The 57th annual session of the ASHP House of Delegates was held at the Boston Convention and Exposition Center, in Boston, MA, in conjunction with the 2005 Summer Meeting.

First meeting

The first meeting was convened at 2 p.m., Sunday, June 12, by Chair of the House of Delegates Marjorie Shaw Phillips. Jill E. Martin, Vice Chair of the Board of Directors, gave the invocation.

Chair Phillips introduced the persons seated at the head table: Daniel M. Ashby, Immediate Past President of ASHP and Vice Chair of the House of Delegates; T. Mark Woods, President of ASHP and Chair of the Board of Directors; Henri R. Manasse, Jr., Executive Vice President of ASHP and Secretary to the House of Delegates; and Joy Myers, Parliamentarian.

Chair Phillips welcomed the delegates and described the purposes and functions of the House. She emphasized that the House has considerable responsibility for establishing policy related to ASHP professional pursuits and pharmacy practice in hospitals and health systems. She reviewed the general procedures and processes of the House of Delegates.

The roll of official delegates was called. A quorum was present, including 192 delegates representing 49 states, the District of Columbia and Puerto Rico, delegates from the federal services, chairs of the sections and forums, ASHP officers, members of the Board of Directors, and ASHP past presidents. Chair Phillips reminded delegates that the report of the 56th annual session of the ASHP House of Delegates had been published on the ASHP Web site and had been distributed to all delegates. Delegates had been advised earlier to review this report. The proceedings of the 56th House of Delegates session were received without objection.

Chair Phillips called on Teresa J. Hudson for the report of the Committee on Nominations. Nominees were presented as follows:

President-elect

Cynthia Brennan, Pharm.D., M.H.A., Seattle, WA, Assistant Director of Ambulatory Pharmacy, Harborview Medical Center; Program Director, Primary Care Specialty Residency, University of Washington Academic Medical Center; and Clinical Professor, University of Washington.

Bonnie L. Senst, M.S., FASHP, Fridley, MN, Director of Pharmacy, Mercy & United Hospitals; Allina Pharmacy Safety & Operations Coordinator; and Assistant Professor, University of Minnesota.

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Charles W. Jastram, Jr., Pharm.D., FASHP, New Orleans, L.A. Associate Professor, University of Louisiana at Monroe and Clinical Coordinator, Medical Center of Louisiana at New Orleans.

Stanley S. Kent, M.S., Evanston, IL, Assistant Vice President – Pharmacy Services, Evanston Northwestern Healthcare and Program Director, pharmacy practice residency.

Sheila L. Mitchell, Pharm.D., FASHP, Germantown, TN, Director of Pharmacy Services, Methodist Hospital Germantown.

Michael D. Sanborn, M.S., FASHP, Dallas, TX, System Director of Pharmacy, Baylor University Medical Center.

Chair, House of Delegates

Marjorie Shaw Phillips, M.S., FASHP, Augusta, GA, Pharmacist/Coordinator, Medical College of Georgia Health Systems, and Adjunct Clinical Professor, University of Georgia College of Pharmacy.

Dennis Williams, Pharm.D., Chapel Hill, NC, Associate Professor, Division of Pharmacotherapy and Experimental Therapeutics, School of Pharmacy, University of North Carolina, and Clinical Specialist at UNC Hospitals in Chapel Hill.

A “Meet the Candidates” session to be held on Monday, June 13, was announced.

Chair Phillips announced the candidates for the executive committees of the four sections of ASHP.

Report of President and Chair of the Board. President Woods referred to the combined report of the Chair of the Board and the Executive Vice President, which had been previously distributed to delegates and which included all of the actions
taken by the Board of Directors since the last House session. He updated and elaborated upon various aspects of the report. (Dr. Woods’s comments to delegates were published in the August 15, 2005, issue of AJHP. The official report on ASHP Board of Directors activities for 2004-2005 is included in these Proceedings.) There was no discussion, and the delegates voted to accept the report of the President and Chair of the Board.

President Woods, on behalf of the Board of Directors, then moved adoption of the proposed policy recommendation titled “Mandatory Labeling of the Presence of Latex” which originated with the Section of Inpatient Care Practitioners. There was no discussion and the policy recommendation was adopted. It reads as follows:

Mandatory Labeling of the Presence of Latex

To urge the Food and Drug Administration to mandate that manufacturers of medications and medication-device combination products include labeling information on whether any component of the product, including its packaging, contains natural rubber latex.

Report of Treasurer. Marianne F. Ivey presented the report of the Treasurer. There was no discussion, and the delegates voted to accept the Treasurer’s report.

Report of Executive Vice President. Henri R. Manasse, Jr., presented the report of the Executive Vice President. His remarks to delegates were published in the August 15, 2005, issue of AJHP. Dr. Manasse also made note of several significant anniversaries of ASHP staff: William A. Zellmer, 35 years, David Edwards, Kathy Litvak, Stan Lowe, Jane Miller, and Mickie Morgan, 20 years

Recommendations. Chair Phillips called on members of the House of Delegates for Recommendations. (The name(s) and state(s) or component(s) of the delegate(s) who introduced the item and the subject of the item precede each Recommendation.)

Ernest Anderson (MA): Prohibiting the Re-Use of Branded Names for OTC Medications

Recommendation: We recommend that ASHP work with the appropriate authorities at the Food and Drug Administration to prohibit OTC manufacturers from re-use of branded names when the original product has been reformulated or when the product deviates from the original contents.

Background: A serious patient safety hazard exists when OTC manufacturers continue to use a branded name after product reformulation. At times, the new product may contain completely different ingredients or be used for other indications (i.e., Kaopectate Suspension now contains bismuth subsalicylate and is indicated for treating diarrhea, while Kaopectate Tablets contain docusate and is used for treating constipation).

Mary Ann Kliethermes (HC): Pharmacy Staff Fatigue and Medication Errors

Recommendation: To encourage ASHP to establish guidelines around best practices for work hours in the various practice settings served by the organization.

Background: Pharmacy staff fatigue and risk of medication errors is a major health concern. Setting time limits universally for the profession, in particular via regulation and mandates, may adversely affect not only medication operations but patient care as well (e.g., Home care on call scheduling). We believe that ASHP has an opportunity to establish guidelines and best practices for work hours in the various practice settings for our members to use as guidelines to address this issue.


