

June 12 and 14, 2011 Denver, Colorado

# Proceedings of the 63rd annual session of the ASHP House of Delegates June 12 and 14, 2011

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HENRI R. MANASSE, JR., SECRETARY

The 63rd annual session of the ASHP House of Delegates was held at the Colorado Convention Center, in Denver, CO, in conjunction with the 2011 Summer Meeting.

#### First meeting

The first meeting was convened at 1:30 p.m. Sunday, June 12, by Chair of the House of Delegates Gerald E. Meyer. Stanley S. Kent, Vice Chair of the Board of Directors, gave the invocation.

Chair Meyer introduced the persons seated at the head table: Lynnae M. Mahaney, Immediate Past President of ASHP and Vice Chair of the House of Delegates; Diane B. Ginsburg, President of ASHP and Chair of the Board of Directors; Henri R. Manasse, Jr., Executive Vice President and Chief Executive Officer of ASHP and Secretary of the House of Delegates; and Joy Myers, Parliamentarian.

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

The roll of official delegates was called. A quorum was present, including 194 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 Meyer reminded delegates that the report of the 62nd 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 62nd House of Delegates session were received without objection.

Chair Meyer called on Michael B. Cockerham for the report of the Committee on Nominations.<sup>a</sup> Nominees were presented as follows:

#### President-elect

Janet L. Mighty, B.S., M.B.A., R.Ph., Assistant Director, Investigational Drug Service, Johns Hopkins Hospital, Baltimore, MD

Kathryn R. Schultz, B.S., Pharm.D., FASHP, Director of Pharmacy, HealthEast Bethesda Hospital, St. Paul, MN

#### Board of Directors (2011-2014)

Ernest Anderson, Jr., M.S., System Vice President of Pharmacy, Steward Health Care System, Brighton, MA

**Paul W. Bush, Pharm.D., M.B.A., FASHP,** Chief Pharmacy Officer, Duke University Hospital, Durham, NC

**Steve Rough, M.S., R.Ph.,** Director of Pharmacy, University of Wisconsin Hospitals & Clinics, Madison, WI

Deborah R. Saine, M.S., R.Ph., FASHP, Medication Safety Manager, Winchester Medical Center, Winchester, VA

#### Chair, House of Delegates

Gerald E. Meyer, Pharm.D., M.B.A., FASHP, Director of Experiential Education, Thomas Jefferson University, Jefferson School of Pharmacy, Philadelphia, PA

James A. Trovato, Pharm.D., M.B.A., BCOP, FASHP, Associate Professor, Department of Pharmacy Practice & Science, University of Maryland School of Pharmacy, Baltimore, MD

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

Chair Meyer announced the candidates for the executive committees of the five sections of ASHP.

Report of President and Chair of the Board. President Ginsburg referred to the summaries of actions taken by the Board of Directors over the past year and updated and elaborated upon various ASHP initiatives. There was no discussion, and the delegates voted to accept the report of the Chair of the Board.

**Report of Treasurer.** Philip J. Schneider 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.

**Recommendations.** Chair Meyer called on members of the House of Delegates for Recommendations. See the Appendix for a complete listing of all Recommendations.

Policy committee reports. Chair Meyer outlined the process used to generate policy committee reports. He announced that the recommended policies from each council would be introduced as a block. He 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 report; requests to divide the question are granted automatically unless another delegate objects. Chair Meyer reminded delegates that policies not separated by dividing the question would be voted on en bloc before the House considered the separated items.

Chair Meyer also announced that delegates could suggest minor wording changes (without introducing a formal amendment) that did not affect the substance of a policy proposal, and that the Board of Directors would consider these suggestions and report its decisions on them at the second meeting of the House.

(Note: The following reports on House action on policy committee recommendations give the language adopted at the first meeting of the House. The titles of policies amended by the House are preceded by an asterisk [\*]. Amendments are noted as follows: italic type indicates material added; strikethrough marks indicate material deleted. If no amendments are noted, the policy as proposed was adopted by the House. For purposes of this report, no distinction has been made between formal amendments and wording suggestions made by delegates.

The ASHP Bylaws [Section 7.3.1.1] require the Board of Directors to reconsider an amended policy before it becomes final. The Board reported the results of its "due consideration" of amended policies during the second meeting of the House; see that section of these Proceedings for the final disposition of amended policies.)

Lisa M. Gersema, Board Liaison to the Council on Therapeutics, presented the Council's Policy Recommendations A through G.

#### \*A. Research on Medical Use of Marijuana

To encourage research to define the *therapeutically active components*, effectiveness, safety, and clinical use of medical marijuana; further,

To advocate for the development of processes that would ensure standardized formulations, potency, and quality of medical marijuana products to facilitate research; further,

To encourage the Drug Enforcement Administration to eliminate barriers to medical marijuana research, including review of medical marijuana's status as a Schedule I controlled substance, and its reclassification, if necessary to facilitate research; further,

To oppose the use of marijuana cigarettes in settings where use of tobacco is similarly prohibited; further,

To oppose state legislation that authorizes the use of medical marijuana until there is sufficient evidence to support its safety and effectiveness and a standardized product that would be subject to the same regulations as a prescription drug product; further,

To oppose the procurement, storage, preparation, or distribution of medical marijuana by licensed pharmacies or health care facilities for purposes other than research; further,

To encourage continuing education that prepares pharmacists to respond to patient and clinician questions about the therapeutic and legal issues surrounding medical marijuana use.

(Note: As defined by the Congressional Research Service, the term "medical marijuana" refers to uses of botanical marijuana that qualify for a medical use exception under the laws of certain states and under the federal Investigational New Drug Compassionate Access Program. Botanical marijuana includes the whole or parts of the natural marijuana plant and therapeutic products derived therefrom, as opposed to drugs produced synthetically in the laboratory that replicate molecules found in the marijuana plant.)

#### \*B. Agricultural Use of Hormone Therapies

To advocate that the Food and Drug Administration and United States Department of Agriculture re-evaluate the agricultural use of hormone *and pro-hormone* therapies for purposes of animal growth promotion based on evidence demonstrating potential adverse effects on human health; further,

To encourage additional research to better define the public health impact of using hormone therapies for agricultural purposes.

#### \*C. Direct-to-Consumer Clinical Genetic Tests

To support research to validate and standardize genetic markers used in genetic testing *direct-to-consumer* (*DTC*) *clinical genetic tests* and guide the application of genetic test results to clinical practice; further,

To encourage the Food and Drug Administration to use existing authority to regulate these tests as medical devices and to work with the National Institutes of Health to expedite establishment of a process to evaluate and approve direct-to-consumer DTC clinical genetic testsing; further,

To advocate that *DTC clinical* genetic tests<del>ing</del> to support disease diagnosis or management of drug therapy be provided to consumers only through the services of appropriate health care professionals that order tests from laboratories that are certified under the Clinical Laboratories Improvement Amendments of 1988 (CLIA); further,

To oppose direct-to-consumer advertising of *DTC clinical* genetic testsing unless such testing includes the established patient-health care provider relationship as a mechanism to provide information and interpretation of test results; further,

To oppose direct-to-consumer advertising of *DTC clinical* genetic testsing unless the following requirements are met: (1) that the relationship between the genetic marker and the disease or condition being assessed is clearly presented, (2) that the benefits and risks of testing are discussed, and (3) that such advertising is provided in an understandable format, at a level of health literacy that allows the intended audience to make informed decisions, and includes a description of the established patient-health care provider relationship as a critical source for information about the test and interpretation of test results; further,

To *encourage pharmacists to* educate consumers and clinicians on the appropriate use of direct-to-consumer *DTC clinical* genetic testsing for disease diagnosis and drug therapy management.

#### \*D. Pharmacogenomics

To advocate that pharmacists take a leadership role in the therapeutic applications of pharmacogenomics, which is essential to individualized therapy; further,

To support research to validate and standardize genetic markers and genetic testing for drug therapy and to support research and other efforts that guide and accelerate the application of pharmacogenomics to clinical practice; further,

To advocate for the inclusion of pharmacogenomic test results in medical and pharmacy records in a format that clearly states the implications of the genetic result on drug therapy and facilitates availability of the genetic information throughout the continuum of care and over a patient's lifetime; further,

To encourage pharmacists to educate prescribers and patients about the use of pharmacogenomic tests and their appropriate application to drug therapy management; further,

To encourage pharmacist education on the use of pharmacogenomics and advocate for the inclusion of pharmacogenomics and its application to therapeutic decision-making in college of pharmacy curricula.

(Note: This policy would supersede ASHP policy 0016.)

#### \*E. Safe and Effective Use of IV Promethazine

To recognize intravenous (IV) promethazine as a viable treatment alternative in some *limited* clinical circumstances; further.

To support health-system efforts to restrict use of IV promethazine by encouraging alternate routes of administration or use of therapeutic alternatives when appropriate; further,

To encourage health systems to establish medication-use processes that reflect nationally recognized best practices to limit the potential for patient harm when IV promethazine use is medically necessary.

#### \*F. Pain Management

To advocate fully informed patient and caregiver participation in pain management decisions as an integral aspect of patient care; further,

To advocate that pharmacists actively participate in the development and implementation of health-system pain management policies and protocols; further,

To support the participation of pharmacists in pain management, which is a multidisciplinary, collaborative process for selecting appropriate drug therapies, educating patients, monitoring patients, and continually assessing outcomes of therapy; further,

To advocate that pharmacists lead efforts to prevent inappropriate use of pain therapies, including engaging in strategies to detect and address patterns of abuse and misuse; further,

To encourage the education of pharmacists, pharmacy students, and other health care providers regarding the principles of pain management *and methods to minimize drug diversion*.

(Note: This policy would supersede ASHP policy 0306.)

#### G. Patient-Reported Outcomes Tools

To advocate for expanded use of validated patient-reported outcomes (PRO) tools in clinical research and direct patient care; further,

To support development of validated PRO tools that are sensitive to differences in cultural and health literacy; further,

To encourage additional research on PRO tools, including studies to assess their correlation to overall patient outcomes; further,

To educate clinicians and patients about the appropriate use of PRO tools.

Christene M. Jolowsky, Board Liaison to the Council on Education and Workforce Development, presented the Council's Policy Recommendations A through H.

\*A. Quality of Pharmacy Education and Expansion of Colleges of Pharmacy

To support the Accreditation Council for Pharmacy Education's continuing role of promulgating accreditation standards and guidelines and engaging in sound accreditation processes to ensure quality in the education provided by colleges of pharmacy; further,

To acknowledge that, in addition to a robust curriculum, access to quality experiential educational sites and the availability of qualified faculty (including preceptors and specialty-trained clinical faculty) are essential determinants of the ability to expand enrollment in existing or additional colleges of pharmacy; further,

To advocate that oppose expansion of enrollment in existing or new colleges of pharmacy only occur if unless well-designed projections demonstrate that such enrollment increases are necessary to maintain a viable pharmacist workforce.

(Note: This policy would supersede ASHP policy 0607.)

#### B. Residency Equivalency

To acknowledge the distinct role of ASHP-accredited residency training in preparing pharmacists to be direct patient-care providers; further,

To recognize the importance of clinical experience in developing practitioner expertise; further,

To affirm that there are no objective means to convert or express clinical experience as equivalent to or a substitute for the successful completion of an ASHP-accredited residency.

#### \*C. Pharmacy Internships

To encourage the National Association of Boards of Pharmacy to develop standardized pharmacy internship hour requirements that would be used uniformly by all state boards of pharmacy; further,

To support structured requirements, *goals, and objectives* for pharmacy internship experiences, in alignment with requirements for introductory and advanced pharmacy practice experiences; further,

To study promote and expand new staffing models that foster expanded roles for pharmacy interns, providing work experiences that build upon their knowledge and help them develop as future pharmacists.

(Note: This policy would supersede ASHP policy 0802.)

#### \*D. State-Specific Requirements for <u>Pharmacist Continuing</u> Education

To support the standardization of state continuing pharmacisty education requirements; further,

To advocate that state boards of pharmacy adopt continuing professional development (CPD) as the preferred model for maintaining pharmacist competence and structure continuing education requirements as a component of CPD.

#### \*E. Innovative Residency Models

To support the development of nontraditional residencies innovative residency models that meet ASHP accreditation requirements.

#### \*F. Professional Socialization

To encourage pharmacists to serve as mentors to *pharmacy technicians*, *support personnel*, students, residents, and colleagues in a manner that fosters the adoption of: (1) high professional standards of pharmacy practice, (2) high personal standards of integrity and competence, (3) a commitment to serve humanity, (4) analytical thinking and ethical reasoning, (5) a commitment to *continuing professional development* lifelong learning, and (6) personal leadership skills.

(Note: This policy would supersede ASHP policy 0110.)

#### G. Nontraditional Pharm.D. Accessibility

To discontinue ASHP policy 0108, which reads:

To encourage colleges of pharmacy to continue to develop innovative ACPE-accredited programs that meet the professional advancement needs of practitioners, using distance learning and other advanced technologies where appropriate; further,

To identify and publicize mechanisms available to baccalaureatedegree pharmacists for overcoming barriers to the attainment of the Pharm.D. degree.

#### H. Non accredited Pharmacy Degree Programs

To discontinue ASHP policy 0107, which reads:

To support the position that every educational program that offers a pharmacy degree must be accredited by the Accreditation Council for Pharmacy Education (ACPE), regardless of licensure status of students enrolled.

Michael D. Sanborn, Board Liaison to the Council on Pharmacy Management, presented the Council's Policy Recommendation A.

A. ASHP Statement on Leadership as a Professional Obligation

To approve the ASHP Statement on Leadership as a Professional Obligation.

Janet L. Mighty, Board Liaison to the Council on Pharmacy Practice, presented the Council's Policy Recommendations A through D.

#### \*A. Pharmacist Accountability for Patient Outcomes

To affirm that pharmacists are obligated by their covenantal relationship with patients to ensure that medication use is safe and effective; further,

To declare that pharmacists, pursuant to their authority over a specialized body of knowledge, are autonomous in exercising their professional judgment and accountable as professionals and health care team members, for safe and effective medication therapy outcomes are autonomous professionals on the interdisciplinary patient-care team and accountable for safe and effective medication therapy outcomes pursuant to their authority over a specialized body of knowledge; further,

To encourage pharmacists to define practices and associated measures of effectiveness that support their accountability for patient outcomes; further, To promote pharmacist accountability as a fundamental component of pharmacy practice to other health care professionals, standards-setting and regulatory organizations, and patients.

#### B. Just Culture

To recognize that the principles of "just culture" promote an environment in health care organizations in which safety is valued, reporting of safety risks is encouraged, and a fair process is used to hold staff and leaders accountable; further,

To encourage hospitals and health systems to include "just culture" as a component in organizational safety culture surveys and quality improvement initiatives.

#### C. Ethical Use of Placebos in Clinical Practice

To affirm that the use of placebos in clinical practice is ethically acceptable only when patients have been informed of and agree to such use as a component of treatment; further,

To encourage hospitals and health systems to develop policies and procedures to guide clinicians in making informed decisions regarding the use of placebos; further,

To oppose the use of pharmacologically active substances or medications as placebos.

(Note: This policy would supersede ASHP policy 0517.)

#### \*D. Pharmacists' Role in Medication Reconciliation

To affirm that an effective process for medication reconciliation reduces medication errors and supports safe medication use by patients; further,

To advocate that pharmacists, because of their distinct knowledge, skills, and abilities, should take a leadership role in interdisciplinary efforts to develop, implement, monitor, and maintain effective medication reconciliation processes; further,

To encourage community-based providers, hospitals, and health systems to collaborate in organized medication reconciliation programs to promote overall continuity of patient care; further,

To declare that pharmacists have a responsibility to educate patients and caregivers on their responsibility to maintain an up-to-date and readily accessible list of medications the patient is taking and that pharmacists should assist patients and caregivers by assuring the provision of a personal medication list as part of patient *counseling*, education, and counseling efforts ongoing personal medical record.

(Note: This policy would supersede ASHP policy 0620.)

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Randy L. Kuiper, Board Liaison to the Council on Public Policy, presented the Council's Policy Recommendations A through E.

#### A. Drug Product Shortages

To advocate that the Food and Drug Administration (FDA) have the authority to require manufacturers to report drug product shortages and the reason(s) for the shortage, and to make that information available to the public; further,

To strongly encourage the FDA to consider, in its definition of "medically necessary" drug products, the patient safety risks created by use of alternate drug products during a shortage; further,

To support government-sponsored incentives for manufacturers to maintain an adequate supply of medically necessary drug products; further,

To advocate laws and regulations that would (1) require pharmaceutical manufacturers to notify the appropriate government body at least 12 months in advance of voluntarily discontinuing a drug product, (2) provide effective sanctions for manufacturers that do not comply with this mandate, and (3) require prompt public disclosure of a notification to voluntarily discontinue a drug product; further,

To encourage the appropriate government body to seek the cooperation of manufacturers in maintaining the supply of a drug product after being informed of a voluntary decision to discontinue that product.

(Note: This policy would supersede ASHP policy 0319.)

\*B. Direct-to-Consumer Advertising of Prescription and Nonprescription Medications

To support oppose direct-to-consumer advertising that unless it is educational in nature about prescription drug therapies for certain medical conditions and that appropriately includes pharmacists as a source of information; further,

To support oppose direct-to-consumer advertising of specific prescription drug products only when unless the following requirements are met: (1) that such advertising is delayed until postmarketing surveillance data are collected and assessed, (2) that the benefits and risks of therapy are presented in an understandable format at an acceptable literacy level for the intended population, (3) that such advertising promotes medication safety and allows informed decisions, (4) that a clear relationship between the medication and the disease state is presented, (5) that no such advertising or marketing information for prescription or nonprescription medication is directed toward minors, and (6) that such advertising include mechanisms that direct consumers to a medication adverse event reporting system (AERS); further,

To advocate that the Food and Drug Administration require an AERS reporting link in direct-to-consumer advertising material available on the Internet; further,

To support the development of legislation or regulation that would require nonprescription drug advertising to state prominently the benefits and risks associated with product use that should be discussed with the consumer's pharmacist or physician.

(Note: This policy would supersede ASHP policy 0609.)

#### C. Regulation of Off-Label Promotion and Marketing

To advocate for authority for the Food and Drug Administration to regulate the promotion and dissemination of information about off-label uses of medications by manufacturers; further,

To advocate that such promotion and dissemination be permitted only if manufacturers submit a supplemental new drug application for new use within a reasonable time after initial dissemination of information about off-label uses.

#### \*D. Poison Control Center Funding

To advocate that poison control centers be considered an essential emergency service; further,

To advocate for new and stable funding mechanisms for poison control centers to continue to provide these essential and valuable services; further,

To support the integration and coordination of poison control center services where appropriate encourage poison control centers to maximize cost-effectiveness in utilizing resources, including integrating and coordinating services.

#### \*E. State Prescription Drug Monitoring Programs

To advocate for uniform state prescription drug monitoring programs that collect standard information about controlled substances prescriptions; further,

To advocate that the design of these programs should balance the need for appropriate *therapeutic* pain management with safeguards against *fraud*, misuse, abuse, and diversion; further,

To advocate that such programs be structured as part of electronic health records and exchanges to allow *prescribers*, *pharmacists*, *and other* practitioners <del>and prescribers</del> to proactively monitor data for appropriate assessment; further,

To advocate for interstate *integration* connectivity to allow for access by practitioners and prescribers across state lines; further,

To advocate for federal and state funding to establish and administer these programs.

Candidates for the position of Chair of the House of Delegates made brief statements to the House of Delegates. The meeting adjourned at 5:28 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.

#### **Election of House Chair**

Chair Meyer announced the appointment of alternate delegates as tellers to canvass the ballots for the election of Chair of the House of Delegates. Those appointed were Meghan Davlin (MD), Robert Parsons (OH), and Marjorie Shaw Phillips (GA).

Chair Meyer instructed tellers on the distribution and collection of ballots to registered delegates. After the balloting process, tellers left the assembly to count the ballots while the business of the House proceeded.

Board of Directors duly considered matters. Pursuant to Bylaws section 7.3.1.1, the Board met on the morning of June 14, 2011, to "duly consider" the amended policies. The Board reported on 16 professional policies that were amended at the first House meeting. The Board presented its recommendations as follows:

- Council on Therapeutics, Policy A, "Research on Medical Use of Marijuana": The Board agreed that the amended language is acceptable with editorial changes. As edited, the policy reads as follows:
- A. Research on Medical Use of Marijuana

To oppose state legislation that authorizes the use of medical marijuana until there is sufficient evidence to support its safety and effectiveness and a standardized product that would be subject to the same regulations as a prescription drug product; further,

To encourage research to define the *therapeutically active components*, effectiveness, safety, and clinical use of medical marijuana; further,

To advocate for the development of processes that would ensure standardized formulations, potency, and quality of medical marijuana products to facilitate research; further,

To encourage the Drug Enforcement Administration to eliminate barriers to medical marijuana research, including review of medical marijuana's status as a Schedule I controlled substance, and its reclassification, if necessary to facilitate research; further,

To oppose the procurement, storage, preparation, or distribution of medical marijuana by licensed pharmacies or health care facilities for purposes other than research; further.

To oppose the <del>use</del> <u>smoking</u> of marijuana <del>cigarettes</del> in settings where <u>smoking</u> <del>use of tobacco</del> is <del>similarly</del> prohibited; further,

To encourage continuing education that prepares pharmacists to respond to patient and clinician questions about the therapeutic and legal issues surrounding medical marijuana

(Note: As defined by the Congressional Research Service, the term "medical marijuana" refers to uses of botanical marijuana that qualify for a medical use exception under the laws of certain states and under the federal Investigational New Drug Compassionate Access Program. Botanical marijuana includes the whole or parts of the natural marijuana plant and therapeutic products derived therefrom, as opposed to drugs produced synthetically in the laboratory that replicate molecules found in the marijuana plant.)

- 2. Council on Therapeutics, Policy B, "Agricultural Use of Hormone and Pro-hormone Therapies": The Board agreed that the amended language is acceptable.
- 3. Council on Therapeutics, Policy C, "Direct-to-Consumer Clinical Genetic Tests": The Board agreed that the amended language is acceptable with editorial changes. As edited, the policy reads as follows:
- C. Direct-to-Consumer Clinical Genetic Tests

To support research to validate and standardize genetic markers used in direct-to-consumer clinical genetic tests and guide the application of test results to clinical practice; further,

To encourage the Food and Drug Administration to use existing authority to regulate these tests as medical devices and to work with the National Institutes of Health to expedite establishment of a process to evaluate and approve direct-to-consumer clinical genetic tests; further,

To advocate that direct-to-consumer clinical genetic tests to support disease diagnosis or management of drug therapy be provided to consumers only through the services of appropriate health care professionals that order tests from laboratories that are certified under the Clinical Laboratories Improvement Amendments of 1988 (CLIA); further,

To oppose advertising of direct-to-consumer clinical genetic tests unless such testing includes the established patient-health care provider relationship as a mechanism to provide information and interpretation of test results; further,

To oppose advertising of direct-to-consumer clinical genetic tests unless the following requirements are met: (1) that the relationship between the genetic marker and the disease or condition being assessed is clearly presented, (2) that the benefits and risks of testing are discussed, and (3) that such advertising is provided in an understandable format, at a level of health literacy that allows the intended audience to make informed decisions, and includes a description of the established patient-health care provider relationship as a critical source for information about the test and interpretation of test results; further,

To encourage pharmacists to educate consumers and clinicians on the appropriate use of direct-to-consumer clinical genetic tests for disease diagnosis and drug therapy management.

4. Council on Therapeutics, Policy D, "Pharmacogenomics": The Board agreed that the amended language is acceptable with editorial changes. As edited, the policy reads as follows:

#### D. Pharmacogenomics

To advocate that pharmacists take a leadership role in the therapeutic applications of pharmacogenomics, which is essential to individualized drug therapy; further,

To support research to validate and standardize genetic markers and genetic testing for drug therapy and to support research and other efforts that guide and accelerate the application of pharmacogenomics to clinical practice; further,

To advocate for the inclusion of pharmacogenomic test results in medical and pharmacy records in a format that clearly states the implications of the results on drug therapy and facilitates availability of the genetic information throughout the continuum of care and over a patient's lifetime; further,

To encourage pharmacists to educate prescribers and patients about the use of pharmacogenomic tests and their appropriate application to drug therapy management; further,

To encourage pharmacist education on the use of pharmacogenomics and advocate for the inclusion of pharmacogenomics and its application to therapeutic decision-making in college of pharmacy curricula.

5. Council on Therapeutics, Policy E, "Safe and Effective Use of IV Promethazine": The Board agreed that the amended language is acceptable with editorial changes. As edited, the policy reads as follows:

#### E. Safe and Effective Use of IV Promethazine

To recognize intravenous (IV) promethazine as a treatment alternative in limited clinical circumstances; further,

To support health-system efforts to restrict use of IV promethazine by encouraging alternate routes of administration or use of therapeutic alternatives when appropriate; further,

To encourage health systems to establish medication-use processes that reflect nationally recognized best practices to limit the potential for patient harm when IV promethazine use is medically necessary.

- 6. Council on Therapeutics, Policy F, "Pain Management": The Board agreed that the amended language is acceptable.
- 7. Council on Education and Workforce Development, Policy A, "Quality of Pharmacy Education and Expansion of Colleges of Pharmacy": The Board agreed that the amended language is acceptable.
- 8. Council on Education and Workforce Development, Policy C, "Pharmacy Internships": The Board agreed that the amended language is acceptable.
- 9. Council on Education and Workforce Development, Policy D, "State-Specific Requirements for Pharmacist Continuing Education": The Board agreed that the amended language is acceptable with editorial changes. As edited, the policy reads as follows:
- D. State-Specific Requirements for Pharmacist Continuing Education

To support the standardization of state pharmacist continuing education requirements; further,

To advocate that state boards of pharmacy adopt continuing professional development (CPD) as the preferred model for maintaining pharmacist competence and structure continuing education requirements as a component of CPD.

- 10. Council on Education and Workforce Development, Policy E, "Innovative Residency Models": The Board agreed that the amended language is acceptable.
- 11. Council on Pharmacy Practice, Policy A, "Pharmacist Accountability for Patient Outcomes": The Board agreed that the amended language is acceptable with editorial changes. As edited, the policy reads as follows:

#### A. Pharmacist Accountability for Patient Outcomes

To affirm that pharmacists are obligated by their covenantal relationship with patients to ensure that medication use is safe and effective; further,

To declare that pharmacists, pursuant to their authority over a specialized body of knowledge, are autonomous in exercising their professional judgment and accountable as professionals and health care team members for safe and effective medication therapy outcomes; further,

To encourage pharmacists to define practices and associated measures of effectiveness that support their accountability for patient outcomes; further,

To promote pharmacist accountability as a fundamental component of pharmacy practice to other health care professionals, standards-setting and regulatory organizations, and patients.

12. Council on Pharmacy Practice, Policy D, "Pharmacists' Role in Medication Reconciliation": The Board agreed that the amended language is acceptable with editorial changes. As edited, the policy reads as follows:

#### D. Pharmacists' Role in Medication Reconciliation

To affirm that an effective process for medication reconciliation reduces medication errors and supports safe medication use by patients; further,

To advocate that pharmacists, because of their distinct knowledge, skills, and abilities, should take a leadership role in interdisciplinary efforts to develop, implement, monitor, and maintain effective medication reconciliation processes; further,

To encourage community-based providers, hospitals, and health systems to collaborate in organized medication reconciliation programs to promote overall continuity of patient care; further,

To declare that pharmacists have a responsibility to educate patients and caregivers on their responsibility to maintain an up-to-date and readily accessible list of medications the patient is taking and that pharmacists should assist patients and caregivers by assuring the provision of a personal medication list as part of patient counseling, education, and maintenance of an individual medical record.

13. Council on Public Policy, Policy B, "Direct-to-Consumer Advertising of Prescription and Nonprescription Medications": The Board agreed that the amended language is acceptable.

- 14. Council on Public Policy, Policy D, "Poison Control Center Funding": The Board agreed that the amended language is acceptable.
- 15. Council on Public Policy, Policy E, "State Prescription Drug Monitoring Programs": The Board agreed that the amended language is acceptable with editorial changes. As edited, the policy reads as follows:

#### E. State Prescription Drug Monitoring Programs

To advocate for uniform state prescription drug monitoring programs that collect standard information about controlled substances prescriptions; further,

To advocate that the design of these programs should balance the need for appropriate therapeutic management with safeguards against fraud, misuse, abuse, and diversion; further,

To advocate that such programs be structured as part of electronic health records and exchanges to allow prescribers, pharmacists, and other practitioners to proactively monitor data for appropriate assessment; further,

To advocate for interstate integration to allow for access by prescribers, pharmacists, and other practitioners across state lines; further,

To advocate for federal and state funding to establish and administer these programs.

16. Council on Public Policy, Policy F, "Professional Socialization": The Board encouraged delegates to reconsider the policy and adopt revised language. A motion was made to reconsider and the revised policy proposed by the Board was adopted. The policy reads as follows:

#### F. Professional Socialization

To encourage pharmacists to serve as mentors to students, residents, and colleagues in a manner that fosters the adoption of: (1) high professional standards of pharmacy practice, (2) high personal standards of integrity and competence, (3) a commitment to serve humanity, (4) analytical thinking and ethical reasoning, (5) a commitment to continuing professional development, and (6) personal leadership skills.

New Business. Chair Meyer announced that, in accordance with Article 7 of the Bylaws, there was 1 (one) item of New Business to be considered.

Chair Meyer called on Mary Hess, Chair, ASHP Section of Clinical Specialists and Scientists, to introduce the item of New Business, titled "Board Certification for Pharmacists." Following discussion, the item was approved for referral. It reads as follows:

Board Certification for Pharmacists

#### Motion:

- 1. To support the principle that pharmacists who practice where a pharmacy specialty has been formally recognized by the profession should become board-certified in the appropriate specialty area; further,
- 2. To recognize the Board of Pharmacy Specialties as an appropriate organization through which specialties are formally recognized and specialty pharmacy certification should occur; further,
- To advocate prioritization for recognition of new specialties in those areas where sufficient numbers of PGY2 residency training programs are established and where adequate numbers of pharmacists are completing accredited training programs to prepare them to practice in the specialty area; further
- To advocate for standardization of credentialing eligibility and recertification requirements to include consistent requirements for advanced postgraduate residency training; further
- 5. To actively encourage and support the development of effective training and recertification programs that prepare specialists for certification examination and ensure the maintenance of core competencies in their area of specialization.

#### Rationale

At present the only statements supporting pharmacists becoming board certified exist in the Supplemental Standards for Postgraduate training where the focus is on the qualifications of the residency program director only and in the Long Range Vision for Pharmacy Work Force in Hospitals and Health Systems which states that pharmacists who provide services in an area where specialty certification exists are expected to be certified in that area.

The Section of Clinical Specialists and Scientists (SCSS) discussed the desired process for formal recognition of new specialty practices. As a group the section was in support of the PPMI recommendation (B10) that pharmacists who provide drug therapy management should be certified through the most appropriate Board of Pharmacy Specialties board-certification process when a specialty has been formally recognized. Drugtherapy management, as defined in the Pharmacy Practice Model Initiative Summit Recommendations, is a multidisciplinary team process for selecting appropriate drug therapies,

educating patients, monitoring patients, and continually assessing outcomes of therapy. Pharmacist activities in drug-therapy management may include, but are not limited to: initiating, modifying, and monitoring a patient's drug-therapy; ordering and performing laboratory and related tests; assessing patient response to therapy; counseling and educating a patient about medications; and administering medications. In addition the Board of Pharmacy Specialties (BPS) is specifically mentioned since it is currently the only organization that certifies pharmacists that is accredited by the National Commission for Certifying Agencies (NCCA). NCAA is an accrediting body that accredits certification programs based on very high quality standards in the professional certification industry.

ASHP policy supports the principle that pharmacy technicians should first complete accredited training followed by PTCB certification. It is important for the profession that our specialists be held to this same standard. While it may not be possible to require training as a prerequisite for all applicants today, the Executive Committee believes that BPS should encourage PGY2 residency training as the preferred prerequisite by establishing consistent requirements across specialties and articulating a vision that includes a future stronger linkage between training and certification. Certification, as defined by Council on Credentialing in Pharmacy (CPP) is the process by which a non-governmental agency or an association grants recognition to an individual who has met certain predetermined qualifications specified by that organization.

New areas of specialty emerge as pioneers begin to practice in emerging areas where there is a need for pharmacist's expertise in managing complex drug therapy. Only some of these practices grow and evolve to the point where the formal establishment of a specialty is valuable. The establishment and recognition of a specialty brings formal recognition of a well-defined area of specialized practice. The combination of formal accredited training and psychometrically valid examination ensures pharmacists, other health professions, and the public a level of quality and consistency among the specialists practicing in a unique specialty. Various organizations often develop an array of credentials designed to demonstate unque knowledge and skill in well defined areas. Examples include multidisciplinary examinations for diabetes education or asthma education. Though some similarities exist in the nature of such programs they do not represent the recognition of unique area of specialization and the development of processes recognized by the profession to ensure the quality of specialty practice within the profession.

To date, the profession has relied upon an episodic petitioning process to identify and recognize new specialties. The Executive Committee believes that the profession should be more strategic in its efforts to grow and mature new specialties and should place emphasis first on growing sufficient numbers of quality training programs to develop and prepare specialists. Recognizing specialties in areas where there has been little interest demonstrated in preparing pharmacists to practice in

a specialty area may be premature. A natural flow from developing specialty training to specialty recognition may strategically make the most sense.

