycle and represent the interests of USP's diverse constituency.

Officers and trustees and Council of Experts. Members voted for officers and members

USP Resolutions for 2005–2010

The following resolutions were passed at the USP convention, held 9–13 March 2005. For additional explanation of the resolutions, please visit the USP Web site (www.usp.org/pdf/meetings/convention/2005-2010AdoptedResolutions.pdf).

- public monographs and reference materials
- integrity and safety of therapeutic products
- new science and technology
- compounding standards and education
- standards for nomenclature and labeling
- USP international presence
- international harmonization
- drug information programs
- promoting safe medication use and disposal
- evidence-based methodologies and algorithms for decision support used in e-prescribing and pharmacy computer systems
- USP convention (Council of the Convention)
- expanded outreach (e.g., biologics, biotechnology, animal health, devices)
- organizational outreach (e.g., pharmacy and other healthcare practitioners).

of the Board of Trustees and the Council of Experts, comprising 38 Standards and 2 Crosscutting Expert Committees. (Detailed information about these individuals is posted on USP's Web site at www.onlinepressroom.net/uspharm/). In addition, 16 Information Expert Committees will be elected after the USP Convention. These committees will be carefully structured to align with USP's potential Phase II Medicare Model Guidelines contract with the Centers for Medicare and Medicaid Services. Later in the spring, the chairs of the Council of Experts will meet to select members of their committees.

Renewal and recommitment. Several convention members commented that Convention 2005 was an exemplary case study of how USP operates as a standards-setting organization in which open discussion among volunteer experts leads to a wide-ranging series of activities. These activities can positively influence public health both domestically and, increasingly, on the world stage. USP now has an updated constitution and bylaws that will enable it to respond with flexibility and vigor to the challenges of the next five-year cycle. With new leadership in the Board of Trustees and a reinvigorated Council of Experts, USP again pledges its energies to facing the real-world challenges of promoting public health. **PT**