Recommendation: ASHP encourage ACPE to work with PhRMA to develop a standard pharmacy educational grant application process.

Background: ACPE needs to be made aware of the difficulty pharmacy organizations are encountering in trying to obtain educational grants from the pharmaceutical industry. Each pharmaceutical company has its own unique application process. These application processes have become very lengthy and cumbersome due to each company’s efforts to meet new legal guidelines. ASHP could also encourage ACPE to work with its counterpart in medicine to develop a process that could work for both types of educational programming.

Michael Cockerham, Tommy Mannino, Helen Calmes (LA): NDC Plus Four: A Medication Validation Database

Recommendation: To advocate the development of the NDC plus Four or similar concept that creates a barcode-capable database for the purpose of identifying individual doses and vital information about them.

Background: The “NDC plus Four” is a numeric barcode-capable database that can be universally disseminated to any entity that can benefit from this information. The value is to utilize the NDC code combined with a four-digit “lot number” to create a 15 digit unique code to serve as a link to a database that will identify the individual doses and information about them. Lot
Background: Technology has enabled pharmacist review of medication orders from remote locations. Applications of this technology are being utilized to supplement order review in periods of high demand in 24-hour pharmacies and to provide 24-hour coverage in non-24-hour pharmacies. In support of ASHP Policy 0403, ASHP should develop practice guidelines for implementation and use of remote medication order review systems.

Stephen R. Novak (NC): Review of Therapeutic Alternatives for Pseudoephedrine

Recommendation: That ASHP commission a review of therapeutic alternatives to pseudoephedrine; if safe and effective therapeutic alternatives exist that are not precursors to methamphetamine or other designer stimulants, ASHP should petition the FDA for removal of pseudoephedrine from the market.

Background: Various states are creating pharmacy regulations that impose restrictions on the sale of pseudoephedrine to reduce its availability for methamphetamine production. The requirements of these regulations, such as for behind-the-counter sales, may put pharmacists at risk and hinder patient care activities. If safe and effective therapeutic alternatives exist, the removal of pseudoephedrine from the market would hinder the production of methamphetamine.

Policy Committee reports. (Note: The recommendations of the ASHP policy committees were published in the April 1, 2005, issue of AJHP. The complete reports, including background on the policy recommendations and information on other activities, were published on the ASHP Web site and were distributed to delegates.)

Chair Phillips outlined the process used to generate policy committee reports. She announced that each of recommended policies would be introduced as a block. She further advised the House that any delegate could raise questions and discussion without having to “divide the question” and that a motion to divide the question is necessary only when a delegate desires to amend a specific proposal or to take an action on one proposal separate from the rest of the recommendations; requests to divide the question are granted unless another delegate objects.

(Note: Policy recommendations are presented here in the order in which they were published, not in the order in which they were discussed for purposes of amendment. Policy recommendations not amended were approved as a block.)

Agatha Nolen, Board Liaison to the Council on Administrative Affairs, presented the council’s policy recommendations A through I.

Following a request to separate Policy A, it was moved and seconded to add the words “involve pharmacists in their development, are evidence-based, and” before the word “promote.” The amendment was approved. It was then moved and seconded to amend the new language to read “are developed with the involvement of pharmacists, are evidence-based, and” before the word “promote.” This amendment was approved. It was then moved and seconded to delete the word “national” before the word “health.” This amendment was approved. Policy A, as amended, was then adopted. It reads as follows (italic type indicates material added; strikethrough indicates material deleted)

A. National Health Care Quality Standards and Pharmacy Service

To advocate that national health care quality improvement programs adopt standard quality measures that are developed with the involvement of pharmacists, are evidence-based, and promote the demonstrated role of pharmacists in improving patient outcomes.

Following a request to separate Policy B, it was moved and seconded to add the words “and small rural facilities” and delete the words “strive to” before the parenthetical term “(CAHs);” to delete the word “the” and add the word “national” following the word “meet” and delete the words “if CAHs choose not to seek JCAHO accreditation” in the first paragraph. And to add the words
and small rural facilities” following the initials “CAHs” and delete the initials “JCAHO” in the second paragraph. The amendments were approved. Policy Recommendation B, as amended, was adopted. It reads as follows (italic type indicates material added; strikethrough indicates material deleted).

**B. Critical-Access Hospitals**

To advocate that critical-access hospitals (CAHs) and small rural facilities strive to meet the national medication management and patient safety standards if CAHs choose not to seek JCAHO accreditation; further,

To provide resources and tools to assist pharmacists who provide services to CAHs and small rural facilities in meeting JCAHO standards related to safe medication use.

**C. Pharmacy Staff Fatigue and Medication Errors**

To oppose state or federal laws or regulations that mandate or restrict work hours for pharmacy staff; further,

To support research on the effects of shift length, fatigue, and other factors on the safe practice of pharmacy.

**D. Health-System Facility Design**

To advocate the development and the inclusion of contemporary pharmacy specifications in national and state health care design standards to ensure adequate space for safe provision of pharmacy products and patient care services; further,

To promote pharmacist involvement in the design planning and space allocation decisions of health care facilities.

**E. Accessibility and Affordability of Pharmaceuticals**

To advocate legislation or regulation that would expand eligibility for federal discount drug-pricing programs (e.g., the 340B program) to inpatient drugs for disproportionate-share hospitals; further,

To advocate administrative simplification of existing and any future federal discount drug-pricing programs with respect to qualification and implementation.

**F. Electronic Information Systems**

To advocate the use of electronic information systems, with appropriate security controls, that enable the integration of patient-specific data that is accessible in all components of a health system; further,

To support the use of technology that allows the transfer of patient information needed for appropriate medication management across the continuum of care; further,

To urge computer software vendors and pharmaceutical suppliers to provide standards for definition, collection, coding, and exchange of clinical data used in the medication-use process; further,

To pursue formal and informal liaisons with appropriate health care associations to ensure that the interests of patient care and safety in the medication-use process are fully represented in the standardization, integration, and implementation of electronic information systems; further,

To strongly encourage health-system administrators, regulatory bodies, and other appropriate groups to provide health-system pharmacists with full access to patient-specific clinical data.