#### Background

The SCSS Executive Committee discussed ASHP's past role as a petitioning organization for specialty practice certification. ASHP has been involved with four of the six currently approved specialty areas of the Board of Pharmacy Specialties. ASHP has been the sole petitioning organization for two specialties and has worked jointly with other organizations in two other areas. Committee members encouraged ASHP to continuously promote to the membership its involvement as a leader in petitioning for and supporting specialty credentialing.

Committee members discussed the merits of being a petitioning organization and agreed that ASHP should continue to support and selectively lead specialty petitions that represent the membership as long as the current petition process and specialty council model is in place. Continuing to support the petitioning and specialty recognition process is a way to keep high-level clinical practitioners engaged with the organization by making appointments to specialty councils and development of examination review courses and recertification materials.

Part of the challenge of credentialing discussions involves an understanding of the terminology and the need to be precise in its use. For the purposes of this discussion, the following standard definitions will be utilized as outlined by the Council on Credentialing in Pharmacy (CCP) "Guiding Principles for Post-licensure Credentialing of Pharmacists":

Credential – documented evidence of qualifications, e.g., diploma, license, certificates, certifications

Credentialing – the process by which an organization or institution obtains, verifies, and assesses a pharmacist's qualifications to provide patient care services

Accreditation – the process by which a private association, organization or government agency, after initial and periodic evaluations, grants recognition to an organization, site or program that has met certain established criteria

Certificate – the document issued to an individual upon successful completion of a certificate program or of a residency or fellowship

Certification – the process by which a non-governmental agency or an association grants recognition to an individual who has met certain predetermined qualifications specified by that organization.

Suggested Outcome: ASHP develop policy on board certification for pharmacists.

**Recommendations.** Chair Meyer called on members of the House of Delegates for Recommendations. See the Appendix for a complete listing of all Recommendations.

**Recognition.** Chair Meyer recognized members of the Board who were continuing in office. He 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 Meyer presented Immediate Past President Ginsburg with an inscribed gavel commemorating her term of office. Ms. Ginsburg recognized the service of Chair Meyer as Chair of the House of Delegates and a member of the Board of Directors.

Chair Meyer recognized Lynnae M. Mahaney'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 Meyer then installed the chairs of ASHP's sections and forums: Erin Fox, Chair of the Section of Clinical Specialists and Scientists; Pamela Stamm, Chair of the Section of Ambulatory Care Practitioners; Jennifer Edwards, Chair of the Section of Inpatient Care Practitioners; Allen Flynn, Chair of the Section of Pharmacy Informatics and Technology; Michael Powell, Chair of the Section of Pharmacy Practice Managers; Stacy Livingston, Chair of the Pharmacy Student Forum, and Jeffrey Little, Chair of the New Practitioners Forum.

Chair Meyer then recognized the remaining members of the executive committees of sections and forums.

Chair Meyer then called on Vice Chair Mahaney to preside over the House for the remainder of the meeting.

Vice Chair Mahaney announced that Gerald Meyer had been elected as Chair of the House.

**Installation.** Vice Chair Mahaney installed Stanley S. Kent as President of ASHP, Larry C. Clark and Thomas J. Johnson as members of the Board of Directors, and Gerald Meyer as Chair of the House of Delegates.

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

Adjournment. The 63rd annual session of the House of Delegates adjourned at 5:33 p.m.

<sup>a</sup>The Committee on Nominations consisted of Michael B. Cockerham (LA), Chair; Kevin Colgan (IL), Vice Chair; Michael Cockerham (LA), Kevin Colgan (IL), Kristina De Los Santos (AZ), Jennifer Tryon (WA), Paul Walker (MI), Michael Schlesselman (CT), and Debra Lynn Cowan (NC).

#### 2011 House of Delegate Recommendations

The delegate[s] who introduced each Recommendation is [are] noted. Each Recommendation is forwarded to the appropriate body within ASHP for assessment and action as may be indicated.

#### <u>Recommendations by Delegates on</u> Sunday, June 12:

1. Nancy Korman (CA): Expansion of Intern Opportunities in Health-System Practice

**Recommendation:** ASHP should develop a position supporting expansion of intern opportunities within health system pharmacy practice.

Background: ASHP has a large number of student members. A small proportion of pharmacy students have the opportunity to intern in health systems. It appears there is a lack of intern positions offered in health-system practice. So that the number of practitioners interested in postgraduate training and health-system practice continues to grow, students need to be introduced to health-system practice early in their training. Health-system leadership should be encouraged to provide additional opportunities.

**2.** Steven Rough (WI): Statement on Medication Reconciliation

**Recommendation:** ASHP should develop a companion statement to ASHP policy 1117, Pharmacist Role in Medication Reconciliation, outlining the components of an optimal medication reconciliation system, including the roles of technicians and students.

Background: The current policy does not specifically describe the full responsibilities that pharmacists should take for ensuring accurate medications lists and reconciliation systems within the health system. The statement should specifically describe the literature comparing pharmacist accuracy and intervention rates versus other providers and affirm the important roles trained pharmacy technicians, students, and interns can play in this process under the supervision of a pharmacist.

**3.** James Rinehart (NE): Establishment of Health-System Pharmacy–Endorsed, Evidence-Based Practice Metrics

**Recommendation:** ASHP should establish a task force to develop health-system pharmacy—endorsed, evidenced-based metrics for the ongoing quantification of the financial value and clinical outcomes of pharmacy practice

Background: Numerous efforts have been taken over the years to address the contribution of health-system pharmacists to medication management. These efforts have included articles on the value of pharmacy practice, the establishment of a workload and productivity section advisory group, and the publishing of a white paper on workload and productivity. Despite these efforts, tangible, profession-endorsed metrics to document the financial value and clinical outcomes of pharmacy practice do not exist.

**4.** Brian Benson (SICP): Role of Medication Safety Leader

**Recommendation:** ASHP should work with other national organizations outside of pharmacy to recognize the unique role and expertise of a medication safety leader.

**Background:** ASHP policy 1019, Medication Safety Officer Role, currently discusses the medication safety officer but does not include specifics on the relationship with other national organizations. We recommend that the policy be enhanced to include the above language.

5. Carlo Lupano, Mitch Sobel, Russ Lazzaro (NJ): Pharmacist's Role in Human Gene TransferTherapy

**Recommendation:** ASHP should develop a policy on the pharmacist's role in human gene transfer therapy (HGTT).

Background: HGTT is an emerging therapeutic field in which human DNA is transferred into the human body, often via live media (e.g., viruses). Many genomic experts agree that by 2025 HGTT will be a substantial therapeutic modality. Some diseases, such as cystic fibrosis, are caused by single genetic malfunction. The potential to "cure" many chronic diseases (e.g., diabetes mellitus, congestive heart failure, chronic obstructive pulmonary disease, and cancer) appears promising and viable. ASHP should develop a policy to guide pharmacy leaders in their roles, replacing ASHP policy 0103, Gene Therapy.

**6.** Terry Audley (WI): CMS Policy of Not Covering Self-Administerable Medications

**Recommendation:** ASHP should work with the Centers for Medicare & Medicaid Services (CMS) to explore alternatives to their policy of not covering self-administerable medications given to patients in observation status.

**Background:** CMS does not cover medications deemed self-administerable given to beneficiaries in observation status

7. William Yee (CA): ACLS Certification Training for Pharmacists

**Recommendation:** ASHP should develop policy to encourage postgraduate year 1 (PGY1) programs to incorporate Advanced Cardiac Life Support (ACLS) training into their core curriculum.

Background: Pharmacists are frequently part of the code blue team; however, in many hospitals, they are not required to maintain ACLS certification. Because ACLS training is frequently required for nurses and other caregivers who respond to codes, this can put the pharmacist in a situation in which other caregivers are better trained in the use of medications used in this setting. Requiring ACLS training for all pharmacists on the code blue team will give the pharmacist essential skills in this environment.

8. Mitch G. Sobel, Carlo Lupano, Russ Lazzaro (NJ): Requirements for Pharmacy Technician Licensure and Continuing Education

**Recommendation:** ASHP should advocate the national standardization of state boards of pharmacy licensure and continuing education requirements for pharmacy technicians.

**Background:** ASHP should adopt a policy that advocates state board of pharmacies adopt a national licensure standard and continuing education requirements for pharmacy technicians that is similar to or parallels pharmacists' licensure and continuing education requirements.

9. Mitch G. Sobel, Carlo Lupano, Russ Lazzaro (NJ): Pharmacy Staff-to-Patient Ratio

**Recommendation:** ASHP should advocate the increase of pharmacy staff-to-patient ratio to support the Pharmacy Practice Model Intitiative (PPMI).

Background: ASHP needs to advocate an increase in the number of pharmacists, pharmacy residents, pharmacy technicians, and pharmacy support personnel per patient at health care systems and hospitals. Specifically, ASHP needs to support increasing the pharmacist per patient ratio to improve expanding clinical and cognitive pharmacy practice roles. Advocating this increase in pharmacy staff will provide better patient outcomes, accountability, cost containment, and meet the objectives of the PPMI.

# **10.** *Donald Lynx, Christina Rivers (IL): Technician Training*

**Recommendation:** ASHP should work with appropriate organizations to establish a professionally accepted core curriculum for all institutions of learning in order for that institution to be accredited to train pharmacy technicians and with health-system facilities to require formal training from accredited institutions for all technicians as a requirement for employment.

**Background:** The time for improving the training of technicians is long overdue. Technicians have become an integral part of the health-system pharmacy service. It is time that we, as a profession, require that the training of the technician incorporate the development of the fundamental skills and knowledge that a technician needs to be fully effective in today's health-system

environment as a prerequisite for employment.

# **11. Sara White (Past President):** House of Delegates Procedures

**Recommendation:** ASHP should appoint an ad hoc task force of delegates and some past House of Delegates chairs to review and if appropriate recommend changes to streamline House processes, such as using electronic voting.

Background: The task force should consider better utilizing the regional delegates conferences to reach consensus on wording changes, obtaining Board approval prior to the House, and using electronic voting for the final process so that there can be enough time for thoughtful consideration of policy intent rather than using the time of the House to wordsmith.

12. Kelley Smith, Jennifer Edwards, Brian Benson (KY,MT, SICP): Demonstration Projects for Residency Model Innovations

**Recommendation:** ASHP should commission national demonstration projects to evaluate the feasibility and impact of innovative models designed to increase pharmacy residency capacity.

Background: Several high-priority items deemed to have high feasibility and impact were identified at the 2011 Pharmacy Residency Stakeholders Conference. To maintain the momentum of the conference findings and foster training innovation (e.g., simulation, centralized program administration, pharmacist attending), select programs should test new models without concern about significant deviation from the current accreditation standard. Findings

should be disseminated and considered when designing the new standard.

# 13. Kelly Smith, Brian Benson, Brian Marden (KY, SICP, ME):

Professionalism of Pharmacy Trainees, Technicians, and Support Personnel

**Recommendation:** ASHP should develop policy delineating the obligation of pharmacists to foster professionalism of all pharmacy trainees, including fellows, pharmacy technicians, and pharmacy support personnel.

**Background:** All postgraduate trainees, including pharmacy fellows, need to be socialized in the profession of pharmacy. Additionally, as the role of pharmacy technicians and other support personnel expands in new practice models, pharmacists must assume an active role in inculcating these colleagues in the profession, its standards, and expectations.

#### 14. Nishaminy Kasbekar (PA):

Collaborative Practice Models with Community Pharmacies

**Recommendation:** ASHP should develop practice models to partner and build collaborative relationships with community pharmacies to promote effective transitions of care.

**Background:** No background was provided.

# **15.** Jennifer Tryon, Kate Farthing (OR): Consultant Qualification Standards

**Recommendation:** ASHP should develop a set of nationally recognized standards for ensuring the quality and qualifications of consultants working within health systems.

**Background:** Such standards would ensure that individuals making recommendations regarding pharmacy resource utilization, finances, and operational issues have the appropriate qualifications, training, and experience to adequately assess, evaluate, and propose changes within health systems. This is especially important since these consultants often have a direct line of communication with decision makers, such as executive teams and C-suites.

# **16. Jennifer Tryon, Kate Farthing (OR):**Statement of Competency for Experienced Pharmacists

**Recommendation:** ASHP should develop a systematic program for employers to evaluate the competency of pharmacists who do not meet the 2020 residency requirements but who have been practicing in direct patient care roles for more than five years.

Background: With the 2020 requirement that all pharmacists practicing in direct patient care roles be residency trained, employers with practitioners currently in those roles without residency training, or practitioners who may apply for those roles without residency training, should have a method to assess competency for those responsibilities. This does not imply equivalence to residency training, rather a formal evaluation of the pharmacist's experience to date by offering a statement of competency based on a recognized standard.

# **17. Roger W. Anderson (Past President):**Pharmacy Practice Strategies in Drug Shortages

**Recommendation:** In addition to public policy activities regarding drug shortages, ASHP should develop and communicate guidelines, procedures, and case reports to

help pharmacists proactively deal with drug shortages.

Background: Shortages of medically necessary drug products will not be resolved any time in the forseeable future. Pharmacists must develop new procurement and inventory management strategies (e.g., dual purchasing awards, increased inventory levels, and active tracking of current status of all medically necessary drugs). In addition, pharmacists must take a leadership role in developing ways to prioritize use and make suggestions for alternative therapies and potential modification of doses.

**18.** *Michael Cockerham (LA):* Creation of a Section of Pharmacy Educators

**Recommendation:** ASHP should create a Section of Pharmacy Educators to serve ASHP members who are members of college or school faculty or administration as well as residency directors and preceptors.

**Background:** Pharmacy educators comprise a large part of ASHP. A section would be devoted to the networking and educational needs of college and school faculty, administrators, and staff as well as residency directors and preceptors. The section would provide educational opportunities directed at these individuals and share educational strategies and best practices. The section would also liaison with the Council on Education and Workforce Development.

# **19.** Stacy Livingston (PSF): Standardization of Introductory and

Stanaaraization of Introductory and Advanced Pharmacy Practice Experiences

**Recommendation:** ASHP should work with other pharmacy organizations to promote standardization of competencies and hours

for introductory and advanced pharmacy practice experiences.

**Background:** It is evident that the Accreditation Council for Pharmacy Education (ACPE) has allowed each college of pharmacy to use its discretion to organize its experiential programs. There is currently a great deal of variability between programs, which creates confusion and frustration for many experiential directors and healthsystem pharmacists. Recently, the American College of Clinical Pharmacy (ACCP) has drafted basic, core domains each student should complete before graduation. ASHP should pursue working with other pharmacy organizations and ACPE to clarify the best way to educate our pharmacy students in their experiential training to help alleviate the concerns of pharmacy students and preceptors.

**20.** Paul Driver, Russ Lazzaro (ID, NJ):
Guidelines and Policy Development on
Use and Handling of Medical Marijuana

**Recommendation:** ASHP must work on developing guidance and/or policy for members concerning the procurement, storage, preparation, or distribution, in light of future and existing state-authorized marijuana dispensaries.

Background: ASHP must work to develop either a guidance statement or, where applicable, other policy that provides members with defensible and logistical methods for providing medical marijuana to patients, who will inevitably show up within our health care institutions. Presently, marijuana is still a C-I drug, with states allowing dispensaries to supply for medical use in the absence of federal authorization at the discretion of the individual state attorneys general.

**21.** Andrea Eberly (WA): Best Practices for Merged State Pharmacy Associations

**Recommendation:** ASHP should study merged state associations to identify best practices to ensure membership is adequately represented and appropriately connected with ASHP, and share those practices with state affiliates.

Background: Many states have merged associations with common concerns about lack of connection between state health-system members and national associations. We feel that tools should be developed by studying high-functioning merged state affiliates to be used by other state associations to improve member satisfaction, action on legislative issues, and participation in national advocacy and policy development.

**22.** Lynn Eschenbacher (NC): Board Certification in Medication Safety

**Recommendation:** ASHP should work with the Board of Pharmacy Specialties to investigate the need for a specialty certification in medication safety.

**Background:** This recommendation is in alignment with the Section of Clinical Specialists and Scientists new business item discussing board certification for pharmacy specialties.

**23.** Carol Rollins (AZ): Development of and CE for Preceptor Development Programs

**Recommendation:** ASHP should develop readily accessable (e.g., online, webinar, self-study) preceptor development programs that meet the specific skills needed to precept residents (rather than students) and provide CE for such programs

Background: Residency accreditation data for 2011 show 74% of PGY1 programs had inadequate preceptor development or residency program directors lacked a plan for improving the quality of preceptors' instruction. Preceptor training for residents rather than students differs, since residents are expected to function with some autonomy. Preceptor needs also differ based on the individual and program experience. Currently, no ASHP training programs focus on residency precepting for either new or experienced preceptors. Programs must be easily accessed given the magnitude of the problem.

**24.** *Mary Hess (SCSS): Pharmacy Preceptor Qualifications* 

**Recommendation:** ASHP should review and support uniform state board of pharmacy requirements related to pharmacy preceptor qualifications.

Background: There are currently state-tostate variations in requirements for serving as a pharmacy preceptor. As the profession attempts to move forward with postgraduate training positions, it may become desirable to utilize current postgraduates as preceptors (e.g., PGY2 residents for a PGY1 resident, or a PGY1 resident for a student). Looking at what qualifications are essential for precepting and standardizing these requirements would be beneficial.

**25.** Angela Stewart (WA): Guidance Needed for Coordination of PGY1 and PGY2 Residency Begin and End Dates

**Recommendation:** ASHP should develop guidance for PGY2 residency begin dates in order to better coordinate with the end dates of PGY1 residencies to ensure adequate time to complete PGY1 requirements and allow relocation to a PGY2 site.

**Background:** PGY1 residents often request early release from their sites in order to make the transition to their PGY2 residency sites. These requests put residency program directors in the difficult position of balancing the needs of their program with the needs of the outgoing resident.

**26.** *Douglas Lang (MO):* Review, Revise, and Update ASHP Statement on Confidentiality of Patient Health Care Information

**Recommendation:** ASHP should review, revise, and update the *ASHP Statement on Confidentiality of Patient Health Care Information* in light of new regulatory mandates related to the protection of patient health care information by health care providers.

Background: Pursuant to the Health Information Technology for Economic and Clinical Health (HITECH) Act, which was part of the American Recovery and Reinvestment Act of 2009, significant new regulatory requirements have been placed on health care providers in the identification of personal health disclosures, assessment of risk for identity theft as related to an unauthorized disclosure, and the reportability of disclosure to regulatory authorities and individual patients.

**27.** Nancy Korman (CA): Utility of Placebo Therapy in Patient Care

**Recommendation:** ASHP should ensure that any ASHP-published comprehensive review of the ethical use of a placebo includes guidance for the pharmacist as to when a placebo is medically appropriate.

**Background:** The focus of the Council on Pharmacy Practice discussion seemed to center on the ethics related to the use of

placebos and the need for the patient to be informed and agree to its use. How does a pharmacist assess an order for a placebo and counsel a patient? A review of evidenced-based literature documenting the utility of placebos would greatly assist the pharmacist in their review of any order for appropriateness, and discussion of the use of placebo both with the provider and patient involved.

**28.** *Deb Saine (VA): Medication Safety Metrics* 

**Recommendation:** ASHP should, in collaboration with other organizations, develop a set of nationally recognized metrics to determine minimum standards for medication safety.

**Background:** Such metrics would have similar rigor, repoducibility, and standard definitions as those seen in other important areas of healthcare. This recommendation is supported by the Section Advisory Group on Medication Safety and delegates from the states of NC, IN, CT, and VA.

**29.** Michael Schlesselman (CT): Original State License Status

**Recommendation:** ASHP should work with the National Association of Boards of Pharmacy (NABP) to standardize the reciprocation process and original state license status.

**Background:** Many state boards of pharmacy look to the original license state to determine eligibility on ability to reciprocate. This practice requires pharmacists to keep multiple licenses and meet multiple CE requirements. While not asking for portability, ASHP should seek an easier means to discontinue a license in the

pharmacist's original state and still have the ability reciprocate at a later date.

**30.** Amanda Hays (AK): Restrictive Medication Administration Timing and Associated Risk for Error

**Recommendation:** ASHP should develop a policy statement in alignment with the Institute for Safe Medication Practices (ISMP) statement related to the CMS 30-minute rule.

**Background:** Please refer to the CMS 30-minute rule and the ISMP statement.

**31.** Frank Sosnowski, Leigh Briscoe-Dwyer (NY): National Standardization of Adult Immunization by Certified Pharmacists

**Recommendation:** ASHP should collaborate with NABP and other pertinent organizations to standardize vaccination legislation throughout the country to allow all certified pharmacist immunizers to administer any vaccine administered in an adult dose to any patient.

**Background:** New York limits pharmacist immunization to pneumococcal and influenza vaccines. We would like to expand to all adult immunizations but are encountering some resistance.

**32.** *Chris Urbanski (SOPIT):* Pharmacists' Professional Practice and Health Information Exchange

**Recommendation:** ASHP should develop policy for direct pharmacist participation in the development and implementation of health information exchange (HIE) so that the specific patient health information requirements of pharmacy practice are met.

Background: HIE will be required as part of meaningful use of the electronic health record under the HITECH act. HIE standards and systems will be used to specify and transmit patient medication-use data for medication reconciliation and other aspects of pharmceutical care. Pharmacists, as medication-use experts, have significant roles and unique information needs with respect to HIE. Continuity of pharmaceutical care relies on HIE to faciliate safe venue transitions, e-prescribing, and medication therapy management.

**33.** Peter Ambrose (CA): Safety and Impact of All Drugs Used in Agriculture

Recommendation: In addition to antimicrobials and hormone/pro-hormone therapies, ASHP should advocate that the FDA and USDA require, and make public, information on the safety and impact (e.g., doping control tests) on humans of all drugs and related compounds used in agriculture for the purposes of growth promotion and treatment.

**Background:** Current ASHP policies are limited to antimicrobials and hormones/prohormones, but many other drugs and related compounds are used for animals and are then consumed by humans.

**34.** Dale English II (OH): Proper Use of the Term "Doctor"

Recommendation: ASHP should be the leading health care organization in moving the pharmacy profession forward and promoting equality among all health care professions by immediately ceasing the use of the term "doctor" on all levels when referring to the occupation of a physician, since the term "doctor" should properly refer to an individual's educational

accomplishments and not an individual's occupation.

**Background:** This action would continue to move the pharmacy profession forward, help dislodge the outdated concept of physicians topping the hierarchy of medical teams, reinforce the idea that all health care professionals bring specific areas of expertise to patient care, and reduce the confusion of the layperson's perception of the term "doctor" by making it clear that

"doctor" is a degree one earns and not an occupation one practices.

**35.** John Lewin (MD): Resident Work Hour Rules

**Recommendation:** ASHP should develop pharmacy-resident-specific work hour rules analogous to those of the Accreditation Council for Graduate Medical Education.

Background: No background was provided.

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#### **DELEGATES** to the 2011 Session of the House

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# **ASHP Board of Directors, 2011–2012**

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# Professional Policies Approved by the 2011 ASHP House of Delegates

DENVER, CO JUNE 14, 2011

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The new professional policies approved by the ASHP House of Delegates at its June 2011 session are listed below. Policies proposed by councils or other ASHP bodies are first considered by the Board of Directors and then acted on by the House of Delegates, which is the ultimate authority for ASHP positions on professional issues.

The background information on these policies appears on the ASHP Web site (www.ashp.org); click on "Practice and Policy" then on "House of Delegates," and then on "Board of Directors Reports on Councils" (http://www.ashp.org/DocLibrary/Policy/HOD/Council Reports.aspx).

The complete proceedings of the House of Delegates will be sent to delegates and will be posted on the ASHP Web site; a printed copy can be requested from the ASHP Office of Policy, Planning and Communications.

#### 1101

#### Medical Marijuana

Source: Council on Therapeutics

To oppose state legislation that authorizes the use of medical marijuana until there is sufficient evidence to support its safety and effectiveness and a standardized product that would be subject to the same regulations as a prescription drug product; further, To encourage research to define the therapeutically active components, effectiveness, safety, and clinical use of medical marijuana; further,

To advocate for the development of processes that would ensure standardized formulations, potency, and quality of medical marijuana products to facilitate research; further,

To encourage the Drug Enforcement Administration to eliminate barriers to medical marijuana research, including review of medical marijuana's status as a Schedule I controlled substance, and its reclassification, if necessary to facilitate research; further,

To oppose the procurement, storage, preparation, or distribution of medical marijuana by licensed pharmacies or health care facilities for purposes other than research; further,

To oppose the smoking of marijuana in settings where smoking is prohibited; further,

To encourage continuing education that prepares pharmacists to respond to patient and clinician questions about the therapeutic and legal issues surrounding medical marijuana use.

(*Note*: As defined by the Congressional Research Service, the term *medical marijuana* refers to uses of botanical marijuana that qualify for a medical use exception under the laws of certain states and under the federal Investigational New Drug Compassionate Ac-

cess Program. Botanical marijuana includes the whole or parts of the natural marijuana plant and therapeutic products derived therefrom, as opposed to drugs produced synthetically in the laboratory that replicate molecules found in the marijuana plant.)

#### 1102

## Agricultural Use of Hormone and Prohormone Therapies

Source: Council on Therapeutics

To advocate that the Food and Drug Administration and United States Department of Agriculture re-evaluate the agricultural use of hormone and prohormone therapies for purposes of animal growth promotion based on evidence demonstrating potential adverse effects on human health; further,

To encourage additional research to better define the public health impact of using hormone therapies for agricultural purposes.

#### 1103

### Direct-to-Consumer Clinical Genetic Tests

Source: Council on Therapeutics

To support research to validate and standardize genetic markers used in direct-to-consumer clinical genetic tests and guide the application of test results to clinical practice; further, To encourage the Food and Drug Administration to use existing authority to regulate these tests as medical devices and to work with the National Institutes of Health to expedite establishment of a process to evaluate and approve direct-to-consumer clinical genetic tests; further,

To advocate that direct-toconsumer clinical genetic tests to support disease diagnosis or management of drug therapy be provided to consumers only through the services of appropriate health care professionals that order tests from laboratories that are certified under the Clinical Laboratories Improvement Amendments of 1988 (CLIA); further,

To oppose advertising of directto-consumer clinical genetic tests unless such testing includes the established patient-health care provider relationship as a mechanism to provide information and interpretation of test results; further,

To oppose advertising of directto-consumer clinical genetic tests unless the following requirements are met: (1) that the relationship between the genetic marker and the disease or condition being assessed is clearly presented, (2) that the benefits and risks of testing are discussed, and (3) that such advertising is provided in an understandable format, at a level of health literacy that allows the intended audience to make informed decisions, and includes a description of the established patient-health care provider relationship as a critical source for information about the test and interpretation of test results; further,

To encourage pharmacists to educate consumers and clinicians on the appropriate use of direct-to-consumer clinical genetic tests for disease diagnosis and drug therapy management.

#### 1104

#### **Pharmacogenomics**

Source: Council on Therapeutics

To advocate that pharmacists take a leadership role in the therapeutic applications of pharmacogenomics, which is essential to individualized drug therapy; further,

To support research to validate and standardize genetic markers and genetic testing for drug therapy and to support research and other efforts that guide and accelerate the application of pharmacogenomics to clinical practice; further,

To advocate for the inclusion of pharmacogenomic test results in medical and pharmacy records in a format that clearly states the implications of the results for drug therapy and facilitates availability of the genetic information throughout the continuum of care and over a patient's lifetime; further,

To encourage pharmacists to educate prescribers and patients about the use of pharmacogenomic tests and their appropriate application to drug therapy management; further,

To encourage pharmacist education on the use of pharmacogenomics and advocate for the inclusion of pharmacogenomics and its application to therapeutic decision-making in college of pharmacy curricula.

This policy supersedes ASHP policy 0016.

#### 1105

#### Safe and Effective Use of IV Promethazine

Source: Council on Therapeutics

To recognize intravenous (IV) promethazine as a treatment alternative in limited clinical circumstances; further,

To support health-system efforts to restrict use of IV promethazine by encouraging alternate routes of administration or use of therapeutic alternatives when appropriate; further, To encourage health systems to establish medication-use processes that reflect nationally recognized best practices to limit the potential for patient harm when IV promethazine use is medically necessary.

#### 1106

#### **Pain Management**

Source: Council on Therapeutics

To advocate fully informed patient and caregiver participation in pain management decisions as an integral aspect of patient care; further,

To advocate that pharmacists actively participate in the development and implementation of health-system pain management policies and protocols; further,

To support the participation of pharmacists in pain management, which is a multidisciplinary, collaborative process for selecting appropriate drug therapies, educating patients, monitoring patients, and continually assessing outcomes of therapy; further,

To advocate that pharmacists lead efforts to prevent inappropriate use of pain therapies, including engaging in strategies to detect and address patterns of abuse and misuse; further,

To encourage the education of pharmacists, pharmacy students, and other health care providers regarding the principles of pain management and methods to minimize drug diversion.

This policy supersedes ASHP policy 0306.

#### 1107

#### **Patient-Reported Outcomes Tools**

Source: Council on Therapeutics

To advocate for expanded use of validated patient-reported outcomes (PRO) tools in clinical research and direct patient care; further,

To support development of validated PRO tools that are sensitive

to differences in cultural and health literacy; further,

To encourage additional research on PRO tools, including studies to assess their correlation to overall patient outcomes; further,

To educate clinicians and patients about the appropriate use of PRO tools.

#### 1108

#### Quality of Pharmacy Education and Expansion of Colleges of Pharmacy

Source: Council on Education and Workforce Development

To support the Accreditation Council for Pharmacy Education's continuing role of promulgating accreditation standards and guidelines and engaging in sound accreditation processes to ensure quality in the education provided by colleges of pharmacy; further,

To acknowledge that, in addition to a robust curriculum, access to quality experiential educational sites and the availability of qualified faculty (including preceptors and specialty-trained clinical faculty) are essential determinants of the ability to expand enrollment in existing or additional colleges of pharmacy; further,

To oppose expansion of enrollment in existing or new colleges of pharmacy unless well-designed projections demonstrate that such enrollment increases are necessary to maintain a viable pharmacist workforce.

This policy supersedes ASHP policy 0607.

#### 1109

#### **Residency Equivalency**

Source: Council on Education and Workforce Development

To acknowledge the distinct role of ASHP-accredited residency training in preparing pharmacists to be direct patient-care providers; further, To recognize the importance of clinical experience in developing practitioner expertise; further,

To affirm that there are no objective means to convert or express clinical experience as equivalent to or a substitute for the successful completion of an ASHP-accredited residency.

#### 1110

#### **Pharmacy Internships**

Source: Council on Education and Workforce Development

To encourage the National Association of Boards of Pharmacy to develop standardized pharmacy internship hour requirements that would be used uniformly by all state boards of pharmacy; further,

To support structured requirements, goals, and objectives for pharmacy internship experiences, in alignment with requirements for introductory and advanced pharmacy practice experiences; further,

To promote and expand new staffing models that foster expanded roles for pharmacy interns, providing work experiences that build upon their knowledge and help them develop as future pharmacists.

This policy supersedes ASHP policy 0802.

#### 1111

#### State-Specific Requirements for Pharmacist Continuing Education

Source: Council on Education and Workforce Development

To support the standardization of state pharmacist continuing education requirements; further,

To advocate that state boards of pharmacy adopt continuing professional development (CPD) as the preferred model for maintaining pharmacist competence and structure continuing education requirements as a component of CPD.

#### 1112

#### **Innovative Residency Models**

Source: Council on Education and Workforce Development

To support the development of innovative residency models that meet ASHP accreditation requirements.

#### 1113

#### **Professional Socialization**

Source: Council on Education and Workforce Development

To encourage pharmacists to serve as mentors to students, residents, and colleagues in a manner that fosters the adoption of: (1) high professional standards of pharmacy practice, (2) high personal standards of integrity and competence, (3) a commitment to serve humanity, (4) analytical thinking and ethical reasoning, (5) a commitment to continuing professional development, and (6) personal leadership skills.

This policy supersedes ASHP policy 0110.

#### 1114

#### Pharmacist Accountability for Patient Outcomes

Source: Council on Pharmacy Practice

To affirm that pharmacists are obligated by their covenantal relationship with patients to ensure that medication use is safe and effective; further,

To declare that pharmacists, pursuant to their authority over a specialized body of knowledge, are autonomous in exercising their professional judgment and accountable as professionals and health care team members for safe and effective medication therapy outcomes; further,

To encourage pharmacists to define practices and associated measures of effectiveness that support their accountability for patient outcomes; further,

To promote pharmacist accountability as a fundamental component

of pharmacy practice to other health care professionals, standards-setting and regulatory organizations, and patients.

#### 1115

#### **Just Culture**

Source: Council on Pharmacy Practice

To recognize that the principles of *just culture* promote an environment in health care organizations in which safety is valued, reporting of safety risks is encouraged, and a fair process is used to hold staff and leaders accountable; further,

To encourage hospitals and health systems to include *just culture* as a component in organizational safety culture surveys and quality improvement initiatives.

#### 1116

### Ethical Use of Placebos in Clinical Practice

Source: Council on Pharmacy Practice

To affirm that the use of placebos in clinical practice is ethically acceptable only when patients have been informed of and agree to such use as a component of treatment; further,

To encourage hospitals and health systems to develop policies and procedures to guide clinicians in making informed decisions regarding the use of placebos; further,

To oppose the use of pharmacologically active substances or medications as placebos.

This policy supersedes ASHP policy 0517.

#### 1117

# Pharmacists' Role in Medication Reconciliation

Source: Council on Pharmacy Practice

To affirm that an effective process for medication reconciliation reduces medication errors and supports safe medication use by patients; further, To advocate that pharmacists, because of their distinct knowledge, skills, and abilities, should take a leadership role in interdisciplinary efforts to develop, implement, monitor, and maintain effective medication reconciliation processes; further,

To encourage community-based providers, hospitals, and health systems to collaborate in organized medication reconciliation programs to promote overall continuity of patient care; further,

To declare that pharmacists have a responsibility to educate patients and caregivers on their responsibility to maintain an up-to-date and readily accessible list of medications the patient is taking and that pharmacists should assist patients and caregivers by assuring the provision of a personal medication list as part of patient counseling, education, and maintenance of an individual medical record.

This policy supersedes ASHP policy 0620.

#### 1118

#### **Drug Product Shortages**

Source: Council on Public Policy

To advocate that the Food and Drug Administration (FDA) have the authority to require manufacturers to report drug product shortages and the reason(s) for the shortage, and to make that information available to the public; further,

To strongly encourage the FDA to consider, in its definition of "medically necessary" drug products, the patient safety risks created by use of alternate drug products during a shortage; further,

To support government-sponsored incentives for manufacturers to maintain an adequate supply of medically necessary drug products; further,

To advocate laws and regulations that would (1) require pharmaceutical manufacturers to notify the appropriate government body at least 12 months in advance of voluntarily discontinuing a drug product, (2) provide effective sanctions for manufacturers that do not comply with this mandate, and (3) require prompt public disclosure of a notification to voluntarily discontinue a drug product; further,

To encourage the appropriate government body to seek the cooperation of manufacturers in maintaining the supply of a drug product after being informed of a voluntary decision to discontinue that product.

This policy supersedes ASHP policy 0319.

#### 1119

#### Direct-to-Consumer Advertising of Prescription and Nonprescription Medications

Source: Council on Public Policy

To oppose direct-to-consumer advertising unless it is educational in nature about prescription drug therapies for certain medical conditions and appropriately includes pharmacists as a source of information; further,

To oppose direct-to-consumer advertising of specific prescription drug products unless the following requirements are met: (1) that such advertising is delayed until postmarketing surveillance data are collected and assessed, (2) that the benefits and risks of therapy are presented in an understandable format at an acceptable literacy level for the intended population, (3) that such advertising promotes medication safety and allows informed decisions, (4) that a clear relationship between the medication and the disease state is presented, (5) that no such advertising or marketing information for prescription or nonprescription medication is directed toward minors, and (6) that such advertising include mechanisms that direct consumers to a medication adverse event reporting system (AERS); further,

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To advocate that the Food and Drug Administration require an AERS reporting link in direct-toconsumer advertising material available on the Internet; further,

To support the development of legislation or regulation that would require nonprescription drug advertising to state prominently the benefits and risks associated with product use that should be discussed with the consumer's pharmacist or physician.

This policy supersedes ASHP policy 0609.

#### 1120

# Regulation of Off-label Promotion and Marketing

Source: Council on Public Policy

To advocate for authority for the Food and Drug Administration to regulate the promotion and dissemination of information about off-label uses of medications by manufacturers; further,

To advocate that such promotion and dissemination be permitted only if manufacturers submit a supplemental new drug application for new use within a reasonable time after initial dissemination of information about off-label uses.

#### 1121

#### **Poison Control Center Funding**

Source: Council on Public Policy

To advocate that poison control centers be considered an essential emergency service; further,

To advocate for new and stable funding mechanisms for poison control centers to continue to provide these essential and valuable services; further,

To support the integration and coordination of poison control center services where appropriate.

#### 1122

#### State Prescription Drug Monitoring Programs

Source: Council on Public Policy

To advocate for uniform state prescription drug monitoring programs that collect standard information about controlled substances prescriptions; further,

To advocate that the design of these programs should balance the need for appropriate therapeutic management with safeguards against fraud, misuse, abuse, and diversion; further, To advocate that such programs be structured as part of electronic health records and exchanges to allow prescribers, pharmacists, and other practitioners to proactively monitor data for appropriate assessment; further,

To advocate for interstate integration to allow for access by prescribers, pharmacists, and other practitioners across state lines; further,

To advocate for federal and state funding to establish and administer these programs.

#### 1123

# ASHP Statement on Leadership as a Professional Obligation

Source: Council on Pharmacy Management

To approve the ASHP Statement on Leadership as a Professional Obligation.\*

\*The ASHP statement approved by the House of Delegates is available on the ASHP Web site (www.ashp.org). Under "Practice and Policy," click on "Policy Positions & Guidelines" and then on "New Guidance Documents."

#### ASHP REPORT

### Inaugural address of the President-elect

# 10,000 hours

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ood morning. Thank you all for being here today. I feel like I'm with 1,000 of my closest friends! As many of you know, ASHP has always meant a lot to me. Thirty years ago, I was a new pharmacist and Dave Zilz was president of ASHP. At that point, I couldn't even imagine being in this position, but you never know where life will lead you.

I'd like to thank the many people who have helped me in my career and in my life. First, since I can't mention everyone by name, I would like to offer a generic acknowledgment to all of the friends I've made in the pharmacy world—you know who you are! Your opinions, accomplishments, friendship, and support have truly been an inspiration.

I also want to give special thanks to the staff at NorthShore, at the Milwaukee County Medical Complex, and at the University of Wisconsin. In particular, I want to acknowledge Pam Ploetz, who always made me think, and Lynn Boecler and George Carro, who have both helped me carry the heaviest loads. You've given me the freedom to pursue my activi-

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ties with ASHP, and I thank you very much.

To all of my past residents (and very soon-to-be past residents), I want you to know that I've learned a lot more from you than you ever learned from me.

To the staff of ASHP and fellow Board members, thank you for all that you do every day. You make this organization hum!

And to Henri Manasse, a special thanks for your leadership and men-

toring. I will try to make your last year as our executive vice president one of your best.

To Debbie Devereaux, Janet Silvester, and Diane Ginsburg, I want you to know that your encouragement and support have made a tremendous difference in my life.

To my mom and sisters (who could not be here today), thank you for your unconditional love and support. Mom has a saying, "Small minds think small thoughts." It has

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helped me stick to my principles and set high standards when others were challenging me.

And finally, to my daughters—Julie, Kathy, and Molly—simply, you are what makes life worth living. I could not be more proud of how you've grown to be intelligent, successful, and independent women. Thank you for being here, and thank you for sitting through my talk. Come to think of it, I don't think any of you ever heard me give a speech—other than at 2:30 in the morning!

#### The value of teamwork

You know, I have been influenced in practice by many pharmacists, but perhaps none as much as by Curt Johnson. Many of you knew Curt. Sadly, he passed away earlier this year from melanoma at too early an age. He was only 63.

Curt was one of my preceptors when I was a resident at the University of Wisconsin. He was one of the first clinical faculty members to establish a practice at University Hospital.

Curt excelled at teamwork. By taking the time to understand and respect others, he was able to have a very effective practice. He respected the relationships that the pharmacists had developed with physicians and nurses and often positioned them to be the heroes when it came to solving drug therapy problems. Because of his keen understanding of the importance of relationships, he went on to become one of the most effective and respected pharmacists in Wisconsin history.

Curt helped me to realize how important those relationships are to one's success in both practice and life. The lessons I learned from Curt are the major reasons behind my career success.

In the months since I was elected, I have been reading inaugural addresses of ASHP presidents and Whitney award lectures from the The following ASHP Reports and information on 2011 ASHP award recipients appear in the online version of this issue (www.ajhp.org):

- "ASHP: Continually in pursuit of truth" by ASHP Executive Vice President and Chief Executive Officer Henri R. Manasse, Jr., Ph.D., Sc.D.
- "Getting it started: A year to remember" by Immediate Past-President Diane B. Ginsburg, B.S.Pharm, M.S., FASHP
- "A Strong and Vibrant Organization": 2011 Report of the Treasurer by ASHP Treasurer Philip J. Schneider, Pharm.D.
- Professional Policies Approved by the 2011 ASHP House of Delegates
- ASHP Board of Directors, 2011–2012
- · ASHP Honorary Membership
- · ASHP Award of Excellence

past 20 years. There is a definite commonality among all of this writing: They all point to the urgent need for leadership and reprofessionalization and for pharmacists to have a passion for what they do. They have inspired me to believe that we all must become more proactive in our health systems.

We must communicate the value of pharmacists to decision-makers, constantly seek new avenues for pharmacy involvement, assert our knowledge and experience, and be leaders when it comes to medication use.

As pharmacists, we tend to be task oriented. In addition to having something to which we can aspire, we like to have something tangible that we can do to make a difference for patients. So, I'm hoping today to offer some steps we can all take to get practice to the next level.

#### 10,000 Hours

I recently read Malcolm Gladwell's book *Outliers: The Story of Success*. You may remember him as the author who wrote *The Tipping Point: How Little Things Can Make a Big Difference*, which is about how little things can result in transformation.

In *Outliers*, Gladwell examines the genesis of success, and what he found may surprise you. In studying why some people succeed, leading remarkably productive and influential lives, he discovered that it's not necessarily genius or talent that tips the balance; rather, it's a combination of time and opportunity.

You may not know this, but studies have found that there is a commonality among top hockey players. The best players tend to have been born in the first three months of the year—January through March. Now you may ask, what does that matter?

Well, if you think about it, as kids, they just miss the cutoff deadline for December hockey leagues. So, they join next year's teams. As a result, at age six, they are bigger, faster, and stronger than their younger teammates. And because they are bigger, faster, and stronger, they get more time on the ice and more opportunities to play. Gladwell points out that something as random as your birth month can make the difference between stardom and second string.

Fortunately, as pharmacists, it doesn't matter what month we are born in! We can use our time to become experts, and then we can take advantage of the opportunities that present themselves.

For every great success, Gladwell estimates that 10,000 hours of dedicated work preceded it. Think about that: 10,000 hours. That's a lot of time. But this labor prepares a person to jump in and take advantage of opportunities that arise.

Likewise, pharmacy superstars don't just come from nowhere . . . they are trained and spend countless hours in the pharmacy trenches helping one patient at a time, and sometimes doors open for them to expand their practice and careers.

This concept of 10,000 hours hit home for me recently. Around the first of the year, our chief quality officer asked me to put together a costeffective proposal to have pharmacists more involved in the medication reconciliation process. After some brainstorming, I proposed adding 3 times as many pharmacy residents rather than the full-time pharmacist positions I had proposed in the past. With Medicare reimbursement, the addition of 14 resident positions would cost less than half of my previous proposals.

At the beginning of March, just before the ASHP Residency Match, I learned that these positions had been approved to be allocated across our four hospitals. While the purpose of these positions is to improve medication reconciliation, in reality they will do much more than that. These residents will extend all of our clinical services and elevate our practice to improve patient care by ensuring that drug therapy is appropriate for every patient.

Adding these positions is perhaps one of the greatest achievements of my career. It demonstrates that when you put in the hours and think creatively, you really can make a difference. But in retrospect, this was not accomplished just between New Year's Day and March 7. It began 18 years ago when I started my job at NorthShore. It was successful because of the years I spent talking with physicians and administrators about the value of pharmacy services. It was successful because of the years spent changing our practice model, hiring the right people, and setting expectations. It was also successful because the opportunity presented itself and because the

leaders in our department had put in the hours.

It is my belief that the pharmacy profession is on the verge of a similar success, because pharmacists collectively put in our 10,000 hours . . . and the opportunities are now presenting themselves. We've done the blocking and tackling—we've renovated our educational system, we are growing our residency programs, and we are now focusing on pharmacy's future.

I feel it with ASHP's Pharmacy Practice Model Initiative (PPMI).

I feel it with our nation's health care reform efforts.

And I feel it with the rise of so many ambitious new practitioners who are ready to go the extra mile for their patients.

I know you have all been following the national health care reform debate. We are starting to see just how this new focus on patient outcomes, error reduction, and fiscal efficiency is playing out. Medical homes, which provide a foundation for accountable care organizations, allow pharmacists to manage chronic diseases, improve compliance, reduce hospital readmissions, and improve safety. Medical homes that incorporate pharmacists provide a new opportunity for those trained in ambulatory care.

All of this is happening at a time when ambulatory care has become a recognized specialty. Our ability to provide integrated care while practicing within our communities is an exciting development that can change our collective future.

A great example can be found in Group Health Cooperative (GHC) in Seattle. GHC employs about 40 pharmacists who work directly with patients and physicians. At GHC, they clearly "get it"—they understand that their pharmacists have spent the 10,000 hours to become experts in medication use, and they are now providing the opportunity for their pharmacists to shine.

#### Issues in pharmacy staffing

Another event that will change the fabric of pharmacy as we know it is the pending oversupply of pharmacists. There are now approximately 12,000 new graduates each year, a 50% increase from just 10 years ago. That number is expected to hit almost 14,000 once all the new schools start graduating students!

I know it has become increasingly difficult for new practitioners to find jobs over the past year or two. But my hope is that this situation will result in a resurgence of professionalism and creativity. These new graduates will need to ask themselves why they became pharmacists and how they can meet our covenant with society of ensuring safe and effective medication use.

Pharmacy students commonly ask me what it will take to get a residency in a health system. I tell them that I want pharmacists with a passion for using their knowledge to help improve patient care. I want pharmacists with the will, the attitude, and the work ethic to move pharmacy practice in ways that have seemed impossible in the past.

These new practitioners need to be willing to serve on committees, provide community service, and be involved in their professional organizations. Clearly, this type of commitment will take more than eight hours a day, and much of it will need to happen on their own time.

I tell these new practitioners that you can't just show up with your license in hand and expect to have a great job handed to you. But if you are willing to put in the 10,000 hours, you will be recognized as a professional and a leader, and you will land a rewarding job.

I am actually excited about the large number of new graduates, because, at least for a while, it will create competition for those who want to practice at the top of their license. I believe this new wave of pharmacists will refuse to be con-

strained by archaic work rules and practices. They won't be stopped by entrenched pharmacy managers, perceived state board limitations, or hourly wages.

These are the pharmacists who will go the extra mile to talk to patients, monitor drug therapy more thoroughly, develop themselves professionally, and provide all of the services that they know they should be providing. I strongly urge managers and residency directors to have high expectations of your pharmacists and residents and to look for the traits I've just described in your hiring.

We may find that this oversupply of pharmacists is actually one of the best things to happen to our profession. These new practitioners will push us to do things we have not been able, or willing, to do before.

# Searching for the ideal pharmacy practice

No talk about the future of pharmacy would be complete without mentioning ASHP's PPMI. At the Pharmacy Practice Model Summit this past November, leaders from across the country started to hone in on what makes an ideal pharmacy practice.

Recommendations ranged from the need for pharmacists to assume accountability for patient outcomes to advancing the roles of properly trained pharmacy technicians.

We know that some hospital pharmacies are practicing at this ideal level already. What is it about them that makes them different? Why can't all pharmacies provide this level of service? This is not a question of luck or even of having an administration that provides substantial support.

I believe that ideal practice sites have a sufficient number of pharmacy leaders (both big "L" and little "l") who have the will and ability to do the planning, marketing, and extensive work required to achieve this level. These leaders have invested their 10,000 hours. They have made significant personal sacrifices with an unparalleled commitment to patient care.

In his Webb lecture, Burnis Breland said, "If we are to achieve all we can for patients, then we must believe in what we know to be true." This has stuck with me ever since I heard it.

So, what do we know to be true? We know that pharmacists are the health care professionals best qualified to manage medication use. We must believe this to make it true. For some of us, that may mean changing jobs and choosing to work in an organization that values our role. At the end of the day, we need to conclude that what we do is more important than anything else.

#### How to act differently

As a profession, pharmacy has clearly put in its 10,000 hours. We are now poised to take advantage of the incredible opportunities that are available through health reform and the PPMI. The question now comes down to each of us on a personal level. How are we going to start acting differently so that we're ready for the next opportunity to improve patient care? I have a few thoughts about that, things that drive the work I do every day.

First, be passionate about what you do—find a job that makes you love getting up and going to work. The wonderful thing about passion is that it's contagious. When you're passionate, it makes others around you care more about what they do (and never forget that apathy is also contagious).

Second, be dedicated. We are professionals, and as such, we do what it takes to take care of our patients. Let me give you an example. Janet Lee is one of my pharmacists at Evanston Hospital. She is relatively new, having only worked there for about two years. One day, a patient who

was hospitalized as part of a clinical trial was distraught because she had forgotten to bring her study medications with her. After much discussion with the patient, her nurse, and her social worker, Janet decided that she would simply drive to the patient's home, get the medication, and bring it back to the hospital.

I know that many of you have done something similar for your patients, something that is above and beyond the call of duty. According to Janet's patient, her act of kindness made a real difference in the way she thought about pharmacists. Janet demonstrates on a daily basis what it means to be dedicated to her patients. No one told her what to do in the situation I have described. She knew what to do intuitively. This is the professional covenant that society expects and deserves from us. I am so proud that Janet works for me.

Third, be engaged. Participate in initiatives within your own organization outside the walls of the pharmacy. Help your boss and organization achieve their goals. And get involved and stay involved in professional organizations. Being engaged is part of your 10,000 hours. I guarantee that you will see a payback.

Fourth, be willing to change and to make the sacrifices needed to practice at the highest level possible. We must begin to demand better from our institutions and from ourselves. Seek work in an environment that values your expertise and ideas.

Fifth, for those of you who are new practitioners, have courage. I know that the job market is uncertain right now, but please know that we need pharmacists with the will, attitude, and work ethic to push progress into places where it has been stagnant. It is time to get your game on and show us what you've got!

Finally, for experienced pharmacists, it's time to step up. We must lose any complacency we have. We have to be ready for this new world—

ready to use the years we have spent building our careers to become experts. As part of that effort, I challenge pharmacy managers to begin creating practice environments that make pharmacists accountable for medication-related outcomes and in which pharmacists can fully use their clinical knowledge.

#### Conclusion

Chip Heath wrote a book entitled *Switch: How to Change Things When Change Is Hard.* In it, he said that "For anything to change, someone has to start acting differently."

We must start acting differently. I believe that every one of us must look in the mirror and ask how personally committed we are to achieving the most we can.

Ladies and gentlemen, pharmacy has come a long way. We've done a good job with pharmacy in health systems, but we can do better, and there are opportunities right now to make it happen.

Our mission as an organization and a profession is to help patients make the best use of their medications, but the continued advancement toward that goal depends on all of us, as individuals, putting in our 10,000 hours.

Thank you.

# **Getting it started: A year to remember**

DIANE B. GINSBURG

Am J Health-Syst Pharm. 2011; 68:e66-8

ood afternoon, and welcome to Denver. I am truly honored to report to you what has been happening over the last year.

You might remember that a year ago in my inaugural address I promised to "get it started." I believe that not only did we get it started in 2010, but we have revved it up, and we are now quite a far way down the road. This has been an amazing year.

ASHP has spent the past 12 months absolutely focused on developing the future of our profession and supporting our members in the provision of patient care. The things that we were able to accomplish this year that were above and beyond business as usual are significant.

A year ago, my inaugural served as a compass to ensure that we were on the right track. I was very clear when I stood before you that I would be accountable for the promises that I made. I wanted ASHP to dive into the issues of pharmacy education, renovating our practice model and moving into being accountable for patient outcomes. Well, I am excited to stand before you today and to say we did just that.

#### Improving pharmacy education

As we all know, pharmacy education represents the future of our We have all been given this amazing gift and privilege of serving patients every day, and we should never doubt that ASHP is always behind us.



profession. If we do not get the balance right in terms of quality, we will end up with a profession that loses its edge and its ability to lead patient care into the next century.

At ASHP, we have become increasingly concerned about the proliferation of pharmacy schools across this country. So, ASHP has partnered with the American Pharmacists Association (APhA) to put out a tough issue paper. We questioned if the rapid expansion of schools and colleges of pharmacy has affected the quality and the ability of institutions to recruit and retain sufficiently prepared faculty and staff.

It is our position that the continued expansion of schools and colleges of pharmacy will compromise the quality of pharmacy graduates. This could have a detrimental impact on our work force and patient needs in the future. As you are probably aware, policy is coming before this House of Delegates today regarding school expansion. You are going to be asked to support the Accreditation Council for Pharmacy Education's continuing role in creating accreditation standards and guidelines to ensure educational quality.

This policy acknowledges that a quality pharmacy education includes

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not only a robust curriculum but also student access to experiential educational sites and the availability of qualified faculty. You will also be asked to advocate that expanding enrollment in existing or new colleges of pharmacy can only occur if we have well-designed projections that demonstrate that such enrollment increases are necessary to maintain a viable pharmacist work force.

It is very clear that our profession needs a review of our work-force needs. So, we are recommending that pharmacy and educational organizations jointly convene a stakeholders' conference on work-force planning to create a process for assessing both short- and long-term needs.

#### The residency problem

The explosive growth of schools and colleges of pharmacy has had a secondary effect: namely, a nation-wide shortage of pharmacy residency positions and programs. This is a critical issue for ASHP and for our profession. When we don't have enough residency positions, patient access to pharmacist services as direct patient care providers is limited.

As ASHP has publically stated, and as this House of Delegates has supported, by the year 2020, all new college of pharmacy graduates who will be providing direct patient care will have completed an ASHP accredited postgraduate year 1 (PGY1) residency. Yet as the number of graduates who pursue PGY1 and postgraduate year 2 residencies continues to increase, the current supply of programs is not keeping up with demand.

To address this critical need for postgraduate training, we partnered with the American Association of Colleges of Pharmacy, the American College of Clinical Pharmacy, the Academy of Managed Care Pharmacy, and APhA to convene a pharmacy residency capacity stakeholder's conference in February. At the conference, we began identifying and

addressing the issues and challenges of residency capacity. The conference provided us a forum to identify ways to bring the supply of accredited programs into better balance with the demand for these types of training opportunities. We have now achieved full agreement by all pharmacy stakeholders that accredited residency training is necessary both for patient care and for the future of our profession.

In addition to providing the kinds of continuing education, web resources, and grants from the ASHP Research and Education Foundation needed to help people get started, ASHP is asking members to see what they can do within their own institutions to either increase current residency capacity or begin new programs. This is a team effort. We are in this together to try to increase both the number and the quality of residency-trained pharmacists. Our patients need us now more than ever.

# Pharmacy Practice Model Initiative update

In November 2010, we launched the ASHP and ASHP Foundation Pharmacy Practice Model Initiative (PPMI) with an amazing summit of thought leaders from around the country. Summit recommendations are posted on the ASHP website and were published in the *American Journal of Health-System Pharmacy* in June.

The recommendations addressed the following broad areas that I would like to talk about this afternoon:

- That all patients should have a right to the care of a pharmacist,
- That we as a profession define the characteristics and requirements of an optimal pharmacy practice model,
- That we advance the application of not only information technology in the medication-use process but also maximize the work of a well-trained, accredited, and educated technician work force, and

 That we define those activities that every pharmacy department should conduct as part of this new practice model.

We are now moving forward with numerous tools to help translate the summit's recommendations into practice. Some of these include a self-assessment tool to help departments examine their own practice model and a launch of PPMI 2020, which will measure the progress of the initiative across the nation.

# The continuing issue of drug shortages

Another critical issue that many of us are facing is that of drug shortages. We know that this problem is causing real challenges for ASHP members, as shortages in hospitals and health systems cause significant disruptions in patient care and increase the potential for medication errors.

ASHP took direct aim at the problem, launching a summit and consequently going into full-blown advocacy mode to ensure that Congress moves on this issue. Some of the recommendations from the summit include expanding the Food and Drug Administration's (FDA's) authority to require manufacturer notification of shortages and market withdrawals by requiring manufacturers to confidentially notify FDA when there is either a single active ingredient or a single manufacturing source. We also would like to see an expedited approval pathway for those unapproved drugs that are deemed critical therapies. ASHP has advocated very hard on Capitol Hill to launch legislation on this issue, and we actually succeeded in having the Preserving Access to Life-Saving Medications Act (S.296) introduced by Senators Amy Klobuchar and Robert Casey.

I am proud to tell you that as of this date, 10 more senators have signed on as cosponsors of this leg-

#### ASHP REPORT A year to remember

islation because of the outreach of ASHP members. I want to thank you for telling your senators and representatives about what drug shortages are doing within your institutions and how they are affecting your patients.

Finally, we continue to do a lot of media outreach and have gleaned some amazing results. The presence of ASHP and its members is being felt everywhere on this issue. I don't think that you can turn on any major news network without seeing Erin Fox from the University of Utah and ASHP's drug shortages website cited. That is the kind of publicity that we want. We need to get our story out there, and I know several people have been contacted in local markets to be interviewed and on the news. Thank you for going out and talking about this issue. Let us know what we can do to assist you.

# Preparing for a changing of the quard

I am delighted to report that ASHP is emerging from the nation's historic recession stronger than ever. As a result of the great stewardship of our Board of Directors and through the efforts of our amazing staff, ASHP has achieved a balanced budget. We are ecstatic about these results because they recognize the hard, innovative work that our staff does every day on behalf of ASHP and its members.

Finally, I have to admit that I am becoming a little bit nostalgic about the upcoming changes that are going to be happening at ASHP. We are losing an amazing executive vice president (EVP) and chief executive officer (CEO) through Dr. Manasse's decision to retire. In the 69-year history of this organization, there have only been three CEOs . . . founding CEO Dr. Gloria Francke; Dr. Joe Oddis, who led this organization for many years and provided a clear vision for the future of health-system pharmacy; and Dr. Manasse, who has taken ASHP to heights in public stature and service that I don't think any of us ever imagined.

We also made history this year when the Board of Directors and search-and-screen committee selected a new EVP designate. At this time, I want to personally recognize the efforts of our committee and the Board in making a great decision.

We are so happy to be welcoming one of our own, Dr. Paul Abramowitz, as the EVP designate. Paul is sure to build on Henri's legacy of innovation and bold action.

#### Conclusion

My very dear friend and colleague, Malcolm Broussard (president of the National Association of Boards of Pharmacy), always says the following: "The price of the privilege is responsibility and accountability." The responsibility to lead this organization over the past year is something that I have taken very seriously. I have done my absolute best to be accountable for our actions, and I feel confident that we have addressed the issues I said that we would tackle during my year in office.

We have all been given this amazing gift and privilege of serving patients every day, and we should never doubt that ASHP is always behind us. As I said a year ago—and I believe firmly even today—we are a radiating force. Our power to effect change in pharmacy is exponential. As I reflect on this most historic year, I am incredibly proud of the impact we have made on the profession.

I want to give a very special thank you and recognition to the ASHP staff who work tirelessly every single day on behalf of our profession and our patients.

And I want to thank the Board for all of your support and your efforts in moving this Society forward. It has truly been my honor and privilege to serve with each of you. I hope you will agree with me that we "got it started" this past year. On Tuesday, it will be my most distinct privilege to pass on the baton to our incoming President Stan Kent. I am confident that Stan not only can start things up, but I know Stan will keep them going.

It has been my honor and distinct privilege to serve as your president.

Thank you.

# 2011 Report of the Executive Vice President and Chief Executive Officer

# **ASHP: Continually in pursuit of truth**

HENRI R. MANASSE, JR.

Am J Health-Syst Pharm. 2011; 68:e62-5

want to start today by saying that I have enjoyed being your executive for the past 16 years. It has been a privilege and an honor to serve as this House's secretary and, more broadly, as the executive vice president (EVP) and chief executive officer (CEO) of ASHP.

When I was at the University of Iowa, I would often have lunch with the dean of the university's law school (the law school was located in the health sciences center). One day, we talked about the fact that the United States has the highest per capita number of lawyers in the world. When I asked the dean how that many lawyers could be justified, his answer was, "Henri, it's a good education . . . the knowledge base, skill sets, and ways of thinking apply to a lot of things."

Well, pharmacy is a similarly good education—with the advent of the Pharm.D., we have a philosophy of clinical care that has been a profession-changing kind of event, at least in terms of a theory of practice and idealized models of care.

When you fast-forward from the advent of this curricular requirement today, what we see Pharm.D.'s

We strive to seek a better future based on experience and evidence, coupled with a strong desire to be accountable for the care we render.

But sometimes... seeking the truth does create tension in the community.



and residents doing now could not have happened without that massive change in the number and skills of pharmacists to serve the nation.

Without that shift, the ASHP and ASHP Research and Education Foundation's Pharmacy Practice Model Initiative (PPMI) could not have happened. We would not be at the tables we are at, doing the things that we are doing. We would not be seeing the shifts in thinking that we

are currently seeing. For example, the American Pharmacists Association's (APhA's) recent move to seek accreditation for community pharmacies says something profound about the accountability that pharmacists are now feeling.

#### Pharmacists as leaders

I'd like to note that this House of Delegates is, and has been, deliberating on substantive policy issues

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that will translate into important actions on behalf of our membership in coming years. In my work, things are much easier if I know that we have the decisions of this House behind us as we guide staff efforts and as the Board of Directors decides on new directions for the Society.

We are at a place in 2011 where we can explore the legal and social consequences of being accountable. This is a serious and new issue for our profession, and I congratulate you as we focus on collaborative and team-based care as well as mutual accountability to the members of our team. This is a major move in our profession.

I think the work speaks clearly to the idealists among you, those who are forward thinkers. There are many visionaries in this House of Delegates, and, as the future unfolds, we will be counting on you to articulate your individual and collective visions. For pharmacists who are grounded in practicality, we will be looking to you to make it all work.

I have just finished reading an amazing book that I received from my children this past Christmas. It is a biography of Rev. Dr. Dietrich Bonhoeffer, a German Lutheran pastor and theological scholar who got his education before the rise of National Socialism in Germany. He participated in the resistance movement against the Nazis and was executed a month before the end of World War II.

Dr. Bonhoeffer recounted a time when he went to Union Theological Seminary in New York City on a sabbatical. He made an interesting observation regarding living in a dormitory: "No one remains alone in the dormitory," he wrote. "The unreservedness of life together makes one person open to another. However, in the conflict between the determination of truth, with all of its consequences, and the will for community, the latter prevails."

Now think about that a little bit. As a community, is it possible that we can explore truth and at the same time retain the integrity of the community? Or, in telling the truth, can we put the community behind those truths for action? This is really profound and really struck me as I read it.

I would like to frame it in a different way as well, because I think in some ways what Dr. Bonhoeffer said describes ASHP to a T. As a community, ASHP does strive for the truth. And, in striving for that truth, we must be prepared to shine a light on any problems or issues we find there.

We strive to seek a better future based on experience and evidence, coupled with a strong desire to be accountable for the care we render. But sometimes, as we know, seeking the truth does create tension in the community.

# Telling the truth

Over the years that I have been at ASHP, I haven't always said things that were popular. However, at least from my perspective, and I believe the Board's perspective, we strove to tell the truth as we saw it.

For example, we pushed back heavily against the American Medical Association's recent comments on the scope of pharmacy practice. We told the truth about pharmacists' education, training, and extraordinary patient care abilities.

As pharmacists, we continue to take this good education of ours and our truth-telling abilities and bring them to bear in every area of policy that we can, telling the truth about the skills and capabilities of pharmacists as well as the documented evidence showing the importance of pharmacist interventions and their impact on health care costs and quality.

Whether it is in the emergency room, in ambulatory care, in operating rooms, in radiology, and on and on, the evidence shows that pharmacists can make a difference.

# Being at the right tables

As President Ginsburg noted, we have had a packed year, and I would like to talk to you about several important initiatives at ASHP.

Along with seven other pharmacy organizations, we have formed the Health IT (Information Technology) Collaborative. As we began to see health care reform unfold, the Department of Health and Human Services' Office of the National Coordinator for Health Information Technology expand, and new regulations on mandatory electronic records and tying them to payments, we knew it was time to do something professionwide in the technology arena.

So, we gathered together several of the profession's organizations and determined that we had to be at these policy tables. We must help design the fields, if you will. We must be part of the technological push to bring this country to electronic medical records, and we must have the kind of data that we need in order to manage patients through these composite records.

I have been amazed at how much the Health IT Collaborative has been able to accomplish to date and how pharmacy has become the go-to profession for critical issues such as drug—drug interactions and alert fatigue. You would never think that this would come up at the level of government, but it is a serious issue for which pharmacy, and particularly ASHP, is being asked to come up with solutions.

I am hoping that this and other continued efforts actually will result in a critical road map for the role of pharmacists in health IT. We are counting on ASHP's Section of Pharmacy Informatics and Technology as well as our other sections to help build that road map and, ultimately, to advocate for it.

I would also like to share with you some work that we are doing with the U.S. Food and Drug Administration (FDA). We have had many productive conversations with personnel at all levels of FDA, from the commissioner to various divisional areas of the agency.

A major area that we are working on collaboratively with several other pharmacy organizations is the evolution of the FDA's Risk Evaluation and Mitigation Strategies (REMS) program. This work started with discussions I had as part of the FDA's Safety and Risk Mitigation Strategy Committee. At that time, there was no REMS program, just black-box warnings. We began to observe that there was no rhyme or reason as we went from one drug to the next with these warnings, and it created all kinds of problems.

I recall when Tikosyn (dofetilide) was being discussed, and pharmacy was given the responsibility to credential physicians before they could prescribe and utilize this medication in the hospital. This policy obviously would be difficult to implement.