(Note: This policy supersedes ASHP policy 0405.)

**G. Financial Management Skills**

To foster the systematic and ongoing development of management skills for health-system pharmacists in the areas of (1) health-system economics, (2) business plan development, (3) financial analysis, (4) pharmacoeconomic analysis, (5) diversified pharmacy services, and (6) compensation for pharmacists' patient-care services; further,

To encourage schools of pharmacy to incorporate these management areas in course work and clerkships.

(Note: This policy supersedes ASHP policy 0003)

**H. Statement on Compensation for Clinical Services by Pharmacists**

To discontinue the ASHP Statement on Third-Party Compensation for Clinical Services by Pharmacists.

**I. Patient-Focused Care**

To discontinue ASHP policy 9401, Patient-Focused Care.

William H. Puckett, Board Liaison to the Council on Educational Affairs, presented the Council’s Policy Recommendations A to C.

Following a request to separate Policy A, it was moved and seconded...
to add three paragraphs to be the beginning of the motion, and to delete the last paragraph and replace it with substitute language. Following discussion, the amendments were approved. Policy A, as amended, was then adopted. It reads as follows (italic type indicates material added; strikethrough indicates material deleted):

A. Developing Leadership and Management Competencies

To advocate that ASHP work with health-system leadership to foster opportunities for pharmacy practitioners to move into pharmacy leadership roles; further,

To encourage current leaders to seek out and mentor practitioners in developing administrative, managerial, and leadership skills; further,

To encourage interested practitioners to obtain the skills necessary to pursue administrative, managerial, and leadership roles; further,

To encourage colleges of pharmacy, ASHP, and state affiliates to foster leadership skills in students through development and enhancement of curricula, leadership conferences, and other programs; further,

To encourage colleges of pharmacy to develop more opportunities for students to pursue combined degree programs; further,

To encourage colleges of pharmacy and health systems to develop more opportunities for students to pursue residency programs that develop administrative, management, and leadership skills; further,

To encourage residency programs to develop leadership skills by mentoring, training, and providing leadership opportunities; further,

To encourage all residency programs to provide training for residents to develop administrative and management skills; further,

To encourage current practitioners to pursue expanded opportunities for developing administrative, managerial, and leadership skills; further,

To foster leadership skills for pharmacists to use on a daily basis in their roles as leaders in medication safety and medication management in patient care.

(Note: This proposed policy would supersede ASHP policy 9913.)

B. Communication among Health-System Pharmacy Practitioners, Patients, and Other Health Care Providers

To foster effective communication (with appropriate attention to patients’ levels of general and health literacy) among health-system pharmacy practitioners, patients, and other health care providers; further,

To develop programs to enable pharmacy students, residents, and health-system pharmacy practitioners to self-assess their levels of health literacy and general communication skills; further,

To develop methods with which pharmacy students, residents, and health-system pharmacy practitioners can assess the level of general and health literacy of patients; further,

To disseminate information about resources for students, residents, and health-system pharmacy practitioners to use in working with patients and others having specific communication needs.

(Note: This policy supersedes ASHP policy 0210.)

C. Professional Development

To recognize that providing professional development opportunities for health-system pharmacy practitioners is an essential component of staff recruitment and retention as well as quality of work life; further,

To strongly encourage health-system pharmacy directors and administrators to support professional development programs as an employee benefit that ultimately improves patient care and aids in recruiting and retaining qualified practitioners; further,

To recognize that professional development encompasses more than staff development programming and includes informal learning among colleagues, mentoring, and other types of learning; further,

To develop educational programs, services, and resources to assist health-system pharmacies in supporting professional development.

Phillip J. Schneider, Board Liaison to the Council on Legal and Public Affairs, presented the Council’s Policy Recommendations A through M.

Following a request to separate Policy Recommendation A, it was moved and seconded to delete the word “full,” add the words “and its Territories, which includes acute, chronic, wellness, and preventative care” after the word “States,” to delete the word “including” after the word “care,” add the words “cognitive pharmacy,” and delete the words “related pharmacist” before the word services” in the first paragraph.

Following discussion, the motion to delete the word “full” was defeated. It was then moved to delete the new language beginning with the words “and its Territories….” It was then moved and seconded to refer Policy
A. The motion for referral was approved.
After a request to separate Policy B, it was moved and seconded to add the words “and safety” after the word “effectiveness” in the first paragraph and to add the words “particularly off-label medications,” before the words “medication devices” in the second paragraph. The amendments were approved. It was then moved and seconded to remove the word “invasive” in the second paragraph. The amendment was approved. Following discussion, it was then moved and seconded to remove the words “particularly off-label medications.” The amendment was approved. Policy B as amended was then adopted. It reads as follows (italic type indicates material added; strikethrough indicates material deleted):

B. Postmarketing Comparative Clinical Studies

To advocate an expansion of comparative clinical studies of the effectiveness and safety of marketed medications in order to improve therapeutic outcomes and promote cost-effective medication use; further,

To advocate that such studies compare a particular medication with (as appropriate) other medications, medical devices, or invasive procedures used to treat specific diseases; further,

To advocate adequate funding for the Agency for Healthcare Research and Quality to carry out such studies; further,

To encourage impartial private sector entities to also conduct such studies.

C. Premarketting Comparative Clinical Studies

To advocate that the Food and Drug Administration (FDA) have the flexibility to decrease the requirement for placebo-controlled studies, and correspondingly impose a requirement for comparative clinical trials, as more new drug applications are filed for products in the same drug class.

D. Postmarketing Safety Studies

To advocate that Congress grant the Food and Drug Administration (FDA) authority to require the manufacturer of an approved drug product or licensed biologic product to conduct postmarketing studies on the safety of the product when the agency deems it to be in the public interest; further,

To advocate that Congress grant FDA broader authority to require additional labeling or withdrawal of the product on the basis of a review of postmarketing studies; further,

To advocate that Congress provide adequate funding to FDA to fulfill this expanded mission related to postmarketing surveillance.