Nonetheless, that scattered program has evolved into the much more formalized program we know as REMS. The exciting thing is that FDA is now listening to pharmacists and physicians about the best ways to bring important but highly dangerous drugs to the market while protecting patients through risk management.

You have no doubt heard about or personally experienced the national problem of drug shortages. Due to the great work of our staff reaching out to Congress and federal agencies, the Government Accountability Office and the Office of the Inspector General are now coming to ASHP for answers to this major public health crisis.

Another area that we all need to be aware of is the pathway for the approval of biosimilars. This subject is on FDA's agenda, and ASHP is going to be recommending to FDA that what we're looking for is, in fact, products that are clinically equivalent. We will be explaining that pharmacists need products that are similar and equivalent in the safety and risk profile in order to use them with confidence.

# The importance of collaboration

I also want to focus today on our collaboration with other pharmacy organizations. I like to remind my colleague Dr. Tom Menighan, CEO of APhA, that I work under the motto that is part of the flag of the state of Illinois. If you take a look at this flag, you will see the motto, "National Union State Sovereignty." Now, think about that. At ASHP, we are prepared as an organization to work with others on issues of national unity and pharmacy. However, we retain the sovereignty to be who we are and to represent the members in our areas of practice and the special needs that

We are working on a new project with APhA that I hope many ASHP members will be interested in. We are examining transitions of care and continuity of care. As we look to the future, we cannot have patients leaving our hospitals and dangling out there somewhere without somebody ensuring that the medications are being used continually and appropriately and that someone is caring for these patients.

Likewise, when our patients come into our hospitals, the guesswork that goes on in the emergency room and in admissions areas about the patient's chemical and biological therapy must be resolved. We need to come up with those solutions. I think policymakers are looking for us to do that.

We also have worked with the Accreditation Council on Pharmacy Education (ACPE) on delineating competencies for hospital and health-system pharmacy practice. We believe that pharmacy schools must achieve those competency levels to ensure that our residency programs are not denigrated into remedial education.

As it turns out, that project was so successful that ACPE now is asking all different sectors of practice to develop the same kinds of competency documents to guide the schools in the development of their curricular and overall objectives.

ASHP is also continuing to work with a number of medical and nursing organizations. I will just focus on one unique coalition today, the Hospital Care Collaborative. The collaborative comprises the American Association of Critical-Care Nurses, the American Association for Respiratory Care, the Case Management Society of America, the Society for Social Work Leadership in Health Care, and the Society of Hospital Medicine.

We have defined a set of principles around collaborative care and mutual accountability. I would advise you to go to ASHP's website to take a look at the group's common principles. More importantly, we are now talking about hosting a conference on high-performance teams sometime in the future.

# Reflections on the past

As I contemplated the fact that this is my last time to talk to the House of Delegates as ASHP's EVP and CEO, I began to feel nostalgic. I have never experienced retirement before, and my wife said that I am probably not going to be very good at it. I am looking forward to my daughter giving birth to twins in November as well as teaching my grandson how to ski next winter.

But I want you to know that I will miss my role in the House of Delegates. I have really appreciated being engaged with this body over the course of my years at ASHP. Because I am not a frontline practitioner, you educate me well on the most pressing issues that affect your work. Your work on behalf of ASHP and the pharmacy profession does pay off in its capacity to allow ASHP staff and our officers to articulate to regula-

tors, legislators, and other health care professions what we stand for, what we believe, what we need, and what we believe should happen for the future of this organization.

We have come a long way over these many years. When I look at the span of time from when I first graduated with a pharmacy degree in 1968 to where we are now, I am comforted that we have made significant progress as a profession. Still, sometimes I really get frustrated that we are still dealing with issues that we began discussing back then. Hopefully, we'll get those resolved one of these days.

I want to also welcome Stan Kent as our new ASHP president, my 17th. Working with 17 distinct, unique personalities has been a pleasure and a privilege. It has been a real delight, so to all of you past presidents, thank you for this opportunity.

I also want to say how much I have appreciated working with many, many Board members and of course many, many officers. We have been through some fabulous times, and we have been through some really rough times—from September 11, 2001, to the recession of 2008.

I have to admit that the past three years have been really tough. Our reserves swung \$25 million in the course of about a year and a half, and yet we are back now to about 59% on our reserves to expenses. That is a real accomplishment.

My duty and commitment have always been to make the president successful, because if the president is successful, then the policies of this House will be successful. As I indicated, I have really enjoyed that role. With the training and guidance that ASHP provides to our incoming Board members and officers, I am convinced that this sophisticated and in-depth work will continue to deal with the many opportunities and challenges ahead.

I cannot overstate how important good, functional governance is to an organization as complex as ASHP. I am very grateful to the Board officers who adhere not only to the principles of good governance but to action in good governance.

## Conclusion

I have been so honored to have served all of you in this position as only the third executive in ASHP history. In the 70-year history of this organization, Dr. Paul Abramowitz is going to be only the fourth executive. I was honored to work closely with Dr. Gloria Francke when she was at APhA and then at the International Pharmaceutical Federation. When I called Gloria on her 80th birthday to tell her that Dr. Joe Oddis and I would pick her up and take her out to lunch, she said not to bother—she would take the Metro!

Of course, I worked very closely for a number of years with Dr. Oddis since I served on various commissions and task forces. During his tenure, in fact, is when I first met Dan Ashby, this year's Whitney Lecture awardee. I am personally a firm believer in sticking with it. I have only had three jobs in my life, and I think it takes at least a decade to make an impact.

I chose 16 years ago to make ASHP my last career move, and I have not regretted one moment of that decision. But before I conclude, I want to publicly acknowledge the staff at ASHP, my colleagues with whom I work day in and day out on very important issues. The House of Delegates couldn't do without the staff's support, and I certainly could not. You have made me look really good.

At any one point, we calculate that we have about 3000 volunteers with whom we work. Staff keeps all those notes going, they bring the reports to the Board, and I think it helps immensely in good decision-making, so thank you to all on our staff.

I also want to thank this House again for always working to keep patients safe and for moving our profession forward to a brighter and stronger future. I am going to be eagerly watching the implementation of the PPMI, and I am going to be watching the language and action that evolve around accountability. Along with that, I hope to see scope-of-practice laws change dramatically as we embrace this notion of accountability and, in fact, become accountable not only to ourselves but to our patients.

Finally, I want to welcome my successor, Dr. Paul Abramowitz. Paul, you and I are going to have the opportunity to work very closely together for four months. I'm looking forward to it!

Again, it has been a great honor to have had this position to serve you. I wish you all well.

# 2011 Report of the ASHP Treasurer

# A strong and vibrant organization

PHILIP J. SCHNEIDER

Am J Health-Syst Pharm. 2011; 68:e69-71

The Society's fiscal year is from June 1 through May 31, coinciding with our policy development process and timetable. This report will describe ASHP's financial performance and planning for three periods, providing (1) the final audited prior-year numbers (for fiscal year 2010), (2) current-year (fiscal year 2011) projected performance, and (3) the budget for the fiscal year ending May 31, 2012.

ASHP segregates its finances into two budgets, the core budget and the program development budget. The core budget represents the revenue and expense associated with the core operations of the organization. The program development budget is intended for expenditures that are (1) associated with new, enhanced, and expanded programs; (2) associated with time-limited programs; (3) capital asset purchases; or (4) supplemental operating expenses. The program development budget is funded only from investment income.

The ASHP Board of Directors appointed the Washington, D.C., firm of Tate & Tryon as the Society's auditors for the fiscal year ended May 31, 2010. The audit of the financial statements of the Society and its subsidiary, the 7272 Wisconsin Building Corp., resulted in an unqualified opinion. Copies of the

... we remain a strong and vibrant organization and will continue to support the needs of our membership ...



audited statements are available by contacting the ASHP Executive Office

# Fiscal Year Ending May 31, 2010— Actual

Last year Treasurer Abramowitz reported that the recovery in the market values of the Society's reserve portfolio was projected to bring positive results to both the statement of income and expense and the net worth itemized on the balance sheet. The actual year-end results were much better than originally projected, despite an unexpected entry to record an increase in the defined benefit pension liability. The Society ended the year with a \$2.793 million surplus in the core budget, and the improvement in the stock market resulted in a \$3.902 million

surplus in the program development budget (Figure 1). These positive results were partially offset by net losses in the pension plan, which required us to record a \$4.058 million pension liability. In total, the net income for the Society was \$2.637 million. Net worth ended the fiscal year at \$19.672 million, 43% of total annual expense. Our long-term financial policy is to maintain net worth at 50% of total ASHP and 7272 Wisconsin Building Corp. expenses, with a ceiling of 65% and a floor of 35%

The Society's May 31, 2010, year-end balance sheet (Figure 2) remains positive. Assets totaled \$46 million, with liabilities of \$26 million. The asset-to-liability ratio rose to \$1.75:\$1.00, up from the May 31, 2009, ratio of \$1.63:\$1.00.

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Presented at the ASHP Summer Meeting, Denver, CO, June 14, 2011.

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# Fiscal Year Ending May 31, 2011— **Projected**

The continued improvement in stock market performance is providing positive results again this fiscal year. Total corporate net income for the fiscal year ended May 31, 2011 (Figure 1) is projected to be \$4.785 million, with a \$1.158 million surplus in the core budget and a \$3.627 million surplus in the program development budget. These surpluses would increase net worth to \$24.457 million at May 31, 2011, or 52% of total expenses.

# Fiscal Year Ending May 31, 2012— **Budget**

The Society's 2012 core and program development budgets collectively produce a surplus. The core budget is balanced (revenue equaling expenses), and investment income exceeds expenses in the program development budget by \$128,482. Revenue in the core budget is targeted at \$40.646 million, \$1.6 million below the 2011 budget and \$68,152 below the projected 2011 revenue. The 2012 core revenue budget reflects the realities of limited to no growth in overall core revenue (Figure 1). Much of this decline is linked to decreases in support from the pharmaceutical industry affecting advertising, exhibit size, and sponsorships. Operating expenses are expected to be \$1.6 million less than the 2011 budget but \$1.3 million over projected 2011 expenses. The Society, like most organizations today, is required to do more with existing resources.

# 7272 Wisconsin Building Corp.

The Society's subsidiary, the 7272 Wisconsin Building Corp., finished the 2010 fiscal year on a positive note, producing a \$1.164 million net income before owner's distribution (Figure 3). The subsidiary owns the headquarters building and derives income from leased commercial and office space.

# Conclusion

The Society continues to face financial challenges in the context of a difficult national economy; however, we are managing our financial resources prudently. Even during these tough economic times, we remain a strong and vibrant organization and will continue to support the needs of our membership notwithstanding limited growth in product and services revenue.

As I complete my first year as your Treasurer, I can tell you I am pleased to have joined a Board of Directors that is committed to advancing and supporting the professional practice of pharmacists in hospitals and health systems. I am proud to be your Treasurer and I look forward to serving you in the years ahead.

Figure 1. ASHP condensed statement of activities (in thousands).

	Actual Fiscal Year Ended May 31, 2010	Projected Fiscal Year Ended May 31, 2011	Budget Fiscal Year Ended May 31, 2012
CORE OPERATIONS Gross revenue	\$ 41,270	\$ 40,715	\$ 40,646
Total expense	(39,781)	(40,430)	(41,776)
Earnings from subsidiary	1,164	750	1,000
Investment income subsidy	140	123	130
Core Net Income	\$ 2,793	\$ 1,158	\$ —
PROGRAM DEVELOPMENT			
nvestment income	\$ 5,353	\$ 5,030	\$ 1,264
Program expenses	(1,451)	(1,403)	(1,135)
Program Development Net Income	\$ 3,902	\$ 3,627	\$ 129
ASHP Net Income	\$ 6,695	\$ 4,785	\$ 129
Pension Plan Adjustment	(4,058)	_	_
ASHP Net Income	\$ 2,637	\$ 4,785	\$ 129
Net Worth Beginning of Year	\$ 17,035	\$ 19,672	\$ 24,457
ASHP Net Income	2,637	4,785	129
Net Worth End of Year	\$ 19,672	\$ 24,457	\$ 24,586
% of Total Expense	43%	52%	53%

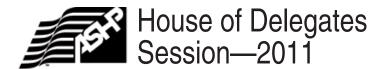
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Figure 2. ASHP statement of financial position (in thousands).

ACCETC	Actual as of May 31, 2010			Actual as of May 31, 2009	
ASSETS Current assets	\$	6,013	\$	6,122	
Fixed assets	Ψ	1,223	Ψ	2,342	
Long-term investments (at market)		35,852		32,579	
Investment in subsidiary		2,552		2,708	
Other assets		308		250	
Total Assets	\$	45,948	\$	44,001	
LIABILITIES					
Current liabilities	\$	14,311	\$	17,909	
Long-term liabilities		11,965		9,057	
Total Liabilities	\$	26,276	\$	26,966	
NET ASSETS					
Net assets	\$	19,672	\$	17,035	
Total Net Assets	\$	19,672	\$	17,035	
Total Liabilities and Net Assets	\$	45,948	\$	44,001	

**Figure 3.** 7272 Wisconsin Building Corp. (ASHP subsidiary) statement of financial position and statement of activites for fiscal year 2010 (in thousands).

REVENUE AND EXPENSE		l Year Ended y 31, 2010		Actual as of May 31, 2010	
Gross revenue Operating expense	\$	6,211 (4,464)	ASSETS Current assets Property and plant (net)	\$	1,141 17,701
Operating Income	\$	1,747	Other assets		1,540
Provision for income taxes	\$	(583)	Total Assets	\$	20,382
Increase in Net Assets	\$	1,164	LIABILITIES		
Owner's distribution and capital contributions	s \$	(1,320)	Current liabilities Mortgage payable Other liabilities	\$	956 16,450 424
Net Increase (Decrease) in Net Assets		(156)	Total Liabilities	\$	17,830
			NET ASSETS		
			Net assets	\$	2,552
			Total Net Assets	\$	2,552
			Total Liabilities and Net Assets	\$	20,382



# Board of Directors Reports on Councils

ASHP councils met in Bethesda, Maryland, September 20–22, 2010.

Each report has three sections:

**Policy Recommendations:** New policies initiated by the council, approved by the Board of Directors, and subject to ratification by the House of Delegates.

**Board Actions:** Board of Directors consideration of council recommendations that did not result in new policies, and actions by the Board in areas for which it has final authority.

**Other Council Activity:** Additional subjects the council discussed, including issues for which it has begun to develop policy recommendations.

# **Policy Recommendations**

#### 1 Council on Therapeutics

- A. Research on Medical Use of Marijuana
- B. Agricultural Use of Hormone Therapies
- C. Marketing and Clinical Application of Genetic Testing
- D. Pharmacogenomics
- E. Safe and Effective Use of IV Promethazine
- F. Pain Management
- G. Patient-Reported Outcomes Tools

# 10 Council on Education and Workforce Development

- A. Quality of Pharmacy Education and Expansion of Colleges of Pharmacy
- B. Residency Equivalency
- C. Pharmacy Internships
- D. State-Specific Requirements for Continuing Pharmacy Education
- E. Nontraditional Residency Training for Pharmacists
- F. Professional Socialization
- G. Nontraditional Pharm.D. Accessibility
- H. Nonaccredited Pharmacy Degree Programs

# 16 Council on Pharmacy Management

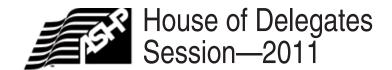
 A. ASHP Statement on Leadership as a Professional Obligation

#### 20 Council on Pharmacy Practice

- A. Pharmacist Accountability for Patient Outcomes
- B. Just Culture
- C. Ethical Use of Placebos in Clinical Practice
- D. Pharmacists' Role in Medication Reconciliation

#### 25 Council on Public Policy

- A. Drug Product Shortages
- B. Direct-to-Consumer Advertising of Prescription and Nonprescription Medications
- C. Regulation of Off-Label Promotion and Marketing
- D. Poison Control Center Funding
- E. State Prescription Drug Monitoring Programs



# Board of Directors Report on the Council on Therapeutics

The Council on Therapeutics is concerned with ASHP professional policies related to the safe and appropriate use of medicines. Within the Council's purview are: (1) the benefits and risks of drug products, (2) evidence-based use of medicines, (3) the application of drug information in practice, and (4) related matters.

Lisa M. Gersema, Board Liaison

#### Council Members

Kimberley W. Benner, Chair (Alabama)
Jill S. Bates, Vice Chair (North Carolina)
Ronald J. Campbell, Jr. (Pennsylvania)
Curtis D. Collins (Michigan)
Edward H. Eiland III (Alabama)
Leslie D. Jaggers (Georgia)
Catherine D. Johnson (Wisconsin)
Bethany A. Kalich, Student (Texas)
Patrick J. McDonnell (Pennsylvania)
Margaret E. McGuinness (Oregon)
Rachel A. Ranz, New Practitioner (Indiana)
Kenneth M. Shermock, Jr. (Maryland)
James A. Trovato, Section of Clinical Specialists and Scientists
Liaison (Maryland)
Cynthia Reilly, Secretary

#### **Policy Recommendations**

## A. Research on Medical Use of Marijuana

- 1 To encourage research to define the effectiveness, safety,
- 2 and clinical use of medical marijuana; further,
- 3 To advocate for the development of processes that would
- 4 ensure standardized formulations, potency, and quality
- 5 of medical marijuana products to facilitate research;
- 6 further,
- 7 To encourage the Drug Enforcement Administration to
- 8 eliminate barriers to medical marijuana research, includ-
- 9 ing review of medical marijuana's status as a Schedule I
- 10 controlled substance, and its reclassification, if necessary
- 11 to facilitate research; further,
- 12 To oppose the procurement, storage, preparation, or
- 13 distribution of medical marijuana by licensed pharma-
- 14 cies or health care facilities for purposes other than
- 15 research; further,
- 16 To encourage continuing education that prepares phar-
- 17 macists to respond to patient and clinician questions
- 18 about the therapeutic and legal issues surrounding
- 19 medical marijuana use.

(*Note:* As defined by the Congressional Research Service, the term "medical marijuana" refers to uses of botanical marijuana that qualify for a medical use exception

under the laws of certain states and under the federal Investigational New Drug Compassionate Access Program. Botanical marijuana includes the whole or parts of the natural marijuana plant and therapeutic products derived therefrom, as opposed to drugs produced synthetically in the laboratory that replicate molecules found in the marijuana plant.)

#### Rationale

This policy reflects discussions by the Council on Therapeutics and the Council on Public Policy in response to a New Business Item from the 2010 ASHP House of Delegates. The councils recognized that there is some evidence supporting the effectiveness of medical marijuana to treat or ameliorate symptoms of disease, including nausea and vomiting associated with cancer or its treatment with chemotherapy, chronic pain, and lack of appetite associated with human immunodeficiency virus infection or acquired immunodeficiency syndrome. However, the extent and quality of this evidence is limited. In addition, little is known about the safety of medical marijuana, especially related to its long-term use. The Board concurred with this assessment. The councils and Board believed additional and well-designed research was necessary to further define the medical use of marijuana, including determination of its active compounds; clinical indications and contraindications; precautions; dosing; routes of administration; adverse effects; drug-drug, drug-disease, and drug-laboratory interactions; and effectiveness compared to existing therapies. Current inconsistencies in product formulation, potency, and quality were also considered a hindrance to developing a strong evidence base. Therefore, the councils and Board recommended standardizing these factors, to the extent possible, to ensure the quality and reliability of research results.

The councils expressed significant concern that existing federal legislation and regulation, including marijuana's classification as a Schedule I substance under the Controlled Substances Act, would remain a barrier to the necessary research. Advocacy to the Drug Enforcement Administration (DEA) to remove or minimize these barriers was recommended by the councils and Board. The Council on Public Policy and the Board believed it was important to oppose the procurement, storage, preparation, or distribution of medical marijuana for uses other than research by pharmacies or health care facilities because those activities could jeopardize the pharmacy or facility's registration with the DEA. Finally, the councils and Board observed the need for continuing education and information about the therapeutic and legal issues on the use of medical marijuana as it continues to evolve so pharmacists are positioned to respond to patient and practitioner inquiries.

#### Background

The councils reviewed evidence on the medical use of marijuana, including recently published studies and an earlier Institute of Medicine report that evaluated the effectiveness and safety of its use in the treatment of nausea and vomiting associated with chemotherapy, chronic pain, and as an appetite stimulant for patients with human immunodeficiency virus or acquired immunodeficiency syndrome. Other studies evaluated the substance's use in the treatment of multiple sclerosis, migraine headache, and obsessive compulsive disorder. Most studies compared marijuana to commercially available alternatives, including a Food and Drug Administration (FDA)approved synthetic cannabinoid and therapies in other therapeutic classes (e.g., antiemetic therapies, opioid analgesics, and appetite stimulants). Some studies demonstrated effectiveness, especially in patients who failed first-line therapies. However, the quality of these studies was questioned and, in some instances, considered biased. Of note, most evaluations were conducted in small patient populations, for short durations, and employed variable formulations, routes of administration (e.g., ingested, inhaled), and delivery devices (e.g., vaporizers, marijuana cigarettes). The councils noted that this variability in product and delivery systems prevented extrapolation of the results to other patient populations. In addition, some studies did not compare marijuana to widely-accepted, FDA-approved therapies for these conditions. While the councils and Board believed that there may be a role for marijuana in the treatment of select diseases and conditions, limitations in the existing evidence base prohibit a thorough assessment of the effectiveness and safety of medical marijuana. Well-designed studies are needed to better define the effectiveness, safety, and clinical role of marijuana compared to existing treatments. The importance of publishing this research in peer-reviewed scientific and medical journals was noted.

Safety concerns were also noted by the councils and Board, especially in patients with respiratory conditions (e.g., asthma, chronic obstructive pulmonary disease) or compromised immune systems (e.g., patients being treated with chemotherapy) that may predispose patients to fungal or other infections when using inhaled or vaporized product formulations. Existing studies report side effects that are non-serious or limited in duration (e.g., dizziness, nervousness). However, these studies were short in duration. Therefore, risks (e.g., lung cancer and altered cognitive skills) that may be associated with long-term use are unknown. The councils and Board recommended more research to evaluate safety of medical marijuana and development of a national patient registry to support assessment of the safety of short- and long-term medical marijuana use.

The councils and Board strongly believed that marijuana is not a drug as currently defined by the FDA and reiterated that this policy should not be construed as acceptance of current scientific evidence to support its use. In addition to limited clinical evidence, uncertainties about active compounds, product inconsistencies, and differences in bioavailability based on formulation and delivery device were highlighted as significant concerns. It was noted that there are more than 400 chemicals in medical marijuana and that the effect and contribution of each to the overall effect of medical marijuana was largely unknown. This myriad of unknown effects contributes to concerns that an FDA-approved product may not provide similar effectiveness. To facilitate research, the development of standard-

ized processes to eliminate or minimize these inconsistencies was encouraged by the councils and Board.

There were significant concerns that existing federal policies would continue to limit or prohibit research on medical marijuana, especially the substance's classification as a Class I controlled substance. Specifically, the Council on Therapeutics discussed whether marijuana met the five-part definition of "currently accepted medical use," which includes (1) the drug's chemistry must be known and reproducible, (2) there must be adequate safety studies, (3) there must be adequate and well-controlled studies proving efficacy, (4) the drug must be accepted by qualified experts, and (5) the scientific evidence must be widely available. The council and Board believed that marijuana does not meet these criteria to an extent that is sufficient to support rescheduling marijuana but recognized this as a conundrum that could prohibit research. Both councils and the Board called for changes to federal legislation and regulations that would remove barriers to the recommended research, including the potential need to reclassify medical marijuana from a Schedule I to Schedule II controlled substance, but only if this change is necessary to conduct research.

Despite federal laws, more than a dozen states now permit medical marijuana use. Product distribution models used by these programs are outside the traditional prescription drug supply chain. Shortcomings of this process include lack of a valid prescription, inability to ensure the chain of product custody, and absence of the traditional prescriber-pharmacist-patient relationship. The Council on Public Policy and the Board believed that it was important to oppose the procurement, storage, preparation, or distribution of medical marijuana by pharmacies or health care facilities because such activities could jeopardize the pharmacy or facility's registration with the DEA. However, while the Council on Public Policy and Board did not wish to endorse medical marijuana programs, they believed that practitioners and patients in states where use of medical marijuana is permitted should be exempt from federal prosecution, civil liability, and professional sanction. Currently, the United States Attorney General has directed federal prosecutors not to initiate proceedings against "individuals whose actions are in clear and unambiguous compliance with existing state laws providing for the medical use of marijuana" (U. S. Department of Justice memorandum, Oct. 19, 2009). However, the Council on Public Policy noted that the current stance to limit enforcement is not binding. Therefore, changes in the extent of enforcement could result in prosecution or other undesirable sanctions against pharmacists. The council and Board strongly encouraged ASHP to actively monitor the situation and take action as appropriate to prevent this development.

The expanding and evolving use of medical marijuana requires that pharmacists have increased knowledge about its use and potential effects on concomitant therapies and medical conditions. It is expected that pharmacists will see an increasing number of patients who are using medical marijuana. Therefore, the councils and Board encouraged ASHP to provide education to members on current medical uses of marijuana, including existing and emerging evidence, risks versus benefits of use, and applicable local and federal requirements.

# B. Agricultural Use of Hormone Therapies

- 1 To advocate that the Food and Drug Administration
- 2 and United States Department of Agriculture re-evaluate
- 3 the agricultural use of hormone therapies for purposes
- 4 of animal growth promotion based on evidence dem-
- 5 onstrating potential adverse effects on human health;
- 6 further,
- 7 To encourage additional research to better define the
- 8 public health impact of using hormone therapies for
- 9 agricultural purposes.

#### Rationale

Natural (e.g., estradiol, progesterone, testosterone) and synthetic (trenbolone, zeranol, melengestrol) hormones are commonly used

for growth promotion in beef cattle raised in the United States. While the European Union has banned the use of these substances for growth promotion based on safety concerns, the United States Department of Agriculture (USDA) and FDA have long supported use of these substances based on studies conducted in the 1970s. Of note, a 2002 statement from the FDA stated that the use of hormones for agricultural purposes was safe. However, recent research has raised new concerns about potential harm to human health, including epidemiological studies demonstrating increased rates of breast cancer in women, testicular cancer and decreased fertility in men. and hormone-related developmental issues in infants and children. The Council believed that use of hormone therapies for agricultural therapies should be re-examined based on this new evidence and improved technology for measuring exposure to hormone substances that has become available since the time of the initial decision by the USDA and FDA, and the Board concurred. The Council and Board also encouraged additional research to examine the public health impact of agricultural uses of hormone therapies.

#### Background

The Council reviewed information about the extent of use of hormone therapies for agricultural purposes, including the use of natural and synthetic hormones to promote animal growth. It has been estimated that more than two-thirds of beef cattle in the United States are treated with these estrogen and androgenic substances to increase weight and muscle gain. While the FDA and the USDA maintain that use of these therapies is safe, the European Union has banned their use in food-producing animals. The Council noted that use of these drugs results in improved meat production, but that residues have been documented in meat products. The impact of this residue on human health has been debated for several decades. Early studies from the 1970s indicated that the potential for human harm was negligible, based on the extent of exposures, which were stated to be similar to natural hormone levels. However, the Council and Board believed that these early assessments included falsely low estimates of exposure due to lack of sensitivity in available technology in measuring the metabolites of steroids, as well as an overestimation of the natural hormone levels in humans. In addition, the Council noted that developing fetuses are especially susceptible to the effects of hormone exposure from maternal consumption during pregnancy and may suffer downstream effects at significantly lower levels of exposure. One recent study demonstrated decreased sperm counts in the adult male offspring of women who consumed higher quantities of beef during pregnancy than male offspring of women who reported lower beef consumption. While these studies indicate an increased potential for human harm, the Council and Board did not support immediate reversal of the earlier FDA-USDA decision, but rather encouraged these federal agencies to complete a new assessment that would include evaluation of new data.

The Council also reviewed policies of other organizations, including the American Public Health Association, that advocate for restricting or banning the use of hormone therapies based on the precautionary principle. The Council and Board appreciated the rationale for this conservative approach but recommended greater emphasis on evaluating existing evidence and more research designed to assess the public health impact of hormone therapies used in beef cattle production. It was noted that recent studies that have raised concerns are epidemiological studies, which by their nature will have plausible alternative explanations for the observed outcomes. The Council and Board encouraged the use of other study designs, including case control studies, to better define the true impact of agricultural uses of hormone therapies on human health. Comparison of United States rates of cancer and infertility with the rates of these conditions in countries that had banned or restricted the agricultural use of hormone therapies was also recommended.

# C. Marketing and Clinical Application of Genetic Testing

- 1 To support research to validate and standardize genetic
- 2 markers used in genetic testing and guide the applica-
- 3 tion of genetic test results to clinical practice; further,

- To encourage the Food and Drug Administration and the
- 5 National Institutes of Health to expedite establishment
- 6 of a process to evaluate and approve direct-to-consumer
- genetic testing; further,
- 8 To advocate that genetic testing to support disease
- 9 diagnosis or management of drug therapy be provided
- 10 to consumers only through the services of appropriate
- 11 health care professionals that order tests from labora-
- 12 tories that are certified under the Clinical Laboratories
- 13 Improvement Amendments of 1988 (CLIA); further,
- 14 To oppose direct-to-consumer advertising of genetic
- 15 testing unless such testing includes the established
- 16 patient-health care provider relationship as a mecha-
- 17 nism to provide information and interpretation of test
- 18 results; further,
- 19 To oppose direct-to-consumer advertising of genetic
- 20 testing unless the following requirements are met:
- 21 (1) that the relationship between the genetic marker
- 22 and the disease or condition being assessed is clearly
- 23 presented, (2) that the benefits and risks of testing are
- 24 discussed, and (3) that such advertising is provided in
- 25 an understandable format, at a level of health literacy
- 26 that allows the intended audience to make informed
- 27 decisions, and includes a description of the established
- 28 patient-health care provider relationship as a critical
- 29 source for information about the test and interpretation
- 30 of test results; further,
- 31 To educate consumers and clinicians on the appropri-
- 32 ate use of genetic testing for disease diagnosis and drug
- 33 therapy management.

#### Rationale

The Council sought to address the use of genetic testing for disease diagnosis and drug therapy management. Discussion addressed tests available in the clinical setting but focused on those available directly to the public. There was significant concern about direct-toconsumer genetic tests. The July 2010 Government Accountability Office (GAO) report, Direct-to-Consumer Genetic Tests: Misleading Test Results Are Further Complicated by Deceptive Marketing and Other Questionable Practices, found that blood samples from the same individuals sent to different direct-to-consumer genetic testing services had significant variability in results. In many instances, this variability can be attributed to the expansive number of markers and genes, including those supported by the FDA, that have been correlated to specific diseases. In the absence of regulation or guidance on which markers are most predictive or reliable, genetic testing companies select freely from among these markers when developing tests, thus resulting in variable results. The Council encouraged additional research to determine the clinical relevance of the genetic and biomarkers used in these tests and establishment of standardized markers to assess for specific diseases and conditions, and the Board concurred. It was also recommended that ASHP advocate to the FDA and the National Institutes of Health (NIH) to establish a thorough process to evaluate and approve genetic testing. The Council cautioned about the accuracy and patient interpretation of these tests, which are generally provided outside the context of an established patient-health care provider relationship that includes dialog and interpretation to support decision-making. The Council and Board strongly believed that these tests should only be provided in the context of that relationship and be performed only by laboratories that are CLIA certified. Further, the Council and Board sought to limit direct-to-consumer advertising of these tests, based on concerns about gaps in regulatory oversight and because the relationship between test markers and disease is often unclear. In addition the Council believed that oversimplification found in many advertisements is misleading to consumers, and the Board agreed. Education of consumers and clinicians about use of these tests was supported by the Council and Board.

#### Background

The Council discussed the growing field of genetic and biomarker testing and its application to patient care. It is anticipated that this emerging field will support efforts to provide personalized medicine. For example, tests that predict predisposition to disease may allow for early use of preventive therapies. Other tests will improve drug therapy selection by better predicting those patients that will respond to a drug therapy and those who are more susceptible to adverse events. Available tests include those that are required prior to drug use as described in FDA-approved labeling and are generally co-developed with the drug (e.g., CCR-5 receptor testing for maraviroc), those developed post-approval that are available for use in the clinical setting (CYP2C9 and CYP2C19 variant tests for warfarin and clopidogrel, respectively), and those marketed directly to consumers (e.g., 23andMe). The Council and Board believe that genetic testing is promising but noted that the relevance and application of research findings to direct patient care is frequently unclear and may be affected by other patient variables (e.g., concomitant diseases or therapies). It was noted that even tests approved by the FDA are approved based on basic scientific principle (e.g., reliability, reproducibility), not clinical relevance.

The greatest area of concern identified by the Council and Board was safety implications related to direct-to-consumer marketing of these tests. As highlighted in the July 2010 GAO report, there is significant variability in outcomes reported from the use of these tests. The Council stated that these differences are, in part, due to the large number of genetic markers that companies can select from to perform testing for the same disease or condition. The FDA does approve tests for specific genetic markers. However, the selection, incorporation, and interpretation of these components by individual laboratories fall outside FDA and CLIA oversight. The Council and Board stated that additional research is needed to clarify which of the available markers is best correlated to the intended disease assessment and how results should be applied in direct patient care in light of other patient-specific variables. The Council believed that rapid advances in scientific knowledge may have led to gaps in FDA regulations for test approval. It was noted that FDA plans to address this issue. The involvement of NIH in this activity was considered important, given their previous work in defining the human genome. Based on current regulatory gaps and oversimplification found in direct-toconsumer marketing, the Council and Board strongly believed that these tests should only be available in the context of an established patient-health care provider relationship. This relationship was considered critical to interpretation of test results and subsequent decision-making by the patient. The Council encouraged education of clinicians and patients about these tests, and the Board agreed.

#### **D.** Pharmacogenomics

- 1 To advocate that pharmacists take a leadership role in
- 2 the therapeutic applications of pharmacogenomics;
- 3 further,
- 4 To encourage pharmacists to educate prescribers and
- 5 patients about the use of pharmacogenomic tests and
- 6 their appropriate application to drug therapy manage-
- 7 ment; further,
- 8 To advocate for the inclusion of pharmacogenomics
- 9 and its application to therapeutic decision-making in
- 10 college of pharmacy curricula.

(Note: This policy would supersede ASHP policy 0016.)

#### Rationale

The Council reviewed ASHP policy 0016, Pharmacogenomics, as part of a larger discussion on marketing and clinical application of genetic tests available to consumers. The Council voted and the Board agreed to recommend amending this policy to more clearly define the role of pharmacists in pharmacogenomic testing.

#### Background

The Council voted and the Board agreed to recommend amending ASHP policy 0016, Pharmacogenomics, as follows (<u>underscore</u> indicates new text; <del>strikethrough</del> indicates deletions):

- 1 To <u>advocate that</u> <del>encourage</del> pharmacists <del>to</del> take a leadership role
- 2 in the therapeutic applications of pharmacogenomics; further,
- 3 To encourage pharmacists to educate prescribers and patients
- 4 about the use of pharmacogenomic tests and their appropriate
- 5 application to drug therapy management; further,
- 6 To advocate for the inclusion of pharmacogenomics and its ap-
- 7 plication to therapeutic decision-making in college of pharmacy
- 8 curricula.

The Council and Board believed that these changes would better define the leadership role of pharmacists in the therapeutic applications of pharmacogenomics. In addition, the revised policy would describe the enhanced role that pharmacists should play in educating prescribers and patients about the application of these tests to ensure appropriate drug use, as well as to dissuade the development of patient-care models in which pharmacists would be excluded from drug therapy decisions made as a result of these tests. The Council and Board also encouraged ASHP to educate clinicians about this important role to ensure that pharmacists are not excluded from drug therapy decisions based on the results of these tests.

# E. Safe and Effective Use of IV Promethazine

- 1 To recognize intravenous (IV) promethazine as a viable
- 2 treatment alternative in some clinical circumstances;
- 3 further,
- 4 To support health-system efforts to restrict use of IV
- 5 promethazine by encouraging alternate routes of ad-
- 6 ministration or use of therapeutic alternatives when
- 7 appropriate; further,
- 8 To encourage health systems to establish medication-
- 9 use processes that reflect nationally recognized best
- 10 practices to limit the potential for patient harm when
- 11 IV promethazine use is medically necessary.

#### Rational

The Council reviewed information regarding safety concerns with IV administration of promethazine. Promethazine is a known vesicant that has been associated with tissue damage and necrosis if extravasation occurs during IV administration. Recent changes in FDA-approved labeling advise against IV administration, and recommendations from the Institute for Safe Medication Practices (ISMP) promoting safe use have raised awareness about risks associated with IV promethazine administration. However, sporadic and significant patient harm continues to occur. The Council noted that although therapeutic alternatives are available for most indications, the alternative therapies are also not without risk and may not be as effective in some clinical situations. The Council recognized that promethazine has demonstrated effectiveness and its use may be warranted in some clinical circumstances, and the Board concurred. The Council and Board believed that these uses warranted continued availability and use of the product, but they recommended support for health-system efforts to restrict its use to these indications and encouraged implementation of processes that would limit the potential for patient harm.

#### Background

The Council considered use of IV promethazine, including its appropriate place in therapy, in light of ongoing safety concerns about the potential for tissue damage and necrosis. While extravasations are uncommon, there is no available antidote, treatment is limited to standard extravasation protocol, and patient harm can be significant. Therapeutic alternatives, including 5-HT, receptor antagonists, prochlorperazine, and metoclopramide, may be equally effective, depending on the indication and clinical situation. While these alternatives may be employed, it was noted that IV promethazine is frequently used in some clinical situations, including acute nausea and vomiting, when symptom relief is not achieved with 5-HT, receptor antagonists or other therapies. In addition, 5-HT<sub>3</sub> antagonists, such as ondansetron, have been associated with cardiac arrhythmias and may not be appropriate for all patients. Promethazine offers the added benefit of H<sub>1</sub>-receptor blockade. For these reasons, and in light of studies demonstrating the effectiveness of IV promethazine, the Council and Board believed there are some clinical circumstances in which its use is warranted.

The Council and Board supported efforts of health systems to restrict use of IV promethazine by recommending other routes of administration and encouraging use of therapeutic alternatives whenever appropriate. When its use is medically necessary, there was strong support for published recommendations, including those from ISMP, that describe safe use of IV promethazine. The Council recommended specific safe-use processes that should be implemented in health systems, including eliminating promethazine from floor stock, using clinical decision support to establish prescribing protocols, limiting IV orders to one dose only rather than as-needed dosing, and establishing procedures for patient monitoring. The Board supported these recommendations. It was noted that similar approaches to the use of phenytoin (another vesicant) and droperidol (a drug associated with significant cardiac adverse effects) had improved the safe use of those drugs. The Council and Board believed that the recommended precautions, along with clinician and patient education, would also improve use of IV promethazine.

# F. Pain Management

- 1 To advocate fully informed patient and caregiver par-
- 2 ticipation in pain management decisions as an integral
- 3 aspect of patient care; further,
- 4 To advocate that pharmacists actively participate in the
- 5 development and implementation of health-system pain
- 6 management policies and protocols; further,
- 7 To support the participation of pharmacists in pain
- 8 management, which is a multidisciplinary, collaborative
- 9 process for selecting appropriate drug therapies, edu-
- 10 cating patients, monitoring patients, and continually
- 11 assessing outcomes of therapy; further,
- 12 To advocate that pharmacists lead efforts to prevent
- 13 inappropriate use of pain therapies, including engaging
- 14 in strategies to detect and address patterns of abuse and
- 15 misuse; further,
- 16 To encourage the education of pharmacists, pharmacy
- 17 students, and other health care providers regarding the
- 18 principles of pain management.

(Note: This policy would supersede ASHP policy 0306.)

#### Rationale

The Council reviewed ASHP policy 0306, Pain Management, in light of data from the Centers for Disease Control and Prevention (CDC) that demonstrate a dramatic increase in the number of emergency department (ED) visits related to misuse of prescription and non-

prescription therapies. Discussion focused on pain therapies, many of which have the potential for abuse if not used appropriately. Specifically, the rate of ED visits for misuse of prescription opioid therapies, including oxycodone, hydrocodone, methadone, morphine, and fentanyl, more than doubled between 2004 and 2008. Information from other sources describes an increased prevalence of opioid analgesic "pill sharing" (medications obtained from family and friends who have a legitimate prescription) and diversion by family members, especially among teens. Abuse of opioid analgesics and other prescription drugs among health care professionals is also on the rise. The Council and Board were cognizant of the delicate balance between under-treatment of pain and barriers to patient access that can occur with the implementation of abuse-prevention strategies. However, the Council strongly believed that increased attention to this issue was warranted given the increasing abuse of these therapies, and the Board agreed. In revising the existing policy, the Council and Board intended to increase awareness about the abuse and misuse of some pain therapies and encourage pharmacists to take a lead role in identifying and preventing inappropriate use through individual clinician efforts (e.g., prescriber and patient education on the potential for abuse) and system-based approaches (e.g., use of information technology systems to monitor for trends that suggest inappropriate prescribing or patient use).

#### Background

The Council voted and the Board agreed to recommend amending ASHP policy 0306, Pain Management, as follows (<u>underscore</u> indicates new text):

- 1 To advocate fully informed patient and caregiver participation
- 2 in pain management decisions as an integral aspect of patient
- 3 care; further,
- 4 To advocate that pharmacists actively participate in the develop-
- 5 ment and implementation of health-system pain management
- 6 policies and protocols; further,
- 7 To support the participation of pharmacists in pain management,
- 8 which is a multidisciplinary, collaborative process for selecting
- 9 appropriate drug therapies, educating patients, monitoring pa-
- 10 tients, and continually assessing outcomes of therapy; further,
- 11 To advocate that pharmacists lead efforts to prevent inappropriate
- 12 use of pain therapies, including engaging in strategies to detect
- 13 and address patterns of abuse and misuse; further,
- 14 To encourage the education of pharmacists, pharmacy students,
- 15 and other health care providers regarding the principles of pain
- 16 management.

The Council reviewed ASHP policy 0306, Pain Management, in the context of information on the extent of prescription drug abuse in the United States, including a September 2010 report from the CDC. A comparison of data from the Drug Abuse Warning Network (DAWN) demonstrates an alarming increase in ED visits related to the nonmedical use of prescription and nonprescription drugs, increasing from 0.5 million visits in 2004 to 1 million visits in 2008. Of note, ED visits for the misuse or abuse of these therapies now equals the number of ED visits for abuse of illicit drugs (e.g., heroin, cocaine), which remained steady at 1 million visits between 2004 and 2008. The rate of ED visits related to misuse of prescription opioid therapies, including oxycodone, hydrocodone, methadone, morphine, and fentanyl, more than doubled during this time period. Avenues for obtaining these therapies without a prescription include pill sharing among family members and friends, theft from family members or friends, illegal prescriptions, diversion from health care facilities, purchases from questionable Internet pharmacies (e.g., those not accredited through the National Association of Boards of Pharmacy's Verified Internet Pharmacy Practice Sites program), and the street sale of products obtained from these sources. The Council highlighted pill sharing from family or friends as a growing area of concern, and the Board concurred.

Prescription drug abuse spans several therapeutic classes (e.g., opioids, benzodiazepines, antidepressants). However, the Council elected to focus discussion on the misuse of opioid therapies based on the CDC data and the significant potential for patient harm when these therapies are used inappropriately. Opioid analgesics have long been the focus of national efforts to curb abuse, but the effect of past approaches may be negligible, as demonstrated by the CDC data. Most recently, the FDA proposed a class-wide Risk Evaluation and Mitigation Strategy (REMS) for long-acting formulations. The potential effect of the proposed REMS on abuse, patient access, and burden on health care providers is unknown. [Note: In the months following the Council's discussion, the FDA initially deferred implementing the proposed REMS following the recommendation of a joint meeting of the Anesthetic and Life Support Drugs and Drug Safety and Risk Management advisory committees, which concluded that the proposed system did not do enough to prevent abuse. In February 2011, the FDA issued a REMS for an immediate-release transmucosal opioid therapy that includes standardized REMS components.]

The Council and Board recognized the success of efforts to improve patient access to needed pain therapies but expressed concern that messages that downplay the addictive properties of these drugs may have inadvertently desensitized clinicians and patients to potential harms. Inappropriate prescribing practices (e.g., use of opioid therapies for short-term musculoskeletal pain, excessive fill quantities) and pill sharing were noted as significant factors that contribute to the misuse and abuse of these therapies. The Council believed that pharmacists should play a central role in preventing abuse of opioid analgesics by educating clinicians on appropriate prescribing, and the Board agreed. Health-system measures, such as use of information technology systems to facilitate appropriate agent selection or monitor for trends that suggest inappropriate prescribing or patient use, may also limit or prevent abuse.

In addition to providing information on therapeutic benefit, the Council and Board suggested that pharmacists educate patients about the risks of misusing these therapies, and perhaps even the legal consequences of diversion and pill sharing. Patient education should also address best practices for drug disposal that prevent diversion. The Council believed that pharmacists' responsibility for these therapies does not end with dispensing, and the Board concurred. However, pill sharing makes patient education challenging because the intended audience includes individuals beyond those who received the initial prescription, who are not available for counseling.

ASHP was also encouraged to educate pharmacists about this issue via educational programming, an article in the *American Journal of Health System Pharmacy (AJHP)*, or web-based resources.

#### **G.** Patient-Reported Outcomes Tools

- 1 To advocate for expanded use of validated patient-
- 2 reported outcomes (PRO) tools in clinical research and
- 3 direct patient care; further,
- 4 To support development of validated PRO tools that are
- 5 sensitive to differences in cultural and health literacy;
- 6 further,
- 7 To encourage additional research on PRO tools, includ-
- 8 ing studies to assess their correlation to overall patient
- 9 outcomes; further,
- 10 To educate clinicians and patients about the appropriate
- 11 use of PRO tools.

#### Rationale

The Council supported expanded use of validated patient-reported outcomes (PRO) tools—assessments of patient satisfaction, healthrelated quality of life, or health status—in clinical research and direct patient care, and the Board agreed. Although PRO tools are most often applied in the research setting, the Council and Board believed that their increased application in direct patient care was warranted as a mechanism to integrate the patient perspective into the assessment and management of disease. Use of PRO tools was noted as consistent with the emphasis on patient-centered care advocated by the Institute of Medicine and other quality improvement initiatives. The Council and Board supported the development of validated PRO tools that account for variability in patient cultural and health literacy and encouraged research to better define the relationship between PRO measures and overall patient outcomes. The need for clinician and patient education on the appropriate use of PRO tools was noted, including the importance of instructing clinicians to select PRO tools that are validated in patient populations that are similar to the populations in which they will be used.

#### Background

The Council evaluated the research and practice application of PRO tools. PRO tools may be disease- or condition-specific (e.g., pain assessment scales) or general (e.g., Hospital Consumer Assessment of Healthcare Providers and Systems). The value of PRO tools in clinical research, including comparative effectiveness research, was highlighted by a recent *New England Journal of Medicine* article that used PROs as a primary endpoint to compare surgery plus physical and medical therapy versus physical and medical therapy alone in the treatment of osteoarthritis of the knee. The Council and Board supported expanded use of PRO tools, especially in clinical practice, where changes in patient perception of their condition may be as important as, or even more important than, clinician-observed changes.

The Council noted that, like other assessments, PRO tools require validation to ensure their appropriate use. The Council encouraged the development of PRO tools that take into account differences in patient cultural and health literacy, and the Board concurred. Clinicians were cautioned to only use validated PRO tools that were studied in patient populations that accurately reflect the characteristics of the population for which its use is intended. In addition, the Council and Board encouraged research to better define the relationship between assessments generated using PRO tools and overall patient outcomes (e.g., morbidity and mortality). Clinician and patient education on the use of PRO tools was recommended to ensure their appropriate use.

The Council acknowledged potential and significant barriers to implementing PRO tools, including lack of knowledge, limited time and resources in the clinical setting, and clinician resistance. However, the Council believed that broader incorporation of PRO tools in clinical practice was imperative, and the Board agreed. ASHP was encouraged to collaborate with public health advocates, such as the American Public Health Association and schools of public health conducting research in this area, to support development and implementation of PRO tools.

#### **Board Actions**

**Metrics for Antimicrobial Stewardship.** The Council recommended and the Board voted

To identify a standard set of metrics for evaluating the effectiveness of antimicrobial stewardship programs.

The Council discussed strategies to measure the effect of antimicrobial stewardship programs, such as those described by the Infectious Diseases Society of America (IDSA) *Guidelines for Developing an Institutional Program to Enhance Antimicrobial Stewardship.* Measures currently used to assess the effectiveness of these programs include defined days of therapy, duration of therapy, length of patient stay, time to administration of first dose, and occurrence of nosocomial *C. difficile* infection. Quality measures provided by the Surgical Care Improvement Project (SCIP) and The Joint Commission are also available. The Council believed that these measures are useful. However, most are process- or cost-focused and, therefore, less effective at measuring improvements in patient outcomes or decreases in antimicrobial resistance.

The Council stated that measuring the impact of antimicrobial stewardship programs is critical for demonstrating return on investment for staffing and other resources used to establish these programs. However, facilities are often uncertain which measures to select for use. Therefore, the Council recommended and the Board approved that ASHP dedicate resources to identify a consistent set of metrics that health systems can use as internal and external benchmarks to evaluate the impact of antimicrobial stewardship programs. This work should be completed by an expert group that includes infectious diseases specialists, quality measure and improvement experts, directors of pharmacy, and frontline clinicians. In addition, ASHP was encouraged to collaborate with the Society of Infectious Diseases Pharmacists, the CDC and other entities exploring this and related topics.

**Endorsement of IDSA 10 x 20 Initiative.** The Council recommended and the Board voted

To endorse the Infectious Diseases Society of America document, The 10 x 20 Initiative: Pursuing a Global Commitment to Developing Ten New Antibacterial Drugs by 2020.

The Council reviewed IDSA's *The 10 x 20 Initiative: Pursuing a Global Commitment to Developing Ten New Antibacterial Drugs by 2020* and other literature published by that organization that identifies the "ESKAPE" pathogens—organisms that IDSA states currently cause the majority of U.S. hospital infections and escape the effect of existing antimicrobials. The Council believed that the approach outlined in the IDSA position paper would assist in addressing concerns about increasing pathogen resistance and the diminishing number of antimicrobial drugs under development to treat disease caused by these organisms. The Council voted and the Board approved endorsement of the position paper.

The Council also recommended research and practice-based approaches to extend the effectiveness of existing antimicrobial therapies. Research on the use of older therapies, including colistin and phosphomycin, was encouraged. Other strategies recommended by the Council include better antimicrobial stewardship to conserve the effectiveness of existing therapies and improved understanding and use of diagnostic tests to target empiric antimicrobial therapy. Development of additional diagnostic tests to support therapeutic decisions at the point of care was also encouraged.

ASHP Therapeutic Position Statement on Daily Use of Aspirin for Preventing Cardiovascular Events. The Council recommended and the Board voted

To discontinue the ASHP Therapeutic Position Statement on Daily Use of Aspirin for Preventing Cardiovascular Events.

The Council discussed the ASHP Therapeutic Position Statement on Daily Use of Aspirin for Preventing Cardiovascular Events as part of sunset review. This therapeutic position statement (TPS) was published in 2005 to address a gap in use of aspirin for primary and secondary prevention of cardiovascular events based on evidence supporting the effectiveness this therapy in reducing patient morbidity and mortality. Recent developments challenge the broad use of this therapy for primary prevention, including updated recommendations from the United States Preventive Services Task Force that stratify the benefit of therapy based on patient age and sex. Evidence regarding primary prevention is rapidly changing; therefore, revision of this TPS is not recommended at this time. For secondary prevention, the Council believed that the previously identified treatment gap had largely been addressed. ASHP was encouraged to provide education (e.g., educational programming, review article or editorial in AJHP) as a mechanism to inform clinicians about the evolving nature of the evidence for primary prevention and its implications on pharmacy practice.

ASHP Therapeutic Position Statement on Appropriate Use of Medications in the Treatment of Attention-Deficit/Hyperactivity Disorder in Pediatric Patients. The Council recommended and the Board voted

To discontinue the ASHP Therapeutic Position Statement on the Appropriate Use of Medications in the Treatment of Attention-Deficit/Hyperactivity Disorder in Pediatric Patients.

The Council discussed this TPS as part of sunset review. The TPS was published in 2005 to address a gap in diagnosis and treatment of attention-deficit/hyperactivity disorder (ADHD). The Council believed that the existing guidance would require only minimal updates for currency but questioned whether a revision was warranted based on the anticipated limited value to ASHP's core membership. It was also noted that the stigma surrounding treatment of pediatric patients has lessened, and therefore the need that this document was intended to address has diminished. Further, current gaps in the treatment of ADHD involve treatment of adult patients. For these reasons, revision of this TPS is not recommended. ASHP was encouraged to provide education (e.g., educational programming, review article or editorial in *AJHP*) about treatment of this condition in adults.

**Sunset Review of Professional Policies.** As part of sunset review of existing ASHP policies, the following were reviewed by the Council and Board and found to still be appropriate. (No action by the House of Delegates is needed to continue these policies.)

- Universal Influenza Vaccination (0601)
- Minimum Effective Doses (0602)

#### **Other Council Activity**

**ASHP Therapeutic Position Statement on Strategies for** Identifying and Preventing Pneumococcal Resistance. The Council reviewed the ASHP Therapeutic Position Statement on Strategies for Identifying and Preventing Pneumococcal Resistance as part of sunset review and voted to revise it. This TPS, which was published in 2005, addresses the appropriate use of antimicrobials and other strategies to prevent the development of drug resistance in Streptococcus pneumoniae. The Council noted that the high prevalence of morbidity and mortality associated with respiratory infections from S. pneumoniae can be prevented by following the recommendations contained in this guidance. Therefore, the Council believed that this guidance was still relevant and voted to revise it. Suggested revisions include updating the sections on surveillance programs and addressing new evidence comparing the effectiveness of antimicrobial therapies (e.g., fluoroquinolones versus third-generation cephalosporins) and vaccination in infants. Provision of information on documentation was also suggested.

**Pharmacist Accountability for Medication-Related Patient Outcomes.** The Council discussed the concept of pharmacist accountability for medication-related outcomes, beginning with the general concept of accountability, which the ASHP Leadership Agenda describes as the "obligation of one party to provide a justification and to be held responsible for its actions by another interested party" (Emmanuel, 1996). The Council believed that pharmacists' drug therapy knowledge and expertise support this expanded responsibility and stated that this accountability includes responsibility to the patient, the health care team that coordinates the overall care of the patient, and the health system that employs the pharmacist. It was noted that safe and effective medication-related outcomes may be achieved through direct patient-care activities (e.g., therapeutic drug monitoring, patient counseling) as well as through system-based approaches (e.g., implementation of clinical protocols).

Accountability for meeting quality measures (e.g., CMS core measures, SCIP measures) frequently requires a team-based approach. The Council debated whether individual accountability was achievable or desirable in this context. It was noted that accountability doesn't necessarily require that the individual clinician affect the change. In fact, system-based approaches (e.g., establishment of clinical pathways and protocols) play a significant role in ensuring appropriate medication-related outcomes. Several Council members expressed concern that some medication-related outcomes occur outside the scope of pharmacist control. For example, a physician may not accept an important recommended change in therapy (e.g., contradiction to prescribed therapy). There was some reluctance to assuming accountability in these scenarios. However, the majority of Council members believed that individual pharmacist interventions and system-based approaches would permit sufficient influence to support accountability.

The potential for increased pharmacist liability was described as a potential barrier to acceptance of greater pharmacist accountability for patient outcomes. However, the Council stated that pharmacists are already accountable for the safe and effective use of drugs through the licensing process. Collaborative drug therapy management programs also require that pharmacists be responsible for drug therapy recommendations. Awareness building and education were recommended as mechanisms to increase pharmacists' understanding of the concept of accountability and remove barriers to its acceptance.

The Council also briefly discussed pharmacy services that are essential to safe and effective medication use. The Council deferred identification of the full range of core services, noting that this issue will be addressed more broadly at the Pharmacy Practice Model Initiative Summit in November 2010.

**ASHP Statement on the Pharmacist's Role in Substance Abuse Prevention, Education, and Assistance.** The Council reviewed the *ASHP Statement on the Pharmacist's Role in Substance Abuse Prevention, Education, and Assistance* as part of the discussion of pain management and prescription drug abuse. The Council recommended that the Council on Pharmacy Practice consider revising

that guidance document, which describes pharmacists' activities that reduce the negative effects that substance abuse has on society, health systems, and the pharmacy profession. The current document briefly discusses abuse of prescription therapies, but focuses predominantly on abuse of illicit drugs and alcohol. The Council recommended that the guidance be updated to address the increasing trend of prescription drug abuse, including incorporation of new morbidity data from the CDC (CDC. Emergency Department Visits Involving Nonmedical Use of Selected Prescription Drugs—United States, 2004-2008. *Morbidity and Mortality Weekly Report*. 2010; 59(23): 705-709.) and strategies to address inappropriate prescribing (e.g., stepwise approach to managing non-cancer pain, quantity limits, incorporation of clinical protocols in CPOE and other information technology systems).

Safety and Effectiveness of Dietary Supplements. The Council discussed the prevalence of dietary supplement use, focusing on the increasing prevalence of unlabeled active drug ingredients (e.g., sibutramine, sildenafil and related analogues, anabolic steroids) in these products. The Council was concerned that only a small percentage of dietary supplements are sold in establishments where a pharmacist or other health care professional is available for consultation. The rise of adulterated products heightened this concern. The Council was supportive of existing ASHP policy 0811, Regulation of Dietary Supplements, which calls for expanded FDA authority in regulating these products. However, the Council believed that changes in the landscape (i.e., high prevalence of unlabeled active ingredients) warranted enhanced advocacy on this issue.

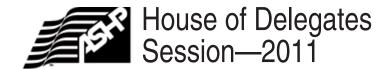
The Council encouraged ASHP to educate pharmacists about these safety issues, including the risks associated with adulterated products, the potential for significant drug-supplement and disease-supplement interactions, and strategies for managing patients who elect to continue these therapies despite the risks. Medication reconciliation was considered a core strategy for preventing harm from these therapies. The Council also briefly discussed scenarios in which patients decline traditional medicine in lieu of alternative therapies, or use supplements as adjunctive or supportive treatment. For some conditions, such as cancer, clinicians actively encourage patients to discontinue therapies that may have an adverse impact on prescribed antineoplastic therapies. The Council also discussed and expressed concern about ungrounded or fraudulent health claims (e.g., coffee grounds enema for treatment of cancer, horse chestnut to alleviate varicose veins).

Health Literacy. The Council reviewed available tools to assess patients' health literacy. The Council stressed the importance of this assessment to support patient education and informed decisionmaking. However, it was noted that several of these tools take 15 minutes or more to administer, which the Council considered a barrier to their use in the busy patient-care setting. The Council reviewed favorably assessment questions described in an article from the Journal of Health Communication (Miller, et al. Using single-item health literacy screening questions to identify patients who read written nonsteroidal inflammatory medicine information provided at pharmacies. J. Health Comm. 2010; 15:413-27.), which demonstrated validity in initial studies and could be easily administered in just a few minutes. ASHP was encouraged to provide education on the importance of assessing health literacy, with a focus on tools and strategies for removing time and other barriers to their use. Education in the pharmacy curriculum and during experiential rotations and residency training was considered important.

The Council also discussed the broader concept of patient education. Simple provision of drug information (e.g., MedGuide, FDA-approved patient package insert, or commercially available leaflets) was considered insufficient to support appropriate drug use. The Council noted that REMS-required drug information documents focus more heavily on drug risks; therefore, these documents alone cannot support a risk-benefit assessment. Pharmacists were encouraged to provide an opportunity for open dialog with the patient and to assess patient understanding of the information provided.

Safety and Effectiveness of Childhood Vaccination. The Council discussed ongoing public concern about the safety of childhood vaccines. Thimerosal, which had previously been theorized to have a causal link to austism, has since been removed from or drastically reduced in all current vaccines. Most recently, the Lancet retracted an article by Wakefield, et al. that had described the measles, mumps, and rubella vaccine as an environmental trigger for developmental problems. Despite these developments, parental and caregiver concerns continue, in part due to media attention and celebrities cautioning about the use of vaccines. The Council reviewed several studies evaluating parental and caregiver concerns about vaccine safety, which found that these concerns were reversed or lessened following education. Based on these findings, the Council suggested that pharmacists provide this education to parents and caregivers and encourage vaccination. It was recommended that ASHP increase awareness about this role, promote existing guidelines in this area, and provide additional tools if needed. An AJHP article reviewing the scientific evidence supporting vaccine safety was also recommended.

The Council also reviewed studies evaluating the requirements of state vaccination exemption programs. An article in the New England Journal of Medicine (Omer, et al. Nonmedical exemptions to school immunization requirements. Secular trends and association of state policies with pertussis incidence. N Engl J Med. 2006; 296(14):1757-63.) identified a trend of higher rates of pertussis infection in states with less-stringent exemption requirements (e.g., signed waiver versus documentation of religious objection). The Council was concerned about the potential effect of less-stringent requirements on herd or conferred immunity (i.e., group resistance to a disease that occurs when a large portion of individuals in that group have immunity, such as that achieved through immunization). Education of pharmacists was again suggested to reinforce their role in advising caregivers about the public health benefits of vaccination. ASHP was encouraged to support and perhaps collaborate with organizations such as the CDC that educate caregivers via the You Call the Shots campaign and other programs.



# Board of Directors Report on the Council on Education and Workforce Development

The Council on Education and Workforce Development is concerned with ASHP professional policies related to the quality and quantity of pharmacy practitioners in hospitals and health systems. Within the Council's purview are (1) student education, (2) postgraduate education and training, (3) specialization, (4) assessment and maintenance of competence, (5) credentialing, (6) balance between workforce supply and demand, (7) development of technicians, and (8) related matters.

Christene M. Jolowsky, Board Liaison

#### **Council Members**

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Lisa L. Deal, Vice Chair (Virginia)
Dianna Borowski-Wright (Arizona)
Michael B. Cockerham (Louisiana)
Dale E. English (Ohio)
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Molly Billstein Leber, New Practitioner (Connecticut)
Natasha C. Nicol (South Carolina)
Eunice Y. Rhee, Student (California)
Jean M. Scholtz (Pennsylvania)
Stephanie D. Sutphin (Kentucky)
Douglas J. Scheckelhoff, Secretary

# **Policy Recommendations**

# A. Quality of Pharmacy Education and Expansion of Colleges of Pharmacy

- 1 To support the Accreditation Council for Pharmacy
- 2 Education's continuing role of promulgating accredita-
- 3 tion standards and guidelines and engaging in sound
- 4 accreditation processes to ensure quality in the educa-
- 5 tion provided by colleges of pharmacy; further,
- 6 To acknowledge that, in addition to a robust curriculum,
- 7 access to quality experiential educational sites and the
- 8 availability of qualified faculty (including preceptors and
- 9 specialty-trained clinical faculty) are essential determi-
- 10 nants of the ability to expand enrollment in existing or
- 11 additional colleges of pharmacy; further,
- 12 To advocate that expansion of enrollment in existing or
- 13 new colleges of pharmacy only occur if well-designed
- 14 projections demonstrate that such enrollment increases
- 15 are necessary to maintain a viable pharmacist workforce.

(Note: This policy would supersede ASHP policy 0607.)

#### Rationale

The growth in the number and capacity of colleges of pharmacy in recent years has been remarkable. Ten years ago, when there was a severe pharmacist shortage, new colleges were welcomed to help meet the anticipated needs of the pharmacy workforce. The pharmacist shortage has now abated, but new colleges continue to be established and capacity of existing colleges expanded. This growth, along with other factors, has led to considerable difficulty

for colleges of pharmacy in locating experienced faculty. There are also growing concerns about the limited number of quality experiential education sites and how future demands for training will be met. These two factors alone have raised worries about the quality of education and the readiness of new pharmacy graduates. High quality can be ensured through the existing mechanism of Accreditation Council for Pharmacy Education (ACPE) accreditation, regardless of the number of colleges and the number of students. However, this assumes rigid enforcement of ACPE's accreditation standards and guidelines, the availability of qualified faculty and preceptors, and an adequate capacity in practice to provide the necessary experiential education.

The Council discussed the mismatch between pharmacy workforce supply and demand. Demand far exceeded supply in 2000, but growth in colleges and other factors now have supply exceeding demand. The Council discussed how there could be better planning to avoid these situations, both of which are costly to the health care system and present risks to quality and patient care. It was suggested that well-designed workforce projections might be useful in determining the need for new or expanded educational capacity.

#### Background

The Council reviewed existing ASHP policies related to quality of education and college growth, notably ASHP policy 0607, Quality of Pharmacy Education and Expansion of Colleges of Pharmacy. The Council recommended and the Board voted to amend policy 0607 as follows (<u>underscore</u> indicates new text; strikethrough indicates deletions):

- 1 To support the Accreditation Council for Pharmacy Education's
- 2 continuing role of promulgating accreditation standards and
- 3 guidelines and engaging in sound accreditation processes to
- 4 ensure quality in the education provided by colleges of phar-
- 5 macy; further,

- 6 To acknowledge that, in addition to a robust curriculum, access to
- 7 quality experiential educational sites and the availability of quali-
- 8 fied faculty (including preceptors and specialty-trained clinical
- 9 faculty) are essential determinants of the ability to expand en-
- 10 rollment in existing or additional colleges of pharmacy; further,
- 11 To support such expansion when it does not compromise the
- 12 quality of pharmacy education.
- 13 To advocate that expansion of enrollment in existing or new
- 14 colleges of pharmacy only occur if well-designed projections
- 15 demonstrate that such enrollment increases are necessary to
- 16 maintain a viable pharmacist workforce.

#### **B. Residency Equivalency**

- 1 To acknowledge the distinct role of ASHP-accredited
- 2 residency training in preparing pharmacists to be direct
- 3 patient-care providers; further,
- 4 To recognize the importance of clinical experience in
- 5 developing practitioner expertise; further,
- 6 To affirm that there are no objective means to convert
- 7 or express clinical experience as equivalent to or a
- 8 substitute for the successful completion of an ASHP-
- 9 accredited residency.

#### Rationale

ASHP's position on the need for residency-trained pharmacists is well established and described in the ASHP Long-Range Vision for the Pharmacy Workforce in Hospitals and Health Systems. It has been suggested that a way to achieve the goal of having all pharmacists in direct patient-care roles be residency trained would be to establish a process for reviewing a "portfolio" against pre-established criteria to grant a "residency equivalency." The Council concluded that both residency training and experience are important and valuable, but different, and that it would not be appropriate to create a process that attempts to convert one into the other. The intent of the goal of having all new college of pharmacy graduates who provide direct patient care residency trained by 2020 is to enhance the skills of those practitioners, and the creation of a residency equivalency process might dilute the value of that residency training and undermine achievement of the goal.