Following discussion, the amendment was approved. It was then moved and seconded to reconsider the amendment. Reconsideration was defeated. It was then moved and seconded to delete the words “undertaken throughout the world” following the words “clinical trials” in the second paragraph. The amendment was approved. Policy E, as amended, was then adopted. It reads as follows (italic type indicates material added; strikethrough indicates material deleted):

E. Mandatory Registry of Clinical Trials

To advocate disclosure of the most complete information on the safety and efficacy of drug products; further,

To advocate that the Department of Health and Human Services establish a mandatory registry for all Phase II, III, and IV clinical trials undertaken throughout the world that are conducted on prescription drugs intended for use in the United States; further,

To advocate that each clinical trial have a unique identifier; further,

To advocate that all data from registered clinical trials be posted electronically with unrestricted access, and that such posting occur (a) after Food and Drug Administration approval of the related new product but before marketing begins and (b) as soon as possible for trials completed after initial marketing.

F. Ethical Use of Placebos

To affirm that the use of placebos in clinical practice is acceptable ethically only when patients grant informed consent for the use of placebos.” Following discussion, the amendment was approved. Policy F, as amended, was then adopted. It reads as follows (italic type indicates material added):

To encourage each health care facility to develop a policy and procedure to guide its clinicians in making informed decisions regarding the use of placebos.
Following a request to separate Policy G, it was moved and seconded to delete the word “and” before the word “regulation,” to add the words “and enforcement” after the word “regulation” and to add the word “standards” following the word “practice” in the last paragraph. There was no discussion and the amendments were approved. Policy G, as amended, was then adopted. It reads as follows (italic type indicates material added):

G. Funding, Expertise and Oversight of State Boards of Pharmacy

To advocate appropriate oversight of pharmacy practice (including nontraditional practice) and the pharmaceutical supply chain by state boards of pharmacy and other state agencies whose mission it is to protect the public health; further,

To advocate adequate representation on state boards of pharmacy and related agencies by pharmacists who are knowledgeable about hospitals and health systems to ensure appropriate oversight of hospital and health-system pharmacy practice; further,

To advocate adequate funding for state boards of pharmacy and related agencies to ensure the effective oversight, and enforcement of pharmacy practice standards and the pharmaceutical supply chain.

H. Approval of Generic Biologic Medications

To encourage the development of safe and effective generic versions of biologic medications in order to make such medications more affordable; further,

To encourage research on scientific methods to ensure the safety, effectiveness, and therapeutic equivalence of generic biologic medications; further,

To support legislation and regulation to allow Food and Drug Administration approval of generic versions of biologic medications.

I. Federal Review of Anticompetitive Practices by Generic Manufacturers

To encourage appropriate federal review of the consolidation of the manufacturers of multisource drug products and other potentially anticompetitive practices by manufacturers that adversely affect drug product availability and price.

Following a request to separate Policy J, it was moved and seconded to delete the paragraph which reads “To note that various interest groups in pharmacy have advocated the creation of new categories of licensed personnel such as ‘pharmacist assistant,’ further,” . There was no discussion and the amendment was approved, Policy J, as amended, was then adopted. It reads as follows (strikethrough indicates material deleted):

J. Opposition to Creation of New Categories of Licensed Support Personnel

To reaffirm the following statement in the White Paper on Pharmacy Technicians (April 1996) endorsed by ASHP and the American Pharmacists Association:

Although there is a compelling need for pharmacists to expand the purview of their professional practice, there is also a need for pharmacists to maintain control over all aspects of drug product handling in the patient care arena, including dispensing and compounding. No other discipline is as well qualified to ensure public safety in this important aspect of health care; Further,

To note that various interest groups in pharmacy have advocated the creation of new categories of licensed personnel such as “pharmacist assistant”; further,

To oppose the creation of new categories of licensed pharmacy personnel; further,

To advocate that all professional pharmacy functions be performed under the supervision of a licensed pharmacist to avoid confusion regarding the roles of pharmacy personnel within health systems.

(Note: This policy supersedes ASHP policy 0025.)

After a request to separate Policy K, there were several amendments and secondary amendments which were eventually withdrawn. It was then moved and seconded to add the word “pharmacist,” in item (c), following the word “prescriber.” This amendment was approved. It was then moved and seconded to add new language as follows “(f) provide for data security and confidentiality.” This was approved. Policy K as amended was then adopted. It reads as follows (italic type indicates material added):

K. New and Emerging Medication Ordering and Distribution Systems

To support the use of new and emerging medication ordering and distribution systems (e.g., via the World Wide Web) when such systems (a) enable pharmacists to provide patient care services, (b) ensure that patients will not receive improperly labeled and packaged, deteriorated, outdated, counterfeit, or non-FDA-approved drug products, (c) provide appropriate relationships between an authorized prescriber pharmacist, and patient, (d) enhance the continuity of patient care, (e) support the pharmacist’s role as a patient care advocate, and (f) provide for data security and confidentiality.
(Note: This policy supersedes ASHP policy 0008.)

Following a request to separate Policy L, it was moved and seconded to add the words “laws and regulations” in the parenthetical phrase in the 2nd paragraph. There was no discussion and the amendment was approved. It was then moved and seconded to add “be based on a bonafide prescriber-pharmacist-patient relationship and the ability for the patient to have” after the word “system” in the fourth paragraph and to delete the words “must provide” following the new language. This amendment was approved. Policy L, as amended, was then adopted. It reads as follows (italic type indicates material added; strikethrough indicates material deleted)

L. **Online Pharmacy and Internet Prescribing**

To support collaborative efforts of the Food and Drug Administration, the National Association of Boards of Pharmacy (NABP), and the Federation of State Medical Boards, as stated in the Principles of Understanding on the Sale of Drugs on the Internet, to regulate prescribing and dispensing of medications via the Internet; further,

To support legislation or regulation that requires pharmacy World Wide Web sites to list the states in which the pharmacy and pharmacists are licensed, and, if prescribing services are offered, requires that the sites (a) ensure that a legitimate patient-prescriber relationship exists (consistent with professional practice standards, laws and regulations) and (b) list the states in which the prescribers are licensed; further,

To support mandatory accreditation by NABP of pharmacy Web sites and appropriate consumer education about the risks and benefits of using Internet pharmacies; further,

To support the principle that any medication distribution or drug therapy management system be based on a bonafide prescriber-pharmacist-patient relationship and the ability for the patient to have **must provide** timely access to, and interaction with, appropriate professional pharmacist patient care services.

(Note: This policy supersedes ASHP policy 0009.)

Following a request to separate Policy M, it was moved and seconded to add the language “assure product integrity and” before the words “allow organized” in the first paragraph. There was no discussion and the amendment was approved. Policy M, as amended, was then adopted. It reads as following (italic type indicates material added)

M. **Prudent Purchasing of Pharmaceuticals**

To support existing laws and legitimate practices that **assure product integrity and allow** organized health care settings to purchase drug products and related supplies at prices that minimize health care costs; further,

To support the principle of purchase of pharmaceutical products and related supplies by public and private entities using appropriate professional practices to achieve that end; further,

To encourage government acknowledgement of existing local professional activities (e.g., drug-use review, formulary systems, pharmacy and therapeutics committees, and patient counseling) already practiced in organized health care settings that are methods of promoting quality and cost-effective pharmacist patient care services.

(Note: This policy supersedes ASHP policy 0014.)

Kevin J. Colgan, Board Liaison to the **Council on Organizational Affairs**, presented the Council’s Policy Recommendations A and B.

A. **Board of Directors Latitude in Adjusting ASHP Components**

To approve a Bylaws amendment that would grant the Board of Directors latitude in adjusting the component structure of ASHP (Proposal A).

B. **Voting Privileges for Public Members of the Commission on Credentialing**

To approve a Bylaws amendment that would grant voting privileges to public members of the Commission on Credentialing (Proposal B).

Janet A. Silvester, Board Liaison to the **Council on Professional Affairs**, presented the Council’s Policy Recommendations A through C.

Following a request to separate Policy Recommendation A, it was moved and seconded to substitute the original language with the following: “To work collaboratively with other interested organizations to minimize the environmental impact of pharmaceutical waste by advocating for (1) research on the public health impact of current disposal methods of unused pharmaceuticals in both inpatient and outpatient settings, and (2) development of strategies for safe disposal of unused pharmaceuticals; further, To support the development of appropriate legal and regulatory framework to fund and implement such strategies; further, To educate health professionals, regulatory bodies, other relevant organizations
and the public regarding safe disposal of pharmaceuticals.” After extensive discussion including a request for a revised title, delegates moved and seconded a recommendation to refer this policy. The motion to refer took precedent over previous motions. The motion to refer was approved.

Following a request to separate Policy B, it was moved and seconded to amend by adding the words “third-party” before the word “mandatory” in the first paragraph and in the parentheses in the second paragraph to add the words “or when a dose is unavailable.” Following discussion, the amendments were defeated. It was then moved and seconded to add the words “or dose is unavailable” in the second paragraph. This amendment was defeated. It was then moved and seconded to strike the word “voluntary” in the second paragraph. Following discussion, the amendment was defeated. Policy recommendation B was then adopted as written. It reads as follows:

B. Mandatory Tablet Splitting for Cost Containment

To oppose mandatory tablet splitting for cost containment in ambulatory care; further,

To encourage pharmacists, when voluntary tablet splitting is considered, to collaborate with patients, caregivers, and other health care professionals to determine whether tablet splitting is appropriate on the basis of the patient’s ability to split tablets and the suitability of the medication (e.g., whether it is scored or is an extended-release product); further,

To urge pharmacists to promote dosing accuracy and patient safety by ensuring that patients are educated on how to properly split tablets; further,

To encourage further research by the United States Pharmacopeia and the Food and Drug Administration on the impact of tablet splitting on product quality.

C. Inline Filters

To discontinue ASHP policy 0018, Inline Filters, which reads:

To support the principle that pharmacists be involved in the development of policies in their practice settings on the use of inline filtration for intravenous administration of fluids, nutrients, and medications.

Cynthia Brennan, Board Liaison to the Commission on Therapeutics, presented the Council’s Policy Recommendation A.

A. ASHP Statement on the Over-the-Counter Availability of Statins

To approve the ASHP Statement on the Over-the-Counter Availability of Statins (Appendix A).

Chair Phillips reminded delegates of the process for submitting New Business items for consideration of the second meeting of the House session. Announcements were made. The meeting adjourned at 5:04 p.m.

Second meeting

The second and final meeting of the House of Delegates session convened on Tuesday, June 14, at 4:30 p.m. A quorum was present.

Chair Phillips announced that there was a revision in the order of the agenda moving the election of Chair to the third item following the ‘quorum call’ and moving recommendations of delegates to follow ‘unfinished and new business.’

Election of House Chair

Chair Phillips announced the appointment of tellers to canvass the ballots for the election of Chair of the House of Delegates. Those appointed were Robert Parsons (OH), Edward Lee (PA) and Paul Driver (ID).

She called delegates to present completed official ballots to tellers, who certified the eligibility of delegates to vote. After the balloting, the tellers counted the ballots.

Board of Directors reintroduction of policy. Council on Legal and Public Affairs, “Full Health Insurance Coverage”: this policy had been referred at the first meeting and was reintroduced by the Board of Directors with minor editorial changes. Following discussion, Policy A was adopted. It reads as follows:

A. Full Health Insurance Coverage

To advocate full health insurance coverage for all persons living in the United States, including coverage of prescription medications and related pharmacist patient-care services; further,

To advocate that all health insurers, both public and private, use the full range of available methods to (1) ensure the provision of appropriate, safe, and cost-effective health care services for their beneficiaries, (2) optimize the treatment outcomes of the insured population, and (3) minimize overall program costs; further,

To advocate that health insurers seek to optimize continuity of care in their design of benefit plans.

Board of Directors duly considered matters. The Board reported on 12 professional policies that were amended at the first House meeting. Pursuant to Bylaws section 7.3.1.1, the Board met on the morning of June 14, 2005, to “duly consider” the
amended policies. The Board presented its recommendations as follows.

1. Council on Administrative Affairs, “Health Care Quality Standards and Pharmacy Services”: the Board agreed that the amended language was acceptable with an editorial change in the title by deleting the word “National.”

2. Council on Administrative Affairs, “Critical-Access, Small and Rural Hospitals”: the Board agreed that the amended language was acceptable. The Board also made editorial changes. Policy B, as adopted, reads as follows:

B. Critical-Access, Small, and Rural Hospitals

To advocate that critical-access hospitals (CAHs) and small and rural hospitals meet national medication management and patient safety standards; further,

To provide resources and tools to assist pharmacists who provide services to CAHs and small and rural hospitals in meeting standards related to safe medication use.