The Council also discussed the process used by ASHP to waive the requirement for a postgraduate year one (PGY1) residency for experienced practitioners who wish to enter a postgraduate year two (PGY2) residency directly. While this process does consider total experience in granting the waiver, and may seem to contradict the recommended policy, the applicant still completes a residency, ultimately gaining those experiences unique to residency training.

#### Background

The Council reviewed ASHP policy 0701, Requirement for a Residency, and ASHP policy 0005, Residency Training for Pharmacists Who Provide Direct Patient Care. The Council felt that policy 0701 only addressed new graduates, but not experienced practitioners. The Council believed that policy 0005 addresses the value of both residency training *and* practice experience, which acknowledges those experienced practitioners who likely have very good clinical skills but are unlikely to return to complete a residency.

The Council discussed a position paper from the American College of Clinical Pharmacy that proposes a residency equivalency for those who have developed clinical maturity and have met pre-established criteria as determined by a portfolio review. They do not take the position, however, that such a portfolio review should replace residencies. They also suggest that the process of granting residency equivalency should be available for a finite period, such as ten years, in order to meet goals set for residency training.

The Council discussed the difficulty in developing such a system. Since experiences vary so greatly, trying to standardize and make the process objective would be challenging. The Council also questioned whether existing practitioners would be motivated to seek a portfolio review.

The possible link between such an equivalency and potential payment for pharmacist services was also discussed. The Council felt that payers would determine the credentials needed for payment, and that attempts to reclassify experience as a residency would not make a difference with payers. Experience would be accounted for on its own merit as part of a privileging and credentialing process, whether conducted by an institution or some other body.

The Council compared the difficulty in measuring a residency equivalency to trying to grant a doctor of pharmacy degree equivalency, and believed that it cannot be done objectively and effectively. The Council noted that it would dilute the meaning of completing a residency if the profession were to call other experiences equivalent. The Council believed that maintaining the integrity of the ASHP-accredited residency credential is vital.

#### C. Pharmacy Internships

- 1 To encourage the National Association of Boards of
- 2 Pharmacy to develop standardized pharmacy internship
- 3 hour requirements that would be used uniformly by all
- 4 state boards of pharmacy; further,
- 5 To support structured requirements for pharmacy intern-
- 6 ship experiences, in alignment with requirements for
- 7 introductory and advanced pharmacy practice experi-
- 8 ences; further,
- 9 To study new staffing models that foster expanded roles
- 10 for pharmacy interns, providing work experiences that
- 11 build upon their knowledge and help them develop as
- 12 future pharmacists.

(Note: This policy would supersede ASHP policy 0802.)

#### Rationale

The pharmacy internship requirement established by state boards of pharmacy has changed little in many states, even with the change to a six-year doctor of pharmacy curriculum. Many states allow some or all internship hour requirements to be completed as part of a student's introductory pharmacy practice experience (IPPE) or advanced pharmacy practice experience (APPE) rotations; others require students to complete internship hours separately.

Inconsistencies in internship requirements between states have had significant implications for pharmacy residents. Pharmacy graduates from a state with minimal internship requirements might match with a residency program in a state with stringent internship requirements, sometimes delaying their eligibility for licensure until they can complete internship requirements in their residency state. Greater standardization would prevent these issues as residents move to other states to start their programs.

Since most states do not specify the roles and duties of pharmacy interns, many work as pharmacy technicians, which may result in a good learning experience but in some cases leaves a negative impression on the student. The lack of standardized goals and objectives for internships has resulted in experiences that are highly variable. Some hospitals have chosen to enhance their internship experience by adding structure and specific goals to be achieved. While these programs are few in number, they are viewed as highly valued learning experiences for those who participate.

The requirements for IPPEs and APPEs should be considered as internship requirements are established. Each experience has a distinct role in the development and education of pharmacy students, and care should be taken to make sure that each experience is maximized and that core elements are not left out.

#### Background

The Council reviewed existing ASHP policies related to pharmacy internships. The Council recommended and the Board voted to amend ASHP policy 0802, Role of Pharmacy Interns, as follows (underscore indicates new text; strikethrough indicates deletions):

- 1 To encourage the National Association of Boards of Pharmacy to
- 2 <u>develop standardized pharmacy internship hour requirements</u>
- 3 that would be used uniformly by all state boards of pharmacy;
- 4 further.
- 5 To support structured requirements for pharmacy internship
- 6 experiences, in alignment with requirements for introductory
- 7 and advanced pharmacy practice experiences; further,
- 8 To advocate for changes in state practice acts and regulations that
- 9 would define a scope of practice for pharmacy interns that is not
- 10 limited to that of a pharmacy technician; further,
- 11 To study explore and promote new staffing models that foster
- 12 expanded roles for pharmacy interns, providing work experi-
- 13 ences that build upon their knowledge and help them develop
- 14 as future pharmacists.

The Council discussed the recent National Association of Boards of Pharmacy proposal that state boards of pharmacy standardize pharmacy internship requirements. This was viewed as a positive step, given the many challenges that arise from the current system and inconsistent requirements.

The Council discussed the mismatch between the supply of internship positions and the number of students who need those positions. The shortage of intern positions is especially acute in cities or regions that have multiple colleges of pharmacy. Council members expressed concern that some hospitals have chosen to not have any intern positions because of the limited availability of students due to college schedules. It was suggested that hospitals should be encouraged to accept interns, especially since they might ultimately benefit from better-trained graduates.

The Council discussed whether internships are needed at all, given the other components of pharmacy education. Internships were established at a time when they represented the entire experiential component for students. Given the evolution of IPPEs and APPEs, Council members envisioned a day when internships might not be needed. It was suggested that colleges should work with sites to coordinate what is covered in IPPEs, APPEs, and internships. At this time, Council members felt that internships continue to play an important role and that experiential education and internship experiences are different.

The Council on Public Policy also discussed the issue of internships, and their suggestions are reflected in the proposed policy recommendation.

# D. State-Specific Requirements for Continuing Pharmacy Education

- 1 To support the standardization of state continuing
- 2 pharmacy education requirements; further,
- 3 To advocate that state boards of pharmacy adopt con-
- 4 tinuing professional development (CPD) as the pre-
- 5 ferred model for maintaining pharmacist competence
- 6 and structure continuing education requirements as a
- 7 component of CPD.

#### Rationale

All 50 states require continuing education for pharmacists as a means of maintaining their competence. State requirements for continuing education differ, in numbers of hours and the time frame within which they must be collected and reported, for example. Some state boards of pharmacy have established specific educational requirements for individual topic areas they concluded should be manda-

tory. These initially included topics such as state-specific pharmacy law and human immunodeficiency virus and acquired immune deficiency syndrome (HIV/AIDS), but more recently states have included requirements for education on medication safety, pain and palliative care, and patient management. Some states also specify the number of hours that must be obtained by "live" presentation rather than home study courses. As more states develop unique requirements, many pharmacists who are licensed in multiple states are finding it difficult to meet the unique requirements of each individual state.

In addition to continuing education required by state boards, many new Risk Evaluation and Mitigation Strategies (REMS) programs will require drug-specific education for pharmacists before they are permitted to handle or dispense the medications.

The Council also discussed the limited use of CPD by pharmacists and the few states that allow CPD as part of their continuing education requirements.

#### Background

The Council considered continuing education and education related to high-risk drugs, such as REMS programs, as distinct issues.

The Council reviewed existing ASHP policy 0916, Continuing Professional Development, and concluded that issues related to state-specific requirements are not addressed but that the need for continued support for the use of continuing professional development should be included in ASHP policies related to continuing education

The Council agreed that having mandated continuing education on topics unrelated to one's practice is illogical. For example, many states require annual education on HIV/AIDS, but for pharmacists who never interact with patients being treated for HIV/AIDS, this requirement may not be a good use of time and resources. Topics such as medication safety, in which virtually all pharmacists have some role, seemed more reasonable to some Council members. Others felt that a topic should only be required if there have been changes in therapy or changes in laws that justified refresher education.

The lack of documented correlation between continuing education and development or maintaining competence was also a concern for Council members.

#### E. Nontraditional Residency Training for Pharmacists

- 1 To support the development of nontraditional residen-
- 2 cies that meet ASHP accreditation requirements.

#### Rationale

A growing number of residency programs have developed residency positions that are nontraditional, in that they do not occur in a contiguous 12-month period beginning in July and finishing the following June. Some of the programs schedule the participant for one month as a resident, followed by two months as staff, with this cycle repeated over a three-year period. This allows some individuals, usually experienced individuals already on staff at the institution, to complete a residency while maintaining a more consistent work schedule and lifestyle. Some other settings have adopted a model geared toward new graduates, alternating months between residency rotation and staffing.

The concept of nontraditional residencies allows another way for established pharmacists to obtain a pharmacy residency when a conventional 12-month contiguous program is not possible. The Council and Board expressed support for this model as long as ASHP accreditation standards and residency goals and objectives are utilized as they would be in a conventional program.

#### Background

The challenges of offering a nontraditional residency were also discussed. For example, many sites have struggled with how to manage the staffing requirement of the residency. In addition, longitudinal residency learning objectives are also difficult, since the residency is intermittent.

The Council also discussed the likelihood that these nontraditional positions would compete with, or limit, the number of traditional residency positions, since there is often a fixed capacity for monthly rotation spots.

The Council felt that ASHP should provide tools and resources to help residency programs develop a limited number of nontraditional programs to advance the training of pharmacists already in practice, and promote these programs as well.

#### F. Professional Socialization

- 1 To encourage pharmacists to serve as mentors to
- 2 students, residents, and colleagues in a manner that
- 3 fosters the adoption of: (1) high professional standards
- 4 of pharmacy practice, (2) high personal standards of
- 5 integrity and competence, (3) a commitment to serve
- 6 humanity, (4) analytical thinking and ethical reasoning,
- 7 (5) a commitment to lifelong learning, and (6) personal
- 8 leadership skills.

(Note: This policy would supersede ASHP policy 0110.)

#### Rationale

One of the most important outcomes of a successful student-preceptor relationship may be the most difficult to measure: the growth of the student as a professional through the development of professional values such as integrity, ethics, leadership, and giving back to the community. Among the barriers that often hinder the professional socialization of students are the inadequate preparation of preceptors to do more than pass along clinical or management knowledge and the lack of a supportive environment that places value on the mentoring role of the preceptor.

Other barriers to effective professional socialization of students through their preceptors relate to declining emphasis on internship by boards of pharmacy, which in effect reduces the amount of time that the intern has with his or her preceptor, and the fact that many preceptors are not filling that role voluntarily but rather are pressured into doing so.

#### Background

As part of sunset review, the Council reviewed ASHP policy 0110, Professional Socialization, and concluded that while the policy's intent was very good, it should be revised. The Council recommended and the Board voted to amend policy 0110 as follows (underscore indicates new text; strikethrough indicates deletions):

- 1 To encourage pharmacists to serve as mentors to students, resi-
- 2 dents, and colleagues in a manner that fosters the adoption of:
- 3 (a1) high professional <u>standards of aspirations for</u> pharmacy
- (a1) high professional standards of aspirations for pharmacy
   practice, (b2) high personal standards of integrity and com-
- 5 petence, (e<u>3</u>) a commitment to serve humanity, (d<u>4</u>) habits of

- analytical thinking and ethical reasoning, and  $(e\underline{5})$  a commit-
- 7 ment to lifelong learning, and (6) personal leadership skills.

The Council felt that leadership skills play such a key role in being a professional, regardless of position, that it should be included, along with other minor wording changes.

### G. Nontraditional Pharm.D. Accessibility

- 1 To discontinue ASHP policy 0108, which reads:
- 2 To encourage colleges of pharmacy to continue to de-
- 3 velop innovative ACPE-accredited programs that meet
- 4 the professional advancement needs of practitioners,
- 5 using distance learning and other advanced technolo-
- 6 gies where appropriate; further,
- 7 To identify and publicize mechanisms available to
- 8 baccalaureate-degree pharmacists for overcoming bar-
- 9 riers to the attainment of the Pharm.D. degree.

#### Rationale

As part of sunset review, the Council reviewed policy 0108 and concluded that the policy is no longer needed. The Council felt that the transition to an entry-level doctor of pharmacy degree had occurred and that ongoing development of new, post-baccalaureate-degree programs was no longer needed.

#### H. Nonaccredited Pharmacy Degree Programs

- 1 To discontinue ASHP policy 0107, which reads:
- 2 To support the position that every educational program
- 3 that offers a pharmacy degree must be accredited by the
- 4 Accreditation Council for Pharmacy Education (ACPE),
- 5 regardless of licensure status of students enrolled.

#### Rationale

Existing ASHP policy supports the value and importance of ACPE accreditation of pharmacy degree programs. Because of this, policy 0107 was considered by the Board to be duplicative and unnecessary.

#### Background

Policy 0107 was approved at a time when there were unaccredited schools of pharmacy offering postbaccalaureate Doctor of Pharmacy training. This is no longer the case, and it is unlikely to recur. Although the Council felt that it was acceptable to keep the policy as stated, the Board disagreed and concluded that it should be discontinued.

## **Board Actions**

**Qualifications of Pharmacy Technicians in Nontraditional or Advanced Roles.** The Council recommended the following new policy:

To support more-stringent training requirements for pharmacy technicians working in nontraditional or advanced roles, including completion of an ASHP-accredited training program, certification through the Pharmacy Technician Certification Board, registration with state boards of pharmacy where it is required, and additional training based on competencies specific to the tasks being performed; further,

To advocate that expansion of pharmacy technician roles into nontraditional areas should be evaluated on the relative patient-care risk of their performing that activity, and that ongoing quality assurance metrics should be established to assure patient safety.

The Board believed that this topic is important, but in light of recommendations from the Pharmacy Practice Model Initiative Summit, they concluded that this policy could be improved if reviewed and modified with consideration of these new developments. The Board voted

To refer the proposed policy back to the Council for further analysis and refinement.

The Council discussed the growing number of hospitals that are employing pharmacy technicians in ways that go beyond their traditional roles in medication preparation, distribution, and purchasing. These nontraditional roles include performing medication reconciliation, collection of laboratory data, management of automation and technology, facilitating IV-to-PO conversion programs, performing drip rounds, and others. While there has been a good deal of discussion about minimum standards for education and training of technicians in general, there has been little discussion about technicians in these specialized roles. The Council reviewed ASHP policy 1015, Minimum Hiring Standards for Pharmacy Technicians, and concluded that this policy established the baseline for pharmacy technicians working in traditional roles. The need for, at a minimum, ASHP-accredited training, certification by the Pharmacy Technician Certification Board (PTCB), and registration with state boards was reaffirmed. The Council felt that expansion of technician duties beyond the norm would also require additional training for technicians in these specialized roles, based on documented competencies for the tasks being performed.

Many of these hospitals have studied the impact on quality and outcomes of technicians working in these capacities, and in most cases there is good evidence that these programs have resulted in improved safety, more efficient services, and redeployment of pharmacists into other patient-care activities. There was consensus that while some of these new and evolving technician roles may offer opportunities to redeploy pharmacists into more clinical roles, they need to be limited to roles that do not pose a potential risk

to patients and that permit quality and safety assurance processes. The Council discussed high-risk therapies and functions in which pharmacy technicians should not be given advanced responsibilities. Examples discussed by the Council included activities associated with oncology therapies or anticoagulation therapy, or others in which there is little margin for error.

The Council also discussed how career ladders for pharmacy technicians might play a role in identifying experienced technicians who could be afforded additional responsibilities in nontraditional roles. They concluded that training and demonstrating competencies for the tasks to be performed was still paramount.

The Council also suggested that ASHP should promote examples of these new roles for pharmacy technicians, especially when there is strong evidence that the new role represents an improvement in quality, services, efficiency, and redeployment of pharmacist to other patient-care roles.

**Sunset Review of Professional Policies.** As part of sunset review of existing ASHP policies, the following policy was reviewed by the Council and Board and found to still be appropriate. (No action by the House of Delegates is needed to continue this policy.)

• Professional Development as a Retention Tool (0112)

#### **Other Council Activity**

# **Education, Training, and Credentials of Medication Safety Officers.** The Council voted:

To develop a statement on the role and responsibilities of the pharmacist charged with leadership on improving safety of medication-use systems, such as a medication safety officer, further;

To explore the development of certificate programs for these positions that would promote mastery of these minimum competencies related to medication safety.

There continue to be a growing number of individuals who have the role or title of Medication Safety Officer. Education and training of these individuals differ greatly, from those having specialty training related to medication or patient safety (such as a residency) to others who are primarily self-taught.

The Council discussed how the role of medication safety officers varies from institution to institution. Many times, the potential impact of the position is limited because it tends to be too retrospective and retroactive. By being more proactive, these positions could help develop safer systems and prevent errors from happening.

The training opportunities for people in, or aspiring to be in, these types of roles were also discussed. There are three ASHP-accredited residency programs in patient safety, the Institute for Safe Medication Practices offers a safety fellowship, and the American Hospital Association and the Virginia Commonwealth University (VCU) have fellowships. These advanced training opportunities are highly regarded, but too few in number. The Council concluded that there needs to be more structured education, possibly through certificate programs or traineeships, to provide more formalized training for the hundreds or thousands of people who might need it.

The Council discussed whether medication safety officers should be pharmacists, or if nurses or physicians are also likely to be effective in this role. The Council concluded that medication safety officers should be pharmacists, but that it is equally critical that they include other disciplines when analyzing errors or developing new medication-use systems. Patient safety officer roles, in contrast, may be better suited for nurses or physicians with appropriate training.

Council members also discussed the need to consider small and rural hospitals, where resources may not allow a dedicated position. Their needs will be unique, and programs, education, resources, and other tools that ASHP might provide must keep small and rural hospitals in mind.

**Increased Capacity for Experiential Education Through New Teaching Models.** The Council discussed how changes in the pharmacy curriculum plus significant growth in the number of colleges of pharmacy has resulted in much greater demand for experiential training sites. This increased demand is creating challenges, since most of these rotations are completed in hospitals, and the number of hospitals is relatively stable.

The Council stated that the two most obvious ways to accommodate more experiential rotations are to expand experiential capacity into places that currently do not offer rotations and to expand capacity at existing sites. The value of standardization, such as with rotation schedules, learning objectives, evaluation forms, and preceptor development, was noted as a win-win for sites and colleges. Involving pharmacy residents in teaching experiential rotations can help, too. It becomes a great development experience for residents while helping meet capacity needs with pharmacy students.

**Role of Board Certification in Credentialing.** The Council discussed the role of board certification in credentialing, reviewing the Council on Credentialing in Pharmacy (CCP) resource paper, *The Scope of Contemporary Pharmacy Practice.* 

The Council discussed the role of a privileging and credentialing process, and where board certification fits into that process. The Council also discussed the structure and credibility of the Board of Pharmacy Specialties (BPS) certification process. The limited number of specialties and the limited number of individuals who are board certified was also discussed.

The Council voiced support for a structured privileging and credentialing process, at the institutional level, to determine competence and determine scope of practice for services to be provided.

Competencies Needed for Practice in Hospitals and Health Systems. There was a review of past Council discussions on the readiness of new pharmacy graduates for practice in hospitals and health systems. In 2009, ASHP and ACPE formed a task force to consider those competencies required specifically for practice in hospitals and health systems. This task force has developed 25 competencies, along with recommendations on how the competencies could be used. The task force report was presented to the Council and discussed.

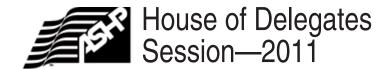
Council members recommended that the competencies be disseminated to colleges of pharmacy for use in developing rotation objectives. Those Council members at colleges of pharmacy acknowledged that with a growing number of competencies being identified by different groups, it becomes difficult to fit them all into the curriculum.

**Capacity for Pharmacy Residency Training.** While the number of residency programs and residency positions continues to grow, the demand for available positions by new pharmacy graduates is growing even faster, far exceeding capacity. The gap between applicants and positions peaked in 2010, with 2,915 applicants vying for just 1,951 available positions. The Council discussed the implications of not having enough residency-trained pharmacists to meet the patient-care needs of the future.

ASHP is planning a stakeholder meeting in early 2011, including other pharmacy organizations, to address the capacity issue. The Council discussed what steps ASHP might take to help grow residency capacity. The Council discussed the role that practice models

could play in residency training – both in training more residents and in creating demand for more residency-trained individuals. Hospitals are moving in this direction, but community pharmacy should be developing practice models that rely on residency-trained practitioners as well.

**National Healthcare Workforce Commission.** The Council discussed pharmacy workforce issues of interest to ASHP that might be topics suggested to the National Healthcare Workforce Commission established through the Accountable Care Act of 2010. Issues identified by the Council included interprofessional education to prepare pharmacists to meet future health care needs, especially in areas such as patient-centered care and team-based care; school expansion and the impact on pharmacist supply; faculty shortages; and availability of experiential sites. Other topics included funding for pharmacy students willing to go to underserved areas, support for state colleges, loan forgiveness for pharmacy students, residency capacity and residency funding, and the need for standardized, ASHP-accredited training and PTCB certification.



# Board of Directors Report on the Council on Pharmacy Management

The Council on Pharmacy Management is concerned with ASHP professional policies related to the process of leading and directing the pharmacy department in hospitals and health systems. Within the Council's purview are (1) development and deployment of resources, (2) fostering cost-effective use of medicines, (3) payment for services and products, (4) applications of technology in the medication-use process, (5) efficiency and safety of medication-use systems, (6) continuity of care, and (7) related matters.

Michael D. Sanborn, Board Liaison

#### **Council Members**

Linda S. Tyler, Vice Chair (Utah)
Larry W. Buie, New Practitioner (North Carolina)
Dominick A. Caselnova (Montana)
Cynthia A. Clegg (Washington)
James A. Klauck (Wisconsin)
Scott J. Knoer, Section of Pharmacy Practice Managers
Liaison (Minnesota)
Nancy A. Konieczny (Missouri)
Donald H. Lynx (Texas)
Ashley M. Overy, Student (Ohio)
Judith K. Schneider (Minnesota)
Ross W. Thompson (Massachusetts)
David B. Weetman (Iowa)
David R. Witmer, Secretary

Thomas E. Kirschling, Chair (Pennsylvania)

#### **Policy Recommendation**

# A. ASHP Statement on Leadership as a Professional Obligation

- 1 To approve the ASHP Statement on Leadership as a
- 2 Professional Obligation (Appendix).

# Background

In 2009, the Council recommended revising ASHP policy 9901, Fostering Pharmacy Leadership, to address the need for ASHP policy on leadership that is distinct from its many policies dealing with management. The Council believed that leadership is not the sole responsibility of pharmacy managers and noted that much of the

profession's progress toward achieving the vision of pharmacy as a clinical profession can be attributed to the leadership of strong clinical leaders who did not hold formal management titles. The Council supported the concept that leadership is a professional obligation of all pharmacists and believed ASHP policy should clearly articulate this concept. The Board was supportive of the intent of the changes but requested the Council to consider the development of a formal ASHP statement, given the broad nature of the topic. The Council agreed with the Board's suggestion and drafted a statement to reflect the Council discussion, the Board's recommendations, and the comments of more than 20 ASHP member reviewers.

#### **Board Actions**

**Sunset Review of Professional Policies.** As part of sunset review of existing ASHP policies, the following were reviewed by the Council and Board and found to still be appropriate. (No action by the House of Delegates is needed to continue these policies.)

- Pharmacy Benefits for the Uninsured (0101)
- Medication Formulary System Management (0102)

- Gene Therapy (0103)
- Patient Satisfaction (0104)
- Computerized Prescriber Order Entry (0105)
- Medication Management for Patient Assistance Programs (0603)
- Minimizing the Use of Abbreviations (0604)

#### **Other Council Activity**

#### Pharmacy's Role in Accountable Care Organizations (ACOs).

The Council discussed billing and reimbursement challenges and changes in health care financing that are likely to impact the way practitioners and health care organizations are compensated for care. Pharmacy directors currently face an increasingly daunting array of impractical and overly complex regulations pertaining to billing and reimbursement. Billing regulations differ in billing for inpatient and outpatient services, both for dispensing of drug products and for professional services. Billing for drugs involves a complex array of coding, including Healthcare Common Procedure Coding System (HCPCS) codes, J-codes, etc., and pharmacy and hospital finance software packages are often not designed to address the full array of coding necessary to bill accurately. Inconsistent interpretation of billing policy by the Centers for Medicare & Medicaid Services (CMS) further complicates billing. Another challenge is that health-system finance departments are not knowledgeable about the complexities of billing for drugs and pharmacists' services. Many pharmacy departments are devoting part or all of a position to working with hospital finance to maximize reimbursement and ensure compliance.

The Council discussed current trends and evolving models for health care reimbursement. The development of ACOs presents an opportunity to shift from the current complex array of billing practices to a model that focuses on delivery of quality, cost-effective care. The Council believed that ASHP should advocate that pharmacy play a key role in improving outcomes and reducing costs through effective implementation of pharmacy programs in ACOs. The Council believed that development of an official ASHP statement would be the best vehicle to communicate ASHP's vision for the role of pharmacy in ensuring the safe and effective use of medications in ACOs and voted to develop a statement on pharmacy's role in ACOs.

**Specialty Supply Channels.** The Council voted to develop ASHP guidelines on the use of specialty pharmacy services in hospitals and health systems. The Council discussed the pharmacy's responsibility for ensuring the safety and quality of drugs used in the care of patients within the health system. An array of specialty supply channels has emerged, resulting in fragmentation of the pharmacy drug supply chain. Pharmacies may be required to utilize a specialty pharmacy supplier as part of a Risk Evaluation and Mitigation Strategy (REMS) program, because insurers require use of that supplier to obtain reimbursement, or because a manufacturer chooses to use specialty pharmacy suppliers due to limited availability of product. In the case of insurance requirements, this sometimes means that the pharmacy must ensure that patients receiving the same treatment receive product from distinct sources. The Council discussed a position paper developed by the Massachusetts Society of Health-System Pharmacy, titled Conditions for Specialty Pharmacy Services in Health-System Pharmacy Practice. The paper establishes requirements for specialty pharmacy suppliers, including documentation of licensure and compliance with legal and regulatory requirements of state and federal authorities, delivery of patient-specific products directly to the pharmacy department in an expeditious fashion, and verification that the product meets all standards and requirements related to product pedigree, stability, sterility, potency, and labeling. All patient-specific medications provided by a specialty pharmacy to a health-system pharmacy must be received by the pharmacy department in a ready-to-administer dosage form at a clinically appropriate dosage, and the health-system pharmacy must be reimbursed appropriately for costs of storage, handling, and disposal.

The Council reviewed various related ASHP policies and the ASHP Guidelines on Outsourcing Sterile Compounding Services. The Council believed that ASHP policies touch on this issue in a broad manner but that there is a need for more specific guidance related to the requirements of specialty pharmacy suppliers and the pharmacy's role in ensuring the quality and safety of products obtained from these sources.

# Formulary Management of Off-Label Use of Medications.

The Council discussed the management of off-label medication use within hospitals and health systems. A significant percentage

of medication use falls outside of the uses listed in official product labeling. This is especially true for certain patient populations, such as oncology and pediatric patients. While the use of medication for indications outside of official labeling has always been common practice, these uses have faced more scrutiny in recent years, and this scrutiny is impacting medication use in hospitals and health systems. The use of drug products for off-label indications increasingly requires prior authorization. There have been significant changes in officially recognized compendia. These compendia vary greatly in the level of evidence required for inclusion of off-label uses.

The Joint Commission (TJC) requirements that took effect in 2009 require that medications must be reviewed for variations in hospital-approved indications for use. Pharmacy and Therapeutics (P&T) committees can adopt off-label uses when a drug is added to the formulary or may add these indications later. If the P&T committee has not approved an off-label indication, then TJC requires that the drug be handled as a nonformulary product. TJC does not allow the use of a blanket statement covering all indications supported by "well-controlled trials." These new requirements are challenging because most medication orders do not include the indication and because pharmacists are often not aware that some common uses are not included in the official labeling. Hospital computer systems are also not designed to support review of orders to identify off-label use for indications not approved by the P&T committee.

The Council reviewed the ASHP Statement on the Use of Medications for Unlabeled Uses, which has not been updated since it was first published in 1992. The Council believed that the statement should be updated to address issues discussed above and voted to revise the statement. Council members also suggested that ASHP should consider increasing efforts to address unlabeled uses in the American Hospital Formulary Service (AHFS) and consider development of a grading system for off-label uses. The Council also encouraged ASHP to provide education and other resources to assist members in complying with TJC requirements.

**Telepharmacy and Remote Pharmacy Services.** The Council discussed the evolution of technology, the pharmacy practice model, and the integration of health systems and voted to create an ASHP statement on telepharmacy and remote pharmacy services. When applied appropriately, technology can be used to supplement and improve the delivery of quality pharmacy services. Technology can also be viewed by some as a way to eliminate pharmacist positions. The Council noted that the term "telepharmacy" is often used in a very broad manner, encompassing a variety of functions, including order entry, order review and approval, supervision of technicians, authorizing distribution from remote dispensing units, and others. The Council noted that as hospitals and health systems merge, pharmacy leaders will be asked to be more efficient and to provide leadership and efficiencies across multiple facilities. It will be important that pharmacy is prepared to respond to these challenges with a clear vision of how technology can be used to enable highquality, cost-effective practice. The Council noted that there is little difference between order entry and review occurring on a different floor or a different building in a medical center complex and this function occurring at a site hundreds of miles away. The Council believed that centralizing some functions in remote locations is not necessarily inconsistent with expanding the access to pharmacists at the bedside. The Council also noted that other disciplines are providing highly complex services and consultations remotely, and current ASHP policy does not describe remote consultation by pharmacists. The Council believed ASHP should embrace a vision that technology should be utilized to support quality, improve efficiency, and expand access to pharmacy services, including workload leveling. The Council also believed that telepharmacy or other remote functions will be employed not just in small or rural hospitals but in large health systems as well. The Council also believed that ASHP should support and encourage research and demonstration projects.

**Managing Risk Evaluation Mitigation Strategies.** The Council discussed the impact of the growing number of REMS requirements on patient care in hospitals and health systems. The U.S. Food

and Drug Administration (FDA) has developed over 120 REMS. REMS are developed by the manufacturer and approved by the FDA. Each REMS is unique and there has been little standardization, resulting in a unique drug distribution system and sometimes a unique drug supply channel for each product. Requirements for education of health care personnel, documentation, source of product, and patient education vary and are not designed to be compatible with health-system computer or drug distribution systems. These programs are creating a growing administrative burden on pharmacy departments, but there is no compensation for this increased workload. While pharmacy departments assume a leadership role in managing compliance with REMS requirements, these programs also add administrative burdens to other health care personnel and departments.

The Council believed that ASHP should develop a preferred framework or a blueprint for REMS programs. Council members questioned whether REMS improve the safety of medication use and whether the fragmentation and confusion created by the lack of a consistent approach have the potential to increase the risk of errors. The Council believed that ASHP members are challenged to manage REMS and believed there may be opportunities for ASHP to develop programs or products that could assist pharmacists with management of these programs. The Council also encouraged ASHP and the ASHP Research and Education Foundation to support research on the impact of REMS. Data regarding the impact of REMS on prescribing, safety, costs, and workload would be useful, as well as information about other unintended consequences of REMS.

**International Organization for Standardization (ISO) Quality Methods and Det Norske Veritas (DNV).** The Council discussed quality measurement systems and their integration within accreditation processes. DNV is an independent foundation with the purpose of safeguarding life, property, and the environment. DNV is the first and only CMS-approved accreditation service that surveys annually and integrates ISO 9001 quality methods with CMS Conditions of Participation. DNV accreditation integrates ISO 9001 quality methods into the hospital setting, resulting in self-sustaining improvement.

The Council discussed the differences in approach between TJC and DNV accreditation. Both focus on quality and are underpinned by CMS Conditions of Participation, but they differ in their approaches. The Council believed ASHP and the Section of Pharmacy Practice Managers should engage members in hospitals and health systems that utilize DNV to learn more about this organization and the implications of this approach on pharmacy practice. ASHP should also educate members about DNV and ISO 9001 quality methods.

Prescriber Discretion in the Use of Recalled Products. The Council discussed prescriber discretion in the use of recalled products in response to a recommendation from the ASHP House of Delegates. The number of drug product recalls surged to 1742 in calendar year 2009 and has been steadily climbing for the last three years. At the same time, the number of drug product shortages has also grown; over 145 product shortages were listed on the ASHP Drug Shortages Resource Center. Both of these alarming trends are increasingly leading to circumstances in which critical, first-line therapeutic agents are not available for patient treatment, resulting in increased risk of treatment failure, medication errors, and adverse effects. In some circumstances, the risks to the patient associated with not using a drug product that is the subject of a Class III recall may outweigh the risks of administering the product. This circumstance potentially puts the provider and the health care institution in the untenable situation of resolving a conflict between the existing law and their ethical responsibilities to the patient.

The Council did not believe that ASHP should encourage the use of recalled products in patient care, except under extremely rare circumstances. Dispensing or administration of a recalled product would violate the Federal Food, Drug, and Cosmetic Act (FDCA), and possible penalties include both fines and imprisonment. The Council believed that only rarely would a situation arise in which no acceptable alternative medication was available and not administering a recalled product would present an imminent risk of harm to

the patient. It was suggested that in such circumstances pharmacists should engage the institution's ethics committee to determine an appropriate course of action to resolve this ethical dilemma. The Council noted that work is beginning on the development of ASHP guidelines on managing drug product recalls and suggested that this topic be included in the guidelines when they are developed.

Standardized Pharmacy Workload Unit. In response to a recommendation from the ASHP House of Delegates, the Council discussed the concept of a standardized pharmacy workload unit. The topic of monitoring and reporting pharmacy workload is one that is continuously on the agenda for the Council and was discussed extensively last year. The Council did not believe that it would be feasible to develop a single workload unit of measure that would be universally applicable but remained concerned that pharmacy directors need to be better equipped to capture productivity data and present and discuss this information effectively with hospital and health-system administrators. Pharmacy leaders need to engage in a process of identifying and capturing key workload and productivity data and linking that data to hospital quality measures. The Council noted that the reporting of workload and quality information needs to be viewed as a process of continuous review and assessment rather than as an outcome.

The Council reviewed resources available to hospitalists and believed that ASHP should aggressively explore the development of similar tools for its members. While it would be useful, the development of a workload monitoring system similar to the old *Pharma-Trends* is not the only product that could meet members' needs. Tools similar to the Society for Hospital Medicine's *Measuring Hospitalist Performance: Metrics, Reports, and Dashboards* that assist members in conceptualizing and implementing an effective program for quality and productivity and in organizing and presenting data to hospital administrators would be extremely useful to pharmacy leaders. The inclusion of templates or model dashboards would also be helpful. The Council strongly encouraged ASHP to devote resources to developing products that support pharmacy leaders' efforts to organize and report quality and productivity measures in their institutions.

Standardized Process for Medication Reconciliation. The Council discussed the management of the medication reconciliation process in hospitals and health systems. The Council noted that there are many approaches to implementing effective medication reconciliation, including use of pharmacists, pharmacy technicians, or technology, as well as coordination of other health care personnel, among others. It was noted that models for providing medication reconciliation are still evolving and will likely evolve further, along with the pharmacy practice model. The Council also noted that state laws vary greatly regarding the use of pharmacy technicians. The Council believed that the development of guidelines would be premature, as best practices are still evolving rapidly. Rather, the Council encouraged ASHP to provide education and networking opportunities. The Council also was aware of discussion by the Council on Pharmacy Practice regarding a consensus statement on key principles of medication reconciliation, titled Making Inpatient Medication Reconciliation Patient Centered, Clinically Relevant, and Implementable: A Consensus Statement on Key Principles and Necessary First Steps and supported the Council on Pharmacy Practice's recommendation that ASHP consider endorsing this document.

**Pharmacy Compounding Accreditation Board (PCAB).** In response to a recommendation from the ASHP House of Delegates, the Council discussed the role of PCAB accreditation when outsourcing pharmacy compounding services. ASHP policy 0617, Accreditation of Compounding Facilities, encourages facilities providing extemporaneous compounding to seek "accreditation by a nationally credible accreditation body." The ASHP Guidelines on Outsourcing Sterile Compounding Services recommend that contract terms should include a requirement that services meet or exceed applicable accreditation and certification standards and includes PCAB among several organizations that might be considered. The Council believed current ASHP policy was sufficient and recommended no changes.

# Appendix—ASHP Statement on Leadership as a Professional Obligation

#### Position

The American Society of Health-System Pharmacists (ASHP) believes that all pharmacists have a professional obligation to serve as leaders in the safe and effective use of medications and encourages pharmacy practitioners, administrators, faculty members, preceptors, and students to advance patient care and strengthen the pharmacy profession by embracing the responsibility to exert leadership in their practices. ASHP urges all pharmacists to accept this responsibility, actively seek the development of leadership skills, and exercise leadership when working with others, including other pharmacists, pharmacy technicians, pharmacy students and residents, administrators, other health professionals, and patients.

ASHP encourages colleges of pharmacy to go beyond management coursework and integrate education on leadership as a practice philosophy throughout the pharmacy curriculum. All pharmacists share the responsibility to mentor pharmacy students, pharmacy residents, other pharmacists, and pharmacy technicians. Pharmacists in formal leadership roles have a specific responsibility to foster the development of leadership skills in pharmacists, facilitate the development of practice models that provide regular opportunities to exercise leadership, and encourage pharmacists to exercise leadership in practice. ASHP also encourages hospital and health-system executives to support the development of leadership skills of all health care professionals.

## **Leadership in Practice**

The ASHP Statement on Professionalism<sup>1</sup> includes leadership as one of ten characteristics of a professional, and the ASHP Statement on the Roles and Responsibilities of the Pharmacy Executive<sup>2</sup> explains the formal leadership roles of the pharmacy executive. But neither of these documents describes the professional obligation every pharmacist has to serve as a leader in the safe and effective use of medications.

Definitions of leadership commonly focus on working toward goals and exerting influence.<sup>3</sup> For example, Nahata states that "[I]eadership is about a vision, direction, strategies, motivating, and inspiring."<sup>4</sup> The focus on goals and influence guides understanding of the inherent requirement for leadership in pharmacy. The success of current pharmacy practice models, and of achieving the goal of implementing future models that may emerge, rests on the ability of members of the profession to successfully influence others. In the complex and evolving health care environment, leadership from pharmacists is required to promote and advance the profession and our care for patients. Thus, leadership is not an option, it is a professional obligation.

The ASHP Research and Education Foundation convened a Student-New Practitioner Leadership Task Force that generated a report titled Addressing the Pharmacy Leadership Gap: Leadership as a Professional Obligation.5 The report addressed several issues regarding the current perceptions of leadership in the pharmacy profession, methods for training pharmacy leaders, and the challenges presented by the leadership gap defined by White in her ASHP Foundation Scholar-in-Residence Report, Will There Be a Pharmacy Leadership Crisis? The Task Force report noted that leadership and management are different, stating that despite the synonymous use of "management" and "leadership" within the literature, hierarchy does not confer leadership, nor does leadership confer hierarchy. As Stephen Covey has said, "Management works in the system; leadership works on the system."7 He has also further differentiated the concepts of leadership and management, saying, "Effective leadership is putting first things first. Effective management is discipline, carrying it out. Although the two terms are often used synonymously, leadership is a broader and more encompassing concept that extends to a wider array of situations, whereas management has a more specific focus.

The most successful organizations facilitate the development of routine leadership roles and encourage participation in those roles. Frontline pharmacists must exhibit themselves as leaders each time they step into the workplace. The practice of effectively influencing the behavior of physicians, nurses, pharmacy technicians, interns, support staff, and others to optimize medication safety and patient outcomes constitutes successful leadership. Innovative practice models can support the development of both clinical and leader-

ship skills. ASHP encourages these types of practice models and their development.

The obligation to develop practitioners prepared for professional leadership requires colleges of pharmacy to adopt such values. Currently, leadership training is inconsistently present both in academic and practice settings. The Task Force report noted that pharmacy curricula commonly offer elective management courses without addressing fundamental leadership skills in a proactive or longitudinal manner, and that the concept of using management training to teach leadership skills has led to further gaps in how new pharmacists perceive leadership. The report emphasized the need for increased focus on leadership training in colleges of pharmacy and recommended that these institutions incorporate formalized leadership training throughout the curriculum in a formal, longitudinal manner and not exclusively through management coursework.<sup>5</sup>

White's survey of student and new practitioners demonstrated that students and new practitioners are likely to be mentored by frontline pharmacists, supporting the critical need for expressions of leadership.<sup>6</sup> All pharmacists should take personal responsibility for leadership of the medication-use process and for mentorship of students, residents, and colleagues. Although it is not the exclusive responsibility of formal pharmacy leaders such as pharmacy directors and managers, formal leaders must foster and support pharmacist leadership.

The report of the American Association of Colleges of Pharmacy Argus Commission, *Building a Sustainable System of Leadership Development for Pharmacy*, also argues that leadership is a responsibility for all pharmacists. The report calls for integration of leadership throughout pharmacy education and offers a number of specific recommendations. To support leadership development of students and practitioners, the report recommends greater focus on fostering leadership education in pharmacy curricula, in residencies, and in practice sites. To cultivate high-quality candidates to fulfill the pharmacy leadership gap, the report also recommends expansion of didactic leadership training, distance learning programs, the use of social media for networking and mentorship, and an increased focus on the full spectrum of leadership. Colleges should also assess leadership potential during the application and selection process.

Pharmacists also have an obligation to exert leadership and participate in shaping the future of the profession. Participation in professional societies such as ASHP provides opportunities to shape the future of the profession and afford excellent opportunities for the development of leadership skills. Professional organizations such as ASHP also have an obligation to encourage the development of leadership skills and support their development among their memberships.

#### Conclusion

Leadership is a professional obligation of all pharmacists and not the exclusive responsibility of pharmacists who hold formal leadership roles or titles. All pharmacists should accept the obligation to develop and exert leadership skills to ensure the safe and effective use of medications. Pharmacy schools, professional organizations, and employers should encourage the development of these skills among students and practitioners and should provide both formal training and create opportunities for pharmacists to develop leadership capacity.

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# Board of Directors Report on the Council on Pharmacy Practice

The Council on Pharmacy Practice is concerned with ASHP professional policies related to the responsibilities of pharmacy practitioners in hospitals and health systems. Within the Council's purview are (1) practitioner care for individual patients, (2) practitioner activities in public health, (3) pharmacy practice standards and quality, (4) professional ethics, (5) interprofessional and public relations, and (6) related matters.

Janet L. Mighty, Board Liaison

#### **Council Members**

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Suzanne R. Schrater (Kansas)
Majid R. Tanas, New Practitioner (Oregon)
Jeffrey T. Thiel (Illinois)
Bona E. Benjamin, Secretary

#### **Policy Recommendations**

# A. Pharmacist Accountability for Patient

- 1 To affirm that pharmacists are obligated by their cov-
- 2 enantal relationship with patients to ensure that medi-
- 3 cation use is safe and effective; further,
- 4 To declare that pharmacists are autonomous profes-
- 5 sionals on the interdisciplinary patient-care team and
- 6 accountable for safe and effective medication therapy
- 7 outcomes pursuant to their authority over a specialized
- 8 body of knowledge; further,
- 9 To encourage pharmacists to define practices and as-
- 10 sociated measures of effectiveness that support their
- 11 accountability for patient outcomes; further,
- 12 To promote pharmacist accountability as a fundamental
- 13 component of pharmacy practice to other health care
- 14 professionals, standards-setting and regulatory organiza-
- 15 tions, and patients.

#### Rationale

The Council agreed that a clear, succinct policy communicating the interrelationship of authority and autonomy with accountability for outcomes, good or bad, is needed. The policy should distill and define ASHP's stance on accountability and draw on concepts implicit in current ASHP policy documents. Pursuant to review of background documents, the Council recognized that authority, autonomy, and accountability are inseparable components of professional practice. Without accountability, the pharmacy profession cedes the ultimate

authority for decision-making in matters of medication therapy to prescribers, calling into question whether pharmacy is, in fact, a profession.

The Council noted that the pharmacist's covenantal relationship with patients is described in the *Pharmacist's Oath*, to which all pharmacy students profess, and which states in part:

- I will consider the welfare of humanity and relief of suffering my primary concerns.
- Î will apply my knowledge, experience, and skills to the best of my ability to assure optimal outcomes for my patients.
- I will embrace and advocate changes that improve patient care.

The Council discussed the attributes of professional status that are defined by sociological, ethical, and legal expectations in literature on this subject. Those commonly cited include:

- Work is based upon the mastery of a complex body of knowledge and skills; a practice founded upon this knowledge is used in the service of others.
- Members are governed by codes of ethics and profess a commitment to competence, integrity, and . . . promotion of the public good within their domain.
- A social contract exists in which, in exchange for these commitments, society recognizes the profession's authority over the knowledge base, autonomy in practice, and the privilege of self-regulation.
- The profession's members are accountable to those served and society.

Despite strong advocacy by pharmacy thought leaders and a wealth of evidence in its support, the precept that pharmacists are accountable for medication therapy outcomes is not widely accepted by other health care disciplines, nor is it broadly integrated into pharmacy practice. Moreover, many pharmacists may

be ambivalent about assuming a role that holds them to high standards of practice and makes them answerable for the welfare of patients.

Accountability is implicit in many ASHP policy documents, most notably in the ASHP Statement on Pharmaceutical Care:

Pharmaceutical care is not a matter of formal credentials or place of work. Rather, it is a matter of a direct personal, professional, responsible relationship with a patient to ensure that the patient's use of medication is optimal and leads to improvements in the patient's quality of life.

The pharmacist's authority over and expertise in use of medications are supported by the Centers for Medicare & Medicaid Services (CMS) Conditions of Participation Interpretive Guidelines, which establish a definition and expectation for pharmaceutical care:

Pharmaceutical care is defined as the direct, responsible provision of medication-related care for the purpose of achieving definite outcomes that improve a patient's quality of life while minimizing patient risk.

The Statement on the Future Vision of Pharmacy Practice from the Joint Commission of Pharmacy Practitioners (JCPP) is explicit in its expectation for pharmacist autonomy and accountability and states in part:

How Pharmacists Will Practice. Pharmacists will have the authority and autonomy to manage medication therapy and will be accountable for patients' therapeutic outcomes. In doing so, they will communicate and collaborate with patients, care givers, health care professionals, and qualified support personnel. As experts regarding medication use, pharmacists will be responsible for rational use of medications, including the measurement and assurance of medication therapy outcomes.... Working cooperatively with practitioners of other disciplines to care for patients, pharmacists will be ... valued patient care providers whom health care systems and payers recognize as having responsibility for assuring the desired outcomes of medication use.

The Council agreed that the JCPP vision statement clearly illustrates the direction that the pharmacy profession must take. In particular, the Council confirmed that pharmacist accountability is a profession-defining issue that must be urgently addressed. However, the Council cautioned that the recommended policy is at most a starting point for the transformation that needs to take place in order to realize the JCPP vision.

The Council stated that unless the pharmacy profession commits to actions that translate the policy into practice, pharmacists are at risk of becoming irrelevant. As changes brought about by health care reform are implemented to add value to health care and reduce costs, the extensive training and high salaries of pharmacists cannot be justified if, as noted by the 2007 Council, "pharmacists are responsible and held accountable only for the acquisition, storage, and dispensing of medications."

The Council called on ASHP to be fearless and persistent in promoting and establishing the JCPP vision within the profession. The Council also recommended that ASHP use its influence to create the "pull" for accountability in pharmacy practice by establishing an expectation of pharmacist accountability by other health care providers, standards-setting and regulatory organizations, and payers.

#### Background

The Council deliberated this topic in light of health care reform, the American Medical Association's recent efforts to limit pharmacists' scope of practice, and the ASHP Pharmacy Practice Model Initiative (PPMI), all of which pose substantial questions about the extent and nature of pharmacist accountability. Although the issue of accountability was a central topic at the PPMI Summit in November 2010, the Council did not see a reason to defer its charge to define accountability and recommend translational actions.

#### **B.** Just Culture

- 1 To recognize that the principles of *just culture* promote
- 2 an environment in health care organizations in which
- 3 safety is valued, reporting of safety risks is encouraged,
- 4 and a fair process is used to hold staff and leaders ac-
- 5 countable; further,
- 6 To encourage hospitals and health systems to include
- 7 just culture as a component in organizational safety
- 8 culture surveys and quality improvement initiatives.

#### Rationale

The Council believed and the Board agreed that a specific ASHP policy supporting *just culture* principles should be developed, and that education on the topic should be an important focus for ASHP. The Council reviewed principles and methods established by David Marx, a systems safety engineer and *just culture* educator, and noted the following (Marx, D. *Whack-a-Mole: The Price We Pay for Expecting Perfection.* Plano, TX: By Your Side Studios; 2009):

- The notion that humans can perform perfectly if they are well trained and continuously vigilant is unrealistic. Humans will never be perfect.
- Safe environments anticipate human error and systems are designed accordingly. However, systems will never be perfect.
- Individuals are accountable for behavioral choices that lead to error and leaders are accountable for establishing environments that encourage reporting of unsafe conditions and adverse events.
- Behaviors that cause or may cause errors are addressed regardless of whether harm occurs.
- Individual culpability for adverse events is assessed using a decision algorithm that defines attributes of behaviors and systems and can be summarized as follows:
  - 1. **Human error:** inadvertent; a mistake; doing other than what should have been done.

*Origin:* System design, processes, procedures, training. *Manage by:* correcting system, supporting employee.

- At-risk behavior: behavioral choice that increases risk where
  risk is not recognized or is mistakenly believed to be justified.
   Origin: System inefficiencies, such as steps that create
  - **Origin:** System inefficiencies, such as steps that create rework, are burdensome, or seem irrelevant to outcome. The system incentivizes workarounds and shortcuts that are unsafe.

**Manage by:** Improving procedures or processes to remove incentives and reward safe behaviors.

Reckless behavior: choosing to behave in a manner that places others at substantial and unjustifiable risk knowing that harmful outcome is likely but indifferent to it.

Origin: the individual.

Manage by: remedial action, punitive action.

4. Negligence: determined by using the substitution test, i.e., would another individual in the same work area with comparable experience and qualifications have behaved any differently?

The Council identified significant advantages to this approach, one of the most important being that it encourages reporting of adverse events and provides essential information for improving systems and processes of care. In addition, holding individuals accountable by using criteria to distinguish between behaviors that do or do not merit punishment was perceived to be fairer than a strictly punitive or strictly blame-free approach. Another positive attribute of *just culture* is that behaviors associated with error are handled with the appropriate responses regardless of whether harm resulted. By focusing on behaviors rather than outcomes, potential errors are averted, safe behaviors are encouraged, and at-risk or reckless behavior is not tolerated.

The Council recognized that while the *just culture* approach has been accepted by safety leaders, implementation is challenging for a number of reasons. The goals of *just culture*—to sustain a nonpunitive reporting and learning environment, yet hold individuals

accountable for their behavior—seem contradictory. Methods for differentiating behaviors for which to hold an individual accountable tend to use subjective, rather than objective, criteria, and may lead to misinterpretation. Maintaining the *just culture* approach is particularly challenging under the pressure of media coverage and legal liability when a patient is harmed or dies from an error. The belief that individual practitioners are solely responsible for their errors continues to predominate in the health care professions.

The Council noted that decision-making tools and education are available to support implementation of a *just culture*. They suggested that ASHP consider providing education and practical tools for implementing fair processes for holding individuals and leadership accountable for medication safety. Council members also characterized *just culture* as a component of the larger issue of culture of safety and proposed that assessment of *just culture* as part of assessing general safety culture should be included in ASHP's national survey.

#### Background

The Council considered this topic in response to Board discussion following revisions of the definition of *just culture* in ASHP policy in the 2009 and 2010 House of Delegates. Board members had suggested that a precise and unambiguous rationale is needed to provide clarity to members on the topic. The Board also noted the challenges of writing such guidance on a model for managing adverse events that has only recently become adopted and that the policy would likely be further refined as the model is tested.

#### C. Ethical Use of Placebos in Clinical Practice

- 1 To affirm that the use of placebos in clinical practice
- 2 is ethically acceptable only when patients have been
- 3 informed of and agree to such use as a component of
- 4 treatment; further,
- 5 To encourage hospitals and health systems to develop
- 6 policies and procedures to guide clinicians in making in-
- 7 formed decisions regarding the use of placebos; further,
- 8 To oppose the use of pharmacologically active sub-
- 9 stances or medications as placebos.

(Note: This policy would supersede ASHP policy 0517.)

#### Rationale

The Council reviewed previous action on ASHP policy 0517, the American Medical Association (AMA) *Opinion on Placebo Use in Clinical Practice*, and the *ASHP Guidelines on Clinical Drug Research*, which state in part:

The principal investigator or designee is responsible for obtaining informed consent from each subject who is eligible for participation in the study (i.e., meets inclusion and exclusion criteria). The informed consent process shall conform to current federal and state regulations. IRB approval of the consent form (and assent form for minors) is required. Review by legal counsel may be desirable.

After comparing use of placebos for research to prescribing for clinical use, the Council agreed with the stance expressed by AMA, i.e., patients should be informed of and agree to use of a placebo as a therapeutic intervention. The Council believed that the informed consent process should be reserved for research and medical interventions, where a consent contract and oral explanation of the patient's rights are required. In addition, the Council expressed concern that advocating informed consent could lead to a mistaken assumption that clinical use of placebos requires the review and approval of an institutional review board.

The Council disputed the AMA definition of a placebo as "a substance provided to a patient that the physician believes has no specific pharmacological effect upon the condition being treated,"

however, and recommended that a placebo should be defined as an inert substance. Research on placebos found differing definitions of the term but did not provide an established or official definition. The Council concluded that the current policy lacks clarity in that it addresses an undefined term. The Council requested that ASHP identify the appropriate standards-setting or regulatory body to provide this definition or determine whether ASHP should establish a definition for the purpose of its policy.

The Council noted a number of other unresolved issues that require further exploration and action by ASHP. These include research for definitive guidance on the ethics of clinical placebo use, potential ethical dilemmas for pharmacists, and compliance with professional standards and regulatory requirements for reviewing placebo orders for appropriateness, labeling placebo prescriptions, and counseling patients. The Council suggested a comprehensive review by a bioethicist be published in *AJHP*.

## Background

The Council voted and the Board agreed to revise ASHP policy 0517, Ethical Use of Placebos, as follows (<u>underscore</u> indicates new text; <u>strikethrough</u> indicates deletions):

- 1 To affirm that the use of placebos in clinical practice is ethically
- 2 acceptable ethically only when patients grant informed consent
- 3 for the have been informed of and agree to such use of placebos
- 4 as a component of treatment; further,
- 5 To encourage each health care facility hospitals and health
- 6 systems to develop a-policiesy and procedures to guide its
- 7 clinicians in making informed decisions regarding the use of
- 8 placebos: further,
- 9 To oppose the use of pharmacologically active substances or
- 10 medications as placebos.

## D. Pharmacists' Role in Medication Reconciliation

- 1 To affirm that an effective process for medication rec-
- 2 onciliation reduces medication errors and supports safe
- 3 medication use by patients; further,
- 4 To advocate that pharmacists, because of their distinct
- 5 knowledge, skills, and abilities, should take a leadership
- 6 role in interdisciplinary efforts to develop, implement,
- 7 monitor, and maintain effective medication reconcili-
- 8 ation processes; further,
- 9 To encourage community-based providers, hospitals,
- 10 and health systems to collaborate in organized medica-
- 11 tion reconciliation programs to promote overall conti-
- 12 nuity of patient care; further,
- 13 To declare that pharmacists have a responsibility to
- 14 educate patients and caregivers on their responsibility
- 15 to maintain an up-to-date and readily accessible list of
- 16 medications the patient is taking and that pharmacists
- 17 should assist patients and caregivers by assuring the
- 18 provision of a personal medication list as part of patient
- 19 education and counseling efforts.

(Note: This policy would supersede ASHP policy 0620.)

#### Rational

The Council reviewed proposed changes to The Joint Commission (TJC) national patient safety goal requiring medication reconciliation. The Council expressed support for TJC's intent to make the goal more achievable while continuing to support patient safety

and recommended policy changes where indicated in order to align with  $\ensuremath{\mathrm{TJC}}$  standards.

The Council noted that ASHP policy did not include an affirmation of the value of medication reconciliation in both patient care and patient safety and recommended a revision in support of the medication reconciliation process. The Council also noted that the revised goal no longer requires a list of medications, only "information on the medications the patient is taking." The Council recommended changes in policy language that delete references to a list as an essential component of medication reconciliation and emphasize the pharmacist's role.

Council members expressed concern that current policy language could be misinterpreted as placing sole responsibility for implementation of medication reconciliation on the pharmacy department and believed the policy should acknowledge other equally invested stakeholders in the medication-use process. The Council emphasized, however, that pharmacists are the health care professionals who should promote medication reconciliation practices that ensure good patient outcomes. They stated that pharmacy leadership in developing and guiding an organizational approach to medication reconciliation is more important than ever.

#### Background

The Council voted and the Board agreed to recommend amending ASHP policy 0620, Pharmacists' Role in Medication Reconciliation, as follows (<u>underscore</u> indicates new text; <del>strikethrough</del> indicates deletions):

- 1 To affirm that an effective process for medication reconciliation
- 2 reduces medication errors and supports safe medication use by
- 3 patients; further,
- 4 To ensure that pharmacists are responsible for coordination
- 5 of interdisciplinary efforts to develop, implement, maintain,
- 6 and monitor the effectiveness of the medication reconciliation
- 7 process; further,
- 8 To advocate that pharmacists, because of their distinct knowl-
- 9 edge, skills, and abilities, should take a provide the leadership
- 10 role in of an interdisciplinary efforts to establish systems for
- 11 ensuring the accuracy and completeness of all medication lists
- 12 taken at admission and for communication of a reconciled list
- 13 of medications at any change in level of care and at discharge;
- 14 develop, implement, monitor, and maintain effective medication
- 15 reconciliation processes; further,
- 16 To encourage community-based providers, hospitals, and health
- 17 systems to collaborate in organized medication reconciliation
- 18 programs to promote overall continuity of patient care; further,
- 19 To declare that pharmacists have a responsibility to educate
- 20 patients and caregivers on their responsibility to maintain an
- 21 up-to-date and readily accessible list of medications the patient is
- 22 taking and that pharmacists should assist patients and caregivers
- 23 by assuring the provision of a personal medication list as part of
- 24 patient education and counseling efforts.

#### **Board Actions**

**Medication Reconciliation.** The Council recommended and the Board voted

To endorse the Society of Hospital Medicine statement, Making Inpatient Medication Reconciliation Patient Centered, Clinically Relevant, and Implementable: A Consensus Statement on Key Principles and Necessary First Steps.

The Council reviewed a guideline document on implementing medication reconciliation as requested by the Society of Hospital Medicine (SHM). The SHM statement summarizes recommendations from the multidisciplinary conference, Medication Reconciliation: A Team Approach, funded by the Agency for Healthcare Research and Quality and held in March 2009. ASHP staff participated in the conference planning task force, the conference, and the document review process.

The Council agreed with the premise of the statement, that medication reconciliation is an important component of medication safety, regardless of the status of accreditation requirements. The concepts presented in the paper were considered to be consistent with ASHP policy on medication reconciliation and appropriate for endorsement by the Board of Directors. The Council noted that, while ASHP has a policy on pharmacists' role in medication

reconciliation, a policy is needed that similarly affirms the value of medication reconciliation as a safety procedure. The Council also noted that one challenge to implementation of medication reconciliation is lack of agreement and/or coordination among the disciplines on their individual roles in medication reconciliation and suggested that the consensus statement would provide useful background for members struggling with these issues.

**Sunset Review of Professional Policies.** As part of sunset review of existing ASHP policies, the following were reviewed by the Council and Board and found to still be appropriate. (No action by the House of Delegates is needed to continue these policies.)

- Pharmacist's Right of Conscience and Patient's Right of Access to Drug Therapy (0610)
- Safe Disposal of Patients' Home Medications (0614)
- Influenza Vaccination Requirements to Advance Patient Safety and Public Health (0615)
- Safe and Effective Extemporaneous Compounding (0616)
- Accreditation of Compounding Facilities (0617)
- Elimination of Surface Contamination on Vials of Hazardous Drugs (0618)
- Integrated Team-Based Approach for the Pharmacy Enterprise (0619)

#### **Other Council Activity**

**Best Practices for Infusion Overfill and Priming Intravenous Administration Sets.** The Council voted to develop guidelines for priming intravenous (IV) sets for hazardous medications. The Council determined that, despite several ASHP guidance documents that include recommendations for priming tubing, practices for implementing these recommendations vary widely.

Council members suggested that additional guidance might promote a standardized approach to priming of IV sets, and one Council member identified a number of procedural questions that remain unresolved. Council members agreed that, while priming IV tubing and the attendant unresolved issues may not require a policy, the need for definitive guidance is an ongoing concern for practitioners. The Council voiced its support for actions to achieve consensus and recommended that development of the proposed guidance should involve content experts from regulatory and patient safety groups as well as other health care stakeholder groups.

**Statement on Reporting Medical Errors.** The Council voted to revise the ASHP Statement on Reporting Medical Errors. In its discussion of the statement as part of sunset review, Council members noted that the Patient Safety and Quality Act of 2005 is not referenced in the statement, but that many of the concepts in the statement are reflected in the legislation. The Council recommended that revisions include supporting the Act and patient safety organizations (PSOs), urging health care organizations to report adverse events to PSOs, incorporating concepts of *just culture*, encouraging a safety culture in health care organizations, and removing the reference to U.S. Pharmacopeia's reporting system. The Council also recommended changing the title of the statement to "ASHP Statement on National Reporting of Medication Errors" or including in the revised statement the rationale for focusing on medical rather than medication errors.

**Professionalism and Social Media.** The Council discussed both the benefits and risks of Web 2.0 applications, specifically the capability of immediately communicating both professional and personal information. They expressed concern that many users, especially students, share personal information freely without regard for who may be viewing it and offered numerous examples of patient condentiality violations. Council members were uncertain regarding guidance provided by schools of pharmacy on professionalism in social media interactions.

The Council also discussed a separate but related issue of using information obtained from social media websites for hiring and other human resource decisions. Council members noted that while this practice is common, it raises a number of questions that should be explored, such as the validity of the information from these sources. The Council encouraged ASHP to continue exploring how best to use social media tools, especially for facilitating professional interaction among pharmacists and between pharmacists and the public.

**Pharmacist Resources for Safe Disposal of Patients' Home Medications.** In its discussion reaffirming ASHP policy 0614, Safe Disposal of Patients' Home Medications, the Council suggested several actions ASHP might consider to implement the policy. The Council characterized disposal of pharmaceutical waste as an emerging societal problem as well as a patient safety risk. The Council considered this issue especially relevant to practice, in part because pharmacists are obligated "to minimize the patient safety consequences and public health impact of inappropriate disposal of patients' home medications," as stated in the policy, as well as to counsel patients appropriately on disposal of home medications. The Council emphasized that some of the available guidance is unclear or lacking such information as methods to effectively educate patients on home disposal, strategies for patients to reduce or avoid waste, and how patients should handle controlled substances.

The Council also noted that there is no clear directive on how hospitals should handle home prescriptions for controlled substances stored upon admission for inpatients but not returned because the prescriptions are no longer needed on discharge. The Council suggested that ASHP evaluate existing guidance on disposal of home medications and determine the need to address unclear areas identified by the Council and take other actions, if indicated.

**Translational Actions for Pharmacist Accountability.** The Council discussed the gap between the proposed policy on pharmacist accountability and current practice, as well as actions to address the disparity and offered a number of suggestions or translational activities.

**Elimination of Surface Contamination on Vials of Hazardous Drugs.** The Council suggested that strong advocacy is needed to encourage FDA action to strengthen requirements for eliminating contamination of the external surfaces of medication containers. In addition, the Council suggested that advocacy include advocating separation of delivery containers for hazardous and nonhazardous products in the supply chain.

National Coordinating Council on Medication Error Reporting and Prevention (NCC MERP) Statement on Criminalization of Errors in Healthcare. The Council reviewed the draft statement and believes the statement aligns with ASHP policy. They had no substantive changes to recommend and requested that the final statement, anticipated to be available in early 2011, be considered for endorsement by ASHP. The Council also suggested for ASHP consideration a number of methods to monitor implications of this issue for the profession and communicate the Society's position.

**Drug Shortages and Patient Safety.** The Council offered their experiences and perspectives on the issue of drug shortages and its implications for patient safety. Council members expressed growing concern about the increased number of shortages, identified the most pressing issues in their organizations, and suggested a number of potential solutions for ASHP evaluation.

**Modernization of CMS Conditions of Participation and Interpretive Guidelines.** The Council reviewed ASHP's 2010 advocacy brief summarizing priority issues on which ASHP should focus advocacy efforts to update CMS standards. The brief was developed as a result of a comparison of guidance in the CMS State Operations Manual (SOM) with ASHP's Best Practices for Hospital & Health-System Pharmacy and methods used by other accrediting organizations.

The Council also reviewed a crosswalk of recommended revisions to applicable SOM statutes and guidance and best practices and provided a number of recommendations for ASHP's consideration.

The Council requested clarity regarding the applicability of the CMS statutes to hospitals that include ambulatory clinics in their services. They also recommended that ASHP consider addressing broader issues, such as inconsistent survey methods among state surveyors and ensuring that CMS standards undergo a periodic review and revision that includes involvement of practitioners and other health care stakeholders.

**Education About Patient Safety in the Medication-Use Process.** Pursuant to its discussion on *just culture*, the Council suggested that the Council on Education and Workforce Development consider amending ASHP policy 0914, Education About Patient Safety in the Medication-Use Process, to include instruction on *just culture* concepts in patient safety education. The Council further recommended that student societies would benefit from resources on *just culture*, such as a sample presentation, and education on legal and public perspectives of medication error, and recommended that this suggestion be forwarded to the ASHP Student Forum.

**Incorporation of** *Just Culture* **Concepts in ASHP Documents on Medication Misadventures.** The Council noted a number of ASHP documents focused on medication misadventures that require updating and suggested that some of these could be consolidated. The Council recognized the magnitude of this proposed work; however, the Council believed that once completed, the clarity and consistency of guidance would greatly strengthen ASHP's influence in setting high standards for medication-use safety. The Council also suggested that ASHP educate other health care disciplines and the public on *just culture* as part of its leadership role in medication-use safety.

# Board of Directors Report on the Council on Public Policy

The Council on Public Policy is concerned with ASHP professional policies related to laws and regulations that have a bearing on pharmacy practice in hospitals and health systems. Within the council's purview are (1) federal laws and regulations, (2) state laws and regulations, (3) analysis of public policy proposals that are designed to address important health issues, (4) professional liability as defined by the courts, and (5) related matters.

Randy L. Kuiper, Board Liaison

#### Council Members

David A. Ehlert, Chair (Minnesota)
Amber J. Lucas, Vice Chair (Kansas)
Emily Alexander (Texas)
Kristina L. Butler (Oregon)
Melanie A. Dodd (New Mexico)
Karen Vitacolonna Falk (New York)
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Kevin C. Marvin (Vermont)
Mitchell A. Pelter (California)
Robert L. Spires (South Carolina)
Greg A. Teale (Missouri)
Brian M. Meyer, Secretary

# **Policy Recommendations**

#### A. Drug Product Shortages

- 1 To advocate that the Food and Drug Administration
- 2 (FDA) have the authority to require manufacturers to
- 3 report drug product shortages and the reason(s) for the
- 4 shortage, and to make that information available to the
- 5 public; further,
- 6 To strongly encourage the FDA to consider, in its defini-
- 7 tion of "medically necessary" drug products, the patient
- 8 safety risks created by use of alternate drug products
- 9 during a shortage; further,
- 10 To support government-sponsored incentives for manu-
- 11 facturers to maintain an adequate supply of medically
- 12 necessary drug products; further,
- 13 To advocate laws and regulations that would (1) require
- 14 pharmaceutical manufacturers to notify the appropri-
- 15 ate government body at least 12 months in advance of
- 16 voluntarily discontinuing a drug product, (2) provide
- 17 effective sanctions for manufacturers that do not com-
- 18 ply with this mandate, and (3) require prompt public
- 19 disclosure of a notification to voluntarily discontinue
- 20 a drug product; further,
- 21 To encourage the appropriate government body to
- 22 seek the cooperation of manufacturers in maintaining

- the supply of a drug product after being informed of a voluntary decision to discontinue that product.
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(Note: This policy would supersede ASHP policy 0319.)

#### Rationale

ASHP advocates strengthened authority for the FDA and other government agencies in addressing drug product shortages. Hospitals and health systems face an increased number of drug product shortages, and some shortages have become chronic. As a result, hospitals and health systems must dedicate additional resources to locating and evaluating alternate products, educating health care professionals, and reprogramming billing and clinical computer systems to accommodate alternate products with different National Drug Code (NDC) numbers, as well as incurring the costs of off-contract or non-preferred drug products. It is therefore important that the FDA be able to respond to all drug product shortages and not merely shortages of products the agency determines to be "medically necessary."

Currently, manufacturers are not required to report a shortage to the FDA. The FDA needs to have the authority to require manufacturers to provide the details about a shortage, as only very general reasons for a shortage are provided by manufacturers when voluntarily reported to the FDA. Additional details provided to the FDA and made available to the public will assist in effectively responding to patient needs.

The agency's current process for defining a "medically necessary" drug product does not address the patient safety implications of changing drug products in response to a shortage. These implications include an increased potential for adverse drug events, administration or compounding errors due to different concentrations of alternate products, and cancellation or postponement of surgeries.

Because some drug shortages and discontinuations are caused by manufacturing production problems, or business decisions to shift production to more profitable products, incentives (e.g., tax credits) should be available to manufacturers if they agree to continue to supply product for a predetermined period of time. These incentives need to be coupled with effective sanctions for manufacturers that fail to provide 12 months notice of a discontinuation.

The Council also observed the influence of "gray market" suppliers on supply and demand as a consequence, but not a cause, of a product being in short supply. Council members noted that a key consideration when using these suppliers is assurance of the integrity of the product. In addition, they noted the importance of reporting price gouging situations to the relevant enforcement agencies, such as the Federal Trade Commission and state attorneys general.

#### Background

The Council voted and the Board agreed to recommend amending ASHP policy 0319, Drug Shortages, as follows (underscore indicates new text; strikethrough indicates deletions):

- To advocate that the Food and Drug Administration (FDA) have
- the authority to require manufacturers to report drug product
- shortages and the reason(s) for the shortage, and to make that
- information available to the public; further,
- To strongly encourage the Food and Drug Administration FDA to
- consider, in its definition of "medically necessary" drug products,
- the impact of medication-use factors, taking into account that if
- an unfamiliar product is introduced in a clinical setting because
- 9 the customary product is unavailable, there is increased risk to
- 10 patient safety the patient safety risks created by use of alternate
- 11 drug products during a shortage; further,
- 12 To support government-sponsored incentives for manufacturers
- 13 to maintain an adequate supply of medically necessary pharma-
- 14 ceutical drug products; further,
- 15 To advocate laws and regulations that would (1) require phar-
- 16 maceutical manufacturers to notify the appropriate government
- 17 body at least 12 months in advance of voluntarily discontinuing a
- 18 medically necessary drug product, (2) provide effective sanctions
- 19 for manufacturers that do not comply with this mandate, and (3)
- 20 require prompt public disclosure of a notification to voluntarily
- 21 discontinue a medically necessary drug product; further,
- 22 To encourage the appropriate government body to seek the
- 23 cooperation of manufacturers in maintaining the supply of
- 24 a medically necessary drug product after being informed of a
- 25 voluntary decision to discontinue that product.

This policy resulted from Council and ASHP staff discussions about the current state of drug product shortages and member input on the need to advocate for more FDA authority to address the issue.

In the first clause of the revised policy, the Council felt it was important for FDA to have authority to respond to all drug product shortages, not merely shortages of products the agency determines to be "medically necessary." The Council also felt that the FDA needs the authority to require manufacturers to provide details about a shortage. Currently, manufacturers are not required to report a shortage to the FDA, and Council members noted that only very general reasons for a shortage are provided by manufacturers when voluntarily reported to the FDA.

In drafting the second clause, the Council noted that the agency's current process in defining a "medically necessary" drug product does not take into account the potentially serious patient safety implications of changing drug products in response to a shortage.

In the third clause, "pharmaceutical" was deleted and replaced with "drug" to be consistent with other terms in the policy. Council members observed that since some drug shortages and discontinuations are caused by manufacturing production problems or business decisions to shift production to more profitable products, certain incentives (e.g., tax credits) should be available to manufacturers if they agree to continue to supply product for a predetermined period of time.

In the fourth clause, the Council also included the elements of policy 0319 that address a manufacturer's voluntary discontinuation of a drug product, not only those determined to be "medically necessary." They noted the need for effective sanctions for manufacturers that fail to provide 12 months' notice of a discontinuation.

In the fifth clause, the Council deleted "medically necessary" and replaced it with "drug" to be consistent with the rest of the

## **Direct-to-Consumer Advertising of Prescription and Nonprescription Medications**

- 1 To support direct-to-consumer advertising that is edu-
- 2 cational in nature about prescription drug therapies for
- 3 certain medical conditions and that appropriately in-
- cludes pharmacists as a source of information; further,
- 5 To support direct-to-consumer advertising of specific
- 6 prescription drug products only when the following re-7
- quirements are met: (1) that such advertising is delayed
- 8 until postmarketing surveillance data are collected and q
- assessed, (2) that the benefits and risks of therapy are
- 10 presented in an understandable format at an acceptable
- literacy level for the intended population, (3) that such
- advertising promotes medication safety and allows in-
- formed decisions, (4) that a clear relationship between 14 the medication and the disease state is presented, (5)
- 15 that no such advertising or marketing information for
- 16 prescription or nonprescription medication is directed
- 17 toward minors, and (6) that such advertising include
- mechanisms that direct consumers to a medication
- adverse event reporting system (AERS); further,
- 20 To advocate that the Food and Drug Administration
- require an AERS reporting link in direct-to-consumer
- advertising material available on the Internet; further,
- To support the development of legislation or regulation
- that would require nonprescription drug advertising
- to state prominently the benefits and risks associated with product use that should be discussed with the
- consumer's pharmacist or physician.

(Note: This policy would supersede ASHP policy 0609.)

#### Rationale

ASHP policy 0609 was revised by the Council as part of ongoing sunset review of policies, and the Board concurred with the revisions. In addition, the Council discussed the emerging use of the Internet and Web 2.0 media to provide direct-to-consumer advertising. The Council reaffirmed the basic intent of policy 0609, adding two requirements or conditions by which direct-to-consumer advertising of a specific prescription drug product could be supported: that advertising should not be directed toward minors, given the potential for misuse and abuse by that population, and that a link to adverse event reporting be prominently and readily accessible to users on the Internet.

#### Background

The Council voted and the Board agreed to recommend amending ASHP policy 0609, Direct-to-Consumer Advertising of Prescription and Nonprescription Medications, as follows (underscore indicates new text; strikethrough indicates deletions):

- To support direct-to-consumer advertising that is educational
- in nature about prescription drug therapies for certain medical
- conditions and that appropriately includes pharmacists as a
- source of information; further,
- To support direct-to-consumer advertising of specific prescrip-
- tion drug products only when the following requirements are
- met: (1) that such advertising is delayed until postmarketing
- surveillance data are collected and assessed, (2) that the benefits
- 9 and risks of therapy are presented in an understandable format
- 10 at an acceptable literacy level for the intended population, (3)
- 11 that such advertising promotes medication safety and allows
- 12 informed decisions, and (4) that a clear relationship between
- 13 the medication and the disease state is presented, (5) that no
- 14 such advertising or marketing information for prescription or
- 15 <u>nonprescription medication is directed toward minors, and (6)</u> 16 that such advertising include mechanisms that direct consumers
- 17 to a medication adverse event reporting system (AERS); further,
- 18 To advocate that the Food and Drug Administration require an
- 19 AERS reporting link in direct-to-consumer advertising material
- 20 available on the Internet; further,
- 21 To support the development of legislation or regulation that
- 22 would require nonprescription drug advertising to state promi-
- 23 nently the benefits and risks associated with product use that
- 24 should be discussed with the consumer's pharmacist or physician.

This policy resulted from sunset review of policy 0609 and the emergence of new Web 2.0 technology. In addition, the Council discussed an earlier public meeting by the FDA as part of its ongoing work to develop a regulatory approach to these new technologies.

#### C. Regulation of Off-Label Promotion and Marketing

- To advocate for authority for the Food and Drug Admin-
- istration to regulate the promotion and dissemination
- of information about off-label uses of medications by
- manufacturers: further.
- 5 To advocate that such promotion and dissemination be
- permitted only if manufacturers submit a supplemental
- new drug application for new use within a reasonable
- time after initial dissemination of information about
- off-label uses.

## Rationale

FDA regulation of the dissemination of information about off-label uses has evolved (see, e.g., the April 9, 2009, edition of the New England Journal of Medicine for an overview of the evolution of this issue). Section 401 of the 1997 Food and Drug Administration Modernization Act (FDAMA) allowed distribution of peer-reviewed articles from scientific journals only if the off-label use was included in a supplemental new drug application (SNDA). Congress let that provision expire in 2006, partially due to unclear federal court decisions. In 2009, the FDA issued final guidance for industry regarding good reprint practices for the distribution of articles on off-label uses. The guidance does not require a manufacturer to seek approval for new uses of a drug. In the absence of new statutory authority and clarification from the courts, ASHP supported the 2009 guidance by the FDA.

The FDA needs authority to regulate promotion of off-label uses similar to that passed by Congress in FDAMA. The SNDA requirement is reasonable and should be required for manufacturer dissemination of information about off-label uses. Without such a requirement, manufacturers have no incentive to sponsor studies on these uses. ASHP acknowledges the challenge of striking a balance between the right of commercial free speech under the First Amendment and legitimate restrictions to ensure that the information prescribers receive about off-label uses is truthful, balanced, evidenced based, and not misleading.

#### Background

The Council noted the impact of the 2009 FDA guidance as well as the potential for statutory changes in FDA authority through the upcoming reauthorization of the Prescription Drug User Fee Act. Existing ASHP policy on off-label uses (policy 0206, and the Statement on the Use of Medications for Unlabeled Uses) does not address dissemination by manufacturers, making this new policy recommendation especially timely. Further, the Council observed state efforts to regulate sales and marketing activity, and suggested ongoing monitoring of this trend.

#### **Poison Control Center Funding**

- To advocate that poison control centers be considered
- 2 an essential emergency service; further,
- 3 To advocate for new and stable funding mechanisms
- 4 for poison control centers to continue to provide these
- 5 essential and valuable services; further,
- 6 To encourage poison control centers to maximize cost-
- 7 effectiveness in utilizing resources, including integrating
- 8 and coordinating services.

#### Rationale

The Council reviewed recent trends by state governments to reduce or eliminate funding for poison control centers and concluded that ASHP policy was needed. The Board concurred. The Council agreed with observations by the American College of Emergency Physicians in its June 2010 task force report that the centers are an essential emergency service and part of the infrastructure for an allhazards emergency preparedness system, including pandemic and bioterrorism response. The Council noted that studies have shown a positive financial benefit provided by the centers; a 2004 report by the Institute of Medicine (IOM) cited a \$6.50 cost savings for every dollar invested in poison control centers. The Council suggested that recent cuts in funding by state governments (e.g., California) as well as proposals to eliminate poison control centers in some states (e.g., New Jersey) demonstrate a need to develop new and stable funding. The Council further noted that the IOM report concluded that poison control centers should be better integrated and coordinated.

## Background

The Council addressed this issue in response to proposals by states to reduce funding for poison control centers and a need for state affiliates to advocate for stable funding. Prior advocacy by ASHP and state affiliates was based on broad ASHP philosophy. Explicit policy will assist members in their advocacy efforts.

#### **State Prescription Drug Monitoring Programs**

- To advocate for uniform state prescription drug monitor-
- ing programs that collect standard information about
- controlled substances prescriptions; further,
- To advocate that the design of these programs should
- balance the need for appropriate pain management with
- safeguards against misuse, abuse, and diversion; further,
- To advocate that such programs be structured as part
- of electronic health records and exchanges to allow

- 9 practitioners and prescribers to proactively monitor data
- 10 for appropriate assessment; further,
- 11 To advocate for interstate connectivity to allow for
- 12 access by practitioners and prescribers across states
- 13 lines; further,
- 14 To advocate for federal and state funding to establish
- 15 and administer these programs.

#### Rationale

The Council reviewed the status of state prescription drug monitoring programs and the report of a National Association of Boards of Pharmacy task force. The Council believed it was important to have policy on this important public health issue, and the Board concurred. It is important that these programs collect standardized

information for analysis and comparison among states. The programs need to have uniform safeguards against abuse and balance the goals of the programs with appropriate pain management. A balanced program would allow appropriate but not unfettered access by law enforcement to the data.

It is also important to ensure the integration and interoperability of these programs with the emerging use of electronic health records and information exchanges so that prescription monitoring programs can be an educational tool for prescribers and practitioners. In addition, practitioners and prescribers should have appropriate access across state lines to assist in meeting the goals of the programs and provide appropriate pain management. Finally, adequate state and federal funding is essential to sustain the viability of these programs.

#### Background

This policy was developed by the Council as part of its review of a task force report by the National Association of Boards of Pharmacy and discussion about appropriate state or federal oversight.

#### **Board Actions**

**Sunset Review of Professional Policies.** As part of sunset review of existing ASHP policies, the following were reviewed by the Council and Board and found to still be appropriate. (No action by the House of Delegates is needed to continue these policies.)

- Generic Pharmaceutical Testing (9010)
- Patient Adherence Programs as Part of Health Insurance Coverage (0116)
- Redistribution of Unused Medications (0611)
- Streamlined Licensure Reciprocity (0612)

## **Other Council Activity**

**Medical Use of Marijuana.** In response to a New Business Item from the 2010 House of Delegates, the Council discussed the issue of medical marijuana programs allowed in 14 states. The Council developed a policy recommendation that was combined with a recommendation from the Council on Therapeutics, since the primary emphasis of the recommendation is on the need for research and evidence on marijuana's therapeutic use. (See the report of the Council on Therapeutics.)

The Council concluded that it is important to oppose the use of medical marijuana until evidence is available to support it. The Council expressed concern that the distribution models of existing state programs fall outside the traditional supply chain for prescription drugs. Significant differences between the two models include the lack of (1) a valid prescription; (2) FDA approval, product labeling, and current good manufacturing practices; (3) assurances of the chain of custody in the distribution chain; and (4) a prescriber-pharmacist-patient relationship.

The Council felt it was important to oppose the procurement, storage, preparation, and distribution of non-research-related medical marijuana in pharmacies or health care facilities, since those activities could impact the pharmacy or facility's registration with the Drug Enforcement Administration (DEA). The Council further noted that the current structure of the Controlled Substances Act and classification of marijuana as a Schedule I substance inhibits the ability for sound scientific research to be conducted to develop the necessary therapeutic evidence. Moreover, the Council suggested that in order to conduct the research necessary for FDA approval, the DEA may need to reclassify medical marijuana from a Schedule I controlled substance, but the Council endorsed a DEA reclassification review only if it is necessary to conduct the research.

The Council also stated that practitioners and patients in states where medical marijuana use is permitted should be exempt from federal prosecution, civil liability, and professional sanction. Currently, the United States Attorney General has directed federal prosecutors not to initiate proceedings against "individuals whose actions are in clear and unambiguous compliance with existing state laws providing for the medical use of marijuana" (U. S. Department

of Justice memorandum, Oct. 19, 2009). This directive from the Attorney General reflects the priorities and allocation of resources of the current Administration and could change under a different Attorney General.

In its discussion, the Council strongly emphasized that it was not endorsing any state-authorized medical marijuana programs or the legalization of marijuana. The Council also observed that smoking medical marijuana would violate hospital policies and laws that prohibit smoking in their facilities.

In addition, the Council reiterated that this policy should not be construed to imply that current scientific evidence on medical cannabis would meet the standard for a prescription drug product.

The Council also observed the need for continuing education and information about the therapeutic and legal issues surrounding the use of medical marijuana as such programs continue to evolve, so pharmacists are positioned to respond to patient and practitioner inquiries.

**Statement on Medication Therapy Management (MTM)** and Collaborative Drug Therapy Management (CDTM). The Council discussed the different federal and state definitions of MTM

and CDTM as well as ASHP policy positions and other statements endorsed by various national pharmacy organizations. The Council agreed to develop a comprehensive position statement on MTM best practices, including CDTM.

Currently, ASHP has multiple policy statements that address MTM, CDTM, credentialing, privileging, and reimbursement for pharmacist services (e.g., ASHP policies 1005, 0905, 0207, 0006, 9801, and 9812). These definitions include different scopes of practice and different training requirements for providers. Reimbursement mechanisms also vary across payers. As a result, the profession and regulators do not have a uniform understanding of MTM and CDTM, which creates confusion. An ASHP statement is needed to advance the quality practice of MTM and CDTM nationally.

The Council felt that a single statement was essential to provide a clear vision on these terms and reduce variability in the provision of these services among federal health programs and definitions

in federal and state law. Specifically, there are two definitions of MTM in federal law. Medicare's Part D prescription drug benefit describes MTM provided by prescription drug plans, while the Affordable Care Act (ACA) has a provision (section 3503) that more closely aligns with the consensus definition developed by national pharmacy organizations. Section 3503 also makes reference to collaborative practice as defined by the states. State CDTM definitions vary, which leads to different state requirements to enter into collaborative agreements and provide services. The Council also noted that in order for pharmacists to be reimbursed for MTM or CDTM, a credentialing and privileging process needs to be established, so that public and private payers can pay for quality services. The Council urged that the Council on Credentialing in Pharmacy move quickly to establish a framework for credentialing in order to address this need for payers.

The Council identified the following stakeholders in need of a comprehensive statement: pharmacists, other health care providers, state boards of pharmacy, state legislatures, Centers for Medicare & Medicaid Services, state Medicaid programs, health insurers, and other public or private payers.

The Council identified a multifaceted use for the statement. Legislative and regulatory bodies could use it to develop or modify regulations for best practices of MTM and CDTM. Pharmacists, health care leaders, and other health care providers could develop model MTM and CDTM programs. Pharmacists and payers could support and develop best practice business models and reimbursement mechanisms.

The Council identified the following topics for discussion in the statement:

- Background information on evidence to support provision of MTM and CDTM, including clinical and economic outcome measures and the best method of delivery (e.g., face-to-face, mailed education, etc).
- 2. What clinical services are included in MTM and CDTM, with reference to various MTM definitions?
- 3. What are the core services that are potentially provided by a pharmacist?
- 4. Who is eligible for MTM and/or CDTM services, including definition of targeted beneficiaries; who will benefit from these services?
- 5. Who is qualified to provide these services, including examples of credentialing and privileging criteria?
- 6. What is the role of non-pharmacist health care providers in provision of these services?
- 7. How are these services reimbursed? Who pays for services? What billing codes should be used?
- The relationship between MTM (i.e., Part D and section 3503), CDTM, and credentialing and privileging of pharmacists to provide these patient care services.
- 9. Technology and patient information needs.
- Documentation and communication with other health care practitioners.

The Council took this action in response to a New Business Item approved by the House of Delegates. In addition, the concept of CDTM as found in state law has evolved to the point that more uniformity would help develop best practices models to provide these services. Additionally, a comprehensive and progressive definition of MTM is beginning to be embraced by policymakers as part of the solution to our nation's medication-use challenges. Finally, ASHP policy and the profession's consensus definition are in need of updating and consolidating into a comprehensive statement. The Council noted that consultation with other national pharmacy organizations may be useful in developing this statement.

**Drug Shortages.** As part of its discussion that led to a proposed policy revision, the Council also felt that the FDA should evaluate manufacturers on their manufacturing performance and track record on dealing with drug shortages. The evaluation would be provided to the public and serve as an incentive to improve performance. This information would help policymakers and the public understand the manufacturing challenges and other causes of drug shortages. Members noted that hospitals and health systems were being required to report performance measures publicly. The Council therefore felt

that these key suppliers, whose activities also impact public health, should be similarly transparent about their performance.

Finally, the Council noted that during drug product shortages, specialty and compounding pharmacies offer products to hospitals and health systems. The Council underscored the importance of consulting the ASHP Guidelines on Managing Drug Product Shortages in Hospitals and Health Systems when obtaining product from these entities.

**Expansion of 340B Drug Discount Program.** In its discussion of the changes to the 340B drug discount program due to enactment of the ACA, the Council noted that changes to ASHP policy 0506, Accessibility and Affordability of Pharmaceuticals (reaffirmed by the Council on Pharmacy Practice in 2009) should be considered. The ACA expanded the program to children's hospitals, freestanding cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals. Policy 0506 only explicitly mentions disproportionate share hospitals. The Council suggested that the policy language be updated at the appropriate time to reflect these changes in the 340B program.

In addition, the Council noted that orphan drugs were not considered covered outpatient drugs for these newly eligible entities under the ACA. It encouraged continued advocacy to include orphan drugs for these entities, since they represent a large component of medication use and are within the intent of policy 0506. In addition, the Council agreed with the thrust of policy 0506 to extend discounts to the inpatient setting.

#### **Board of Pharmacy Requirements for Intern Registration.**

The Council discussed definitions of "intern" and "internship" as described by state boards of pharmacy and the Model Act and Regulations of the National Association of Boards of Pharmacy. It noted experiential requirements of the Accreditation Council on Pharmacy Education as well as the discussion of this topic by the Council on Education and Workforce Development during its revision of policy 0802.

Council members offered the following points for the Council on Education and Workforce Development to consider in revising policy 0802 or developing new policy: (1) internships continue to be important and relevant, (2) there is value in standardization of internship requirements across the United States and North America, (3) interns and students should have adequate exposure to hospital practice, and (4) mechanisms and incentives should be developed to encourage small and rural hospitals to provide experiential sites.

The Council further described the notion of standardized internship requirements across states. There is a need for consistent policy about when the internship hours can be performed, the maximum number of hours that can be satisfied during the school year and outside of the academic year, and the stage in the professional year that a student can become an intern.

Scope of Practice Acts. The Council reviewed current advocacy by physicians and others regarding state scope of practice laws and noted the need for checks and balances in the prescribing, dispensing, and administration functions, as well as the overall responsibility for the medication-use system. The Council noted the existing checks and balances function well in the institutional setting through the formulary system. It noted the differences in the community setting, where those organizational checks and balances do not exist. However, Council members noted that professional liability, scope of practice, and credentialing serve a similar function. Council members acknowledged ASHP's response to the resource materials developed for state medical associations. In addition, they felt that the planned ASHP statement on medication therapy management and collaborative drug therapy management described earlier would serve as a resource in addressing the need for these checks and balances in the community setting.

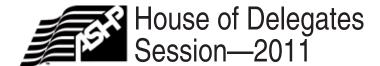
**Direct-to-Consumer Advertising, Marketing, and Social Networking Sites.** In its discussion on revising ASHP policy 0609, the Council identified a number of issues and topics that were in need of further discussion. The Council expressed a desire to identify a source for guidance to aid the public in navigating medication-related

information on websites, including but not limited to seeking out pharmacists as a source of medication information. In addition, the Council noted that Internet users seeking health care information should be able to have an experience free from spam.

The Council also noted the challenge in identifying and verifying the source of information on the Internet to assess possible conflict of interest. The Council also suggested research to determine ways to promote transparency by encouraging disclosure through voluntary monitoring of websites or through regulatory authority.

The Council discussed information presented in 2009 FDA hearings on direct-to-consumer advertising presentation of risk and benefit information to media users. Further information is needed to evaluate existing evidence of the efficacy of placement strategies for risk and benefit information on websites, including information about how the Internet user seeking health information with a typical literacy level navigates web pages during the process. Additional new policy may emanate from this discussion and should consider the following:

- Certification and validation of Internet sites that contain medication-related information.
- Research on the best methods to communicate medications' risk and benefit information at the appropriate health literacy level for the general population.
- Encouraging the FDA to work in collaboration with patient advocates and other stakeholders to create evidence-based models and standards, including establishment of a universal literacy level, for consumer medication information (CMI).
- Advocating that research be conducted to validate these models in actual-use studies in pertinent patient populations.
- Advocating that state boards of pharmacy require that pharmacies comply with FDA-established standards for content, format, and distribution of CMI.
- Identification of drug information websites that are consistent with ASHP policy on direct-to-consumer advertising.
- Guidance for Internet users on evaluating website content about medications.
- Identification on websites that protect user confidentiality and do not result in unsolicited advertising.



## Reports on Sections and Forums

ASHP sections consist of members within five well-defined areas of health-system pharmacy who collaborate to advance professional practice in their respective areas. ASHP members may enroll in as many sections as they wish; practitioner members are asked to select one section as their primary "home," which allows them to vote for the chair and members of the executive committee of that section.

The ASHP Student Forum consists of all student members. The New Practitioners Forum consists of all practitioner members who are within five years of graduation from a school or college of pharmacy.

Each section and forum is led by an Executive Committee elected (sections) or appointed (forums) from the ASHP membership. Each Executive Committee met face to face June 4 and December 4 or 5, 2010, to review the past year's activities and plan for the coming year. The committees also met by telephone periodically during the year to assess progress on initiatives and discuss new trends or events that warranted section or forum activity. Each section and forum has its own mission, vision, goals, and objectives.

- 1 ASHP Section of Ambulatory Care Practitioners
- 3 ASHP Section of Clinical Specialists and Scientists
- 6 ASHP Section of Inpatient Care Practitioners
- 9 ASHP Section of Pharmacy Informatics and Technology
- 12 ASHP Section of Pharmacy Practice Managers
- 14 ASHP New Practitioners Forum
- 17 ASHP Pharmacy Student Forum

### ASHP Section of Ambulatory Care Practitioners

The mission of the ASHP Section of Ambulatory Care Practitioners is to improve patient care and patient health outcomes by advancing and supporting the professional practice of pharmacists who are medication-use specialists, patient care providers, and operational specialists in home, ambulatory, and chronic care settings. The Section dedicates itself to achieving a vision of pharmacy practice in which pharmacists who are medication-use specialists, patient care providers, and operational specialists in home, ambulatory, and chronic care settings will improve patient care and patient health outcomes. To achieve this vision, the Section will provide guidance that improves both the use of medications by patients and the medication-use process in ways that enhance patients' health-related quality of life and patient outcomes.

The Section's goals are to (1) promote the clinical and administrative roles of pharmacists and contribute to the advancement of care across the health-care continuum; (2) serve as the voice of and a resource for the Section's practitioners within ASHP, especially in ASHP governance and policy development; (3) engage those who want to improve their professional knowledge and skills with leaders and experts in their practice settings; (4) recruit and cultivate members who are active within the profession, providing a mechanism to develop the future leaders of ASHP; (5) develop a membership that is actively involved in ASHP, that is widely utilized as a resource throughout the profession, and whose contributions are clearly recognized by the Section, ASHP, and other professional organizations; (6) communicate effectively with Section members to ensure that they understand, support, and contribute to the direction and role of the Section in representing their interests; (7) promote collaboration, including networking and services, among the Section's members; (8) create or foster the creation of ASHP products, educational programs, and services that meet the unique needs of the Section's membership, including products, educational programs, and services that utilize advanced technologies for delivery via the Internet or the World-Wide Web; and (9) work with other professional organizations to develop products, educational programs, and services that meet the unique needs of the Section's membership.

**2010–2011 Section Highlights.** In January 2011, the ASHP Board of Directors approved the Section's name change from Section of Home, Ambulatory, and Chronic Care Practitioners to the Section of Ambulatory Care Practitioners. This name change, recommended by the Section's Executive Committee, will encompass a broader expanse of the ASHP membership, help to maintain a strong section, and enable ASHP's Public Relations and Marketing Divisions to utilize the name in an effective manner.

As of December 2010, there were 8747 members in the Section, with 2228 choosing the Section as their primary section. Overall, the Section membership is up 13.1% since 2009, which surpassed the Executive Committee's goal of increasing membership by 10%, and the Section's membership numbers continue to grow. Section members elected Dr. Stamm as Chair and Ms. Johnson as Directors-at-Large, and both individuals will be installed at the 2011 Summer Meeting.

The Section selected Edith Nutescu as the winner of the Section of Home, Ambulatory and Chronic Care Practitioners' Distinguished Service Award. Established in 2007, the ASHP Pharmacy Practice Sections' Distinguished Service Award recognizes a member of each section whose volunteer activities have supported the section's mission and helped advance the profession. The award was presented at the 2010 Midyear Clinical Meeting (MCM).

In addition, a number of Section leaders were very active in the Pharmacy Practice Model Initiative (PPMI) Summit as participants, document authors, and presenters. The Section will continue to provide support for ASHP and ASHP Foundation education and advocacy efforts related to the PPMI.

#### **Executive Committee**

Roger S. Klotz, Chair (California)
Pamela L. Stamm, Chair-elect (Alabama)
Timothy R. Brown, Immediate Past Chair (Ohio)
Anna Nowobilski-Vasilios, Director-at-Large (Illinois)
Seena L. Haines, Director-at-Large-elect (Florida)
Cathy Johnson, Director-at-Large-elect (Ohio)
Randy L. Kuiper, Board Liaison (Montana)
Justine Coffey, Secretary

**Educational and Networking Opportunities.** The Section's Educational Steering Committee is charged with developing programming that will be of interest to ambulatory care practitioners. The Committee is also charged with identifying programming priorities. The 2010–2011 Committee planned 25 hours of 2010 ASHP MCM educational programming specifically for ambulatory and chronic care practitioners. Topics included information on cutting-edge ambulatory care practices, a 2010 home care regulations update, charging for pharmacy services, and a pre-meeting workshop on pain management across the continuum of care. The Section also held three networking sessions at the 2010 MCM on home infusion, billing for pharmacy services, and ambulatory care practice models.

The Section's electronic NewsLink is distributed once a month to over 7200 ASHP members, providing news and current information on medical research, regulatory and health policy issues, health care, and reimbursement issues. The Section Chair's Message is also distributed once a month to NewsLink subscribers and provides news on Section and ASHP programs and initiatives. The Section's electronic discussion group provides a forum for Section members to exchange information and ideas on a wide variety of topics related to ambulatory care. Currently, more than 2500 members participate in the discussion group.

**Ambulatory Care Specialty Credential.** ASHP, along with the American College of Clinical Pharmacy and the American Pharmacists Association, continues to support the process for establishing an ambulatory care specialty credential. With the specialty now approved, the Section supports ASHP and its role with the Board of Pharmacy Specialties as the exam and preparatory courses are developed and the credential is promoted. A number of Section leaders served as faculty for the first ASHP Ambulatory Care Pharmacy Review Course held at the 2010 MCM.

**Advocacy.** Many Section members represent ASHP on various coalitions and committees. These include The Pharmacy Services Technical Advisory Coalition, The Joint Commission Professional and Technical Advisory Committees on Ambulatory Care and Home Care, and the National Asthma Education and Prevention Program. Section members on these groups and committees provide the pharmacist's perspective in discussions that have an impact on patient care nationwide. Section members continue to support ASHP's efforts in advocating for the expansion of medication management services and the payment of pharmacists.

**Advisory Group on Clinical Business Development.** The Section Advisory Group on Clinical Business Development was established in 2009 to address the growing number of issues challenging pharmacists in their ability to be reimbursed for clinic-based patient-care services. This new advisory group is focusing on the business and advocacy elements necessary