3. Council on Administrative Affairs, “Health-System Facility Design”: the Board agreed that the amended language was acceptable.

4. Council on Educational Affairs, “Developing Leadership and Management Competencies”: the Board agreed that the amended language was acceptable with editorial changes. Policy Recommendation A as adopted reads as follows:

A. Developing Leadership and Management Competencies

To work with health-system leadership to foster opportunities for pharmacy practitioners to move into pharmacy leadership roles; further,

To encourage current leaders to seek out and mentor practitioners in developing administrative, managerial, and leadership skills; further,

To encourage interested practitioners to obtain the skills necessary to pursue administrative, managerial, and leadership roles; further,

To encourage colleges of pharmacy and state affiliates to foster leadership skills in students through development and enhancement of curricula, leadership conferences, and other programs; further,

To encourage colleges of pharmacy to develop more opportunities for students to pursue combined degree programs; further,

To encourage residency programs to develop leadership skills by mentoring, training, and providing leadership opportunities; further,

To encourage residency programs to provide training for residents to develop administrative and management skills; further,

To foster leadership skills for pharmacists to use on a daily basis in their roles as leaders in medication safety and medication management in patient care.

(Note: This policy supersedes ASHP policy 9913.)

5. Council on Legal and Public Affairs, “Postmarketing Comparative Clinical Studies”: the Board agreed that the amended language was acceptable.

6. Council on Legal and Public Affairs, “Mandatory Registry of Clinical Trials”: the Board agreed that the amended language was acceptable.

7. Council on Legal and Public Affairs, “Ethical Use of Placebos”: the Board agreed that the amended language was acceptable.

8. Council of Legal and Public Affairs, “Funding, Expertise and Oversight of State Boards of Pharmacy”: the Board agreed that the amending language was not acceptable. Following a request for reconsideration of the original language, it was moved, seconded and adopted as originally presented. Policy G reads as follows:

G. Funding, Expertise, and Oversight of State Boards of Pharmacy

To advocate appropriate oversight of pharmacy practice (including nontraditional practice) and the pharmaceutical supply chain by state boards of pharmacy and other state agencies whose mission it is to protect the public health; further,

To advocate adequate representation on state boards of pharmacy and related agencies by pharmacists who are knowledgeable about hospitals and health systems to ensure appropriate oversight of hospital and health-system pharmacy practice; further,

To advocate adequate funding for state boards of pharmacy and related agencies to ensure the effective oversight and regulation of pharmacy practice and the pharmaceutical supply chain.

10. Council on Legal and Public Affairs, “New and Emerging Medication Ordering and Distribution Systems”: the Board agreed that the amended language was acceptable with an editorial change. Policy Recommendation K as adopted reads as follows:

K. New and Emerging Medication Ordering and Distribution Systems

To support the use of new and emerging medication ordering and distribution systems (e.g., via the World Wide Web) when such systems (1) enable pharmacists to provide patient care services, (2) ensure that patients will not receive improperly labeled and packaged, deteriorated, outdated, counterfeit, or non-FDA-approved drug products, (3) provide appropriate relationships among an authorized prescriber, pharmacist, and patient, (4) enhance the continuity of patient care, (5) support the pharmacist’s role as a patient care advocate, and (6) provide for data security and confidentiality.

(Note: This policy supersedes ASHP policy 0008.)

11. Council on Legal and Public Affairs, “Online Pharmacy and Internet Prescribing”: the Board agreed that the amended language was acceptable. Following a request for reconsideration of the original language, it was moved, seconded and adopted as originally presented. Policy L reads as follows:

L. Online Pharmacy and Internet Prescribing

To support collaborative efforts of the Food and Drug Administration, the National Association of Boards of Pharmacy (NABP), and the Federation of State Medical Boards, as stated in the Principles of Understanding on the Sale of Drugs on the Internet, to regulate prescribing and dispensing of medications via the Internet; further, To support legislation or regulation that requires pharmacy World Wide Web sites to list the states in which the pharmacy and pharmacists are licensed, and, if prescribing services are offered, requires that the sites (1) ensure that a legitimate prescriber-patient relationship exists (consistent with professional practice standards) and (2) list the states in which the prescribers are licensed; further,

To support mandatory accreditation by NABP of pharmacy Web sites and appropriate consumer education about the risks and benefits of using Internet pharmacies; further,

To support the principle that any medication distribution or drug therapy management system must provide timely access to, and interaction with, appropriate professional pharmacist patient-care services.

(Note: This policy supersedes ASHP policy 0009.)

12. Council on Legal and Public Affairs, “Prudent Purchasing of Pharmaceuticals”: the Board agreed that the amended language was acceptable.

New Business. Chair Phillips announced that, in accordance with Article 7 of the Bylaws, there was one item of New Business to be considered. She noted that if an item of New Business is approved for referral to the Board, the delegates’ discussion, ideas, and comments on the item become a part of the referral.

Chair Phillips called on Dennis Williams (NC) to introduce the item of New Business, titled, “Compounding Activities by Pharmacists.” Following discussion, the item was approved for referral. It reads as follows:

Compounding Activities by Pharmacists

Motion: To support compounding activities by pharmacists only when a legitimate medical need exists, including the lack of a commercially available product or dosage form.

Background: The profession has long affirmed that pharmacists’ right to compound products to meet the needs of patients. There are many legitimate medical needs that can be met with a product compounded by a pharmacist including medications for pediatric, adult, and geriatric patients. However, some compounding practices often do not meet a legitimate medical need. These may include compounding of commercially available products, or slight modifications of dose to make the compounded product appear distinctly different from available products. There has been much public attention about this issue and a general opinion among lay groups and other medical professionals that pharmacists are opposed to any restrictions on compounding, even in these questionable areas. There are several examples of compounded products being dispensed to patients when a brand name has been prescribed. ASHP current policy (0225 and 0411) address compounding versus manufacturing, and compliance with 797. These do not adequately address this issue. A policy from the Society would be helpful to improve understanding about the profession’s stance on these issues.

Suggested Outcome: A policy from the Society that can be used to communicate internally and externally about this issue. Consideration by a council can result in development of policy recommendations that will reflect ASHP’s position on this issue and related areas. Discussion by the HOD can generate more background
material and relevant materials for consideration by the councils.

Recommendations. Chair Phillips called on members of the House of Delegates for Recommendations. (The name(s) and state(s) or category of the delegate(s) who introduced the item and the subject of the item precede each Recommendation.)

Randy Kuiper (MT): Advocate that CMS be allowed to negotiate pharmaceutical prices for the Medicare prescription drug program

Recommendation: ASHP should develop a policy advocating that CMS negotiate prices directly with drug manufacturers on behalf of the Medicare program.

Background: The Medicare Modernization Act does not allow for negotiation to obtain better prices for pharmaceuticals. ASHP should develop policy that would support a legislative fix that would allow the Secretary of Health and Human Services to negotiate with pharmaceutical companies to get better prices on prescription drugs. This would save money for both Medicare recipients and taxpayers.

Carl Grove (MA): Ethical Use of Placebos in Clinical Practice

Recommendation: For the Council on Legal and Public Affairs to remove the requirement of informed consent, but rather, require that patients be fully informed that the use of placebos may be a component of their treatment.

Background: The informed consent process/requirement is becoming more and more lengthy and tedious in hospitals. I believe informed consent to be overkill in the achievement of this policy. I believe in the concept but not the mechanism currently set forth. The use of placebos should be in the category of fully informing the patient like we do with all other treatments that do not require informed consent.

Teri Miller (CA): Suggested policy clarification-Full Health Insurance Coverage

Recommendation: That the Board consider clarifying the newly adopted policy, “Full Health Coverage,” by clearly separating its multiple components (example follows):

“ASHP advocates:
(1) Full health insurance coverage for all persons living in the United States;
(2) Coverage of prescription medications and related pharmacist patient-care services as a vital component of full health insurance coverage;
(3) That all health insurers, both public and private, use the full range of available methods to (a) ensure the provision of appropriate, safe and cost-effective health care services for their beneficiaries, (b) optimize the treatment outcomes of the insured population, and (c) minimize overall program costs;
(4) That health insurers seek to optimize continuity of care in their design of benefit plans.

Background: Discussion during the caucuses revealed confusion on the part of delegates over whether this policy was intended to focus on the broad-based goal of support for full (universal) health coverage; the inclusion of pharmacist patient-care services in full health insurance coverage, or both. Separation of these components into clearly distinct, yet related concepts will clarify and strengthen the policy.

Sara J. White (Past President): Leadership annual report

Recommendation: At least on an annual basis, ASHP should provide the entire membership a single “report” of specific accomplishments to ensure enough competent health-system pharmacy leaders.

Scott Meyers, Don Lynx, Jim Dorociak (IL): E-prescribing and the Medicare Modernization Act

Recommendation: That ASHP work with CMS to clarify and direct the pharmacist’s role in managing information exchange resulting from e-prescribing and to create accompanying programs, products and services for its members as they address implementation of the rules of the Medicare Modernization Act.

Background: The Medicare Modernization Act calls for implementation of guidelines pertaining to e-prescribing. Pharmacists have and will continue to play a role in individual health-system e-prescribing systems. ASHP should take a leadership role in oversight of the rule drafting and implementation process and use that involvement to create necessary resources that will assist its members.

Eric Hola (NJ): Redistribution of prescription medication

Recommendation: That ASHP develop policy for the safe redistribution of prescription medication.

Background: The States of Texas, Oklahoma, Louisiana, Ohio, Nebraska, California, Maine, and Washington have passed or are considering legislation regarding this topic. An ASHP policy would be useful guidance.


Donna Soflin (NE): Handling, compounding and disposal of hazardous drugs
Recommendation: To advocate the adoption, in all applicable federal laws and regulations governing hazardous drugs, of the intent of the requirements and the outcomes for health professional and public safety as described in Occupational Safety and Health Administration (OSHA), Section VI: Chapter 2, Controlling Occupational Exposure to Hazardous Drugs, 1994; further,

To support the recommendations for preventing occupational exposure to hazardous drugs as outlined in the National Institute for Occupational Safety and Health (NIOSH) “alert” titled “Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Setting,” March 24, 2004; further,

To support members of ASHP with a Web-based resource page with primary literature on the risk associated with the exposure of hazardous drugs, recommendations from NIOSH, OSHA regulations, EPA requirements for disposal of hazardous drugs, primary literature on surface contamination of vials from the manufacturers, listing of vendors for personal protective equipment, listing of vendors for biological safety cabinets, etc.

Background: Understanding that ASHP is in the process of revisiting the Technical Assistance Bulletin (TAB) on Handling Cytotoxic and Hazardous Drugs, this recommendation highlights the need for information beyond that provided in the current TAB related to all aspects of handling hazardous drugs.

Jim Dorociak (IL): Electronic voting in the House of Delegates

Recommendation: That ASHP explore and implement, if feasible, an electronic (or audience feedback type) voting system in the House of Delegates.

Background: Audience response systems are now used regularly in CE meetings and educational sessions. This technology would: (1) provide a quick and accurate method to handle voting and feedback at the HOD meetings, and (2) provide a method to avoid peer pressure when voting.


Recommendation: To have ASHP policy making bodies review the deliberations and comments at the Regional Delegate Conferences, open hearing and caucuses for political strengthening of these current policy statements.

Background: The policy making process of ASHP review the proposed language amendments to these policy statements to seek further strengthening and clarity; further, when applicable, seek feedback on policy formulation from other national pharmacy organizations or pharmacy stakeholders in the formulation of such policy.

Larry Clark (CO): Sharing of collaborative drug therapy management agreements

Recommendation: That ASHP develop methods to facilitate sharing of collaborative drug therapy management agreements among its members.

Background: Many states have approved pharmacist collaborative drug therapy practice. The ability to share the practice agreements developed by others would facilitate efforts to implement and spread the practice of collaborative drug therapy management. The increased practice of drug therapy management will facilitate reimbursement strategies.

R. Paul Baumgartner (Past President): State society continuing education assistance program

Recommendation: ASHP should initiate a program to assist affiliated state societies in the creation, planning, funding, and implementation of quality CE programs that meet the professional needs of their members.

Background: ACPE’s decision to no longer accredit pharmaceutical manufacturers as providers of CE has presented a major challenge to fund and carry out CE programs. Currently, many state societies lack this expertise to meet the new funding requirements of sponsors or to fully satisfy ACPE standards. This situation provides a major opportunity for ASHP to strengthen its relationship with affiliated state societies by providing training, guidance and model programs. State societies now have an opportunity to create programs that better meet the needs of their members.

James Stevenson (MI): Distribution of medications from manufacturers patient assistance programs

Recommendation: To advocate for the implementation of requirements for drug distribution through manufacturers patient assistance programs that ensure that (1) the elements of medication safety and medication therapy management are provided by pharmacists,(2) there are proper drug controls, labeling, and packaging, and (3) unauthorized access to medications is prevented.

Background: Many patient assistance programs are designed so that drugs are distributed to clinics, physician offices, and hospitals in a package form that does not provide for proper drug controls, labeling, packaging, and pharmacist involvement in the medication use process. In addition, millions of doses are provided to
patients without the benefit of a pharmacist providing basic medication therapy management to ensure efficacy, safety, and appropriate education. In addition, to these problems, current methods of distribution create regulatory compliance issues for health systems. ASHP should encourage manufacturers to pursue alternative forms of distribution, such that the professional patient care services of a pharmacist may be provided and the fundamental elements or a safe medication distribution system are met.

**Doug Lang (MO): Formulation of policy to address return and re-use of medications**

Recommendation: ASHP develop a policy to address the issue of the return and re-use of medications.

**Background:** Currently, pharmacy practitioners and boards of pharmacies are under tremendous pressures by payers, legislatures and other health care policy decision makers to accept the return and reuse of medications for patients. Current national pharmacy standard’s of bodies such as USP and other national pharmacy organizations have standards and policies that speak directly to this issue.

**Kathleen Donley (OH): Compounding activities guideline.**

Recommendation: That ASHP develop policy language supporting the concept that any compounded preparation would be judged by a reasonable and prudent pharmacist to be safe and effective.

**Background:** There appear to be increasing numbers of compounding pharmacies that will prepare any product for sale regardless of the known characteristics of the principal ingredient; of specific concern are changes in dosage form, e.g. oral to suppository and oral to topical.

**Scott Myers (IL), Teri Miller (CA), Debra Feinberg (NY), Robert Parsons (OH): An organization for state affiliate executives**

Recommendation: ASHP foster the formation of an organization of state health-system pharmacy society executives as a means of fostering collaboration and cooperation and as an entity that could participate at other national forums.

**Background:** State pharmacy association executives have NCSPAE. Some ASHP affiliated state societies executives are prohibited from participating as full active members. There would be many opportunities for ASHP’s affiliated executives to participate if a supporting organization existed.

**Robert Ignoffo (CA): Efficient use of time at meetings**

Recommendation: Re-evaluate voting process for election of Chair.

**Background:** More than 15 minutes was devoted to voting for Chair. The process can be shortened by collecting votes utilizing tellers at aisles. Although the existing procedure is an ASHP tradition, it is not the best use of delegate time.

**Karen Kier (OH): Thank you to ASHP**

Recommendation: The Ohio delegation would like to thank ASHP officers and staff for providing replacement textbooks free of charge for Ohio Northern University pharmacy students whose personal belongings and textbooks were destroyed in a fire.

**Tom Brenner, Fern Kaufman, Gerry Meyer, Milan Moncilovich, and Jean Scholtz (PA): Elimination of surface contamination of hazardous drug vials**

Recommendation: To advocate that manufacturers of hazardous drugs incorporate practices that eliminate the risk of surface contamination of drug vials to provide a safer work environment for all personnel involved with handling of these products.

**Background:** A recently published article and accompanying editorial in AJHP highlighted and reviewed the external contamination of chemotherapy drug vials. The article referenced numerous studies that demonstrate external contamination with potentially hazardous chemicals at potentially dangerous levels. The article further described existing techniques that could be employed to reduce this workplace hazard.

**R. David Anderson (Past President)**

To request a moment of silence in memory of Past Presidents Donald Beste and Milton Skolaut who passed away earlier this year.

(Note: Chair Phillips thanked Mr. Anderson for his request and asked delegates to be silent for a few minutes in honor of Past Presidents Beste and Skolaut.)

**Recognition.** Chair Phillips recognized members of the Board who were continuing in office. She also introduced members of the Board who were completing their terms of office.

As a token of appreciation on behalf of the Board of Directors and members of ASHP, Chair Phillips presented President Woods with an inscribed gavel commemorating his term of office. President Woods recognized the service of Chair Phillips as Chair of the House of Delegates and a member of the Board of Directors.

Chair Phillips recognized Daniel Ashby’s years of service as a member of the Board, in various
presidential capacities, as Chair of the Board, and as Vice Chair of the House of Delegates.

Chair Phillips then installed the chairs of ASHP’s sections and forums: Susan Goodin, Section of Clinical Specialists and Scientists, Carol Rollins, Section of Home, Ambulatory, and Chronic Care Practitioners, Megan McMurray, Section of Inpatient Care Practitioners, David Kvan cz, Section of Pharmacy Practice Managers, Rema Thyagarajan, Student Forum, and Jennifer Askew, New Practitioners Forum. Dr. Phillips then recognized the remaining members of the executive committees of sections and forums.

Chair Phillips then called on Vice Chair Ashby to preside over the House for the remainder of the meeting.

Vice Chair Ashby announced that Marjorie Shaw Phillips had been elected as Chair of the House.

**Installation.** Vice Chair Ashby installed Jill E. Martin as President of ASHP, Diane B. Ginsburg and Lynnae M. Mahaney as members of the Board of Directors, and Marjorie Shaw Phillips as Chair of the House of Delegates. He introduced the families of newly installed Board members.

**Parliamentarian.** Vice Chair Ashby thanked Joy Myers for service to ASHP as parliamentarian.

Before adjourning, the delegate from Idaho announced that the ISHP is celebrating its 50th anniversary.

Vice Chair Ashby thanked members from the State of Massachusetts for their hospitality in welcoming ASHP to Boston for its Summer Meeting.

**Adjournment.** The 57th annual session of the House of Delegates adjourned at 5:45 p.m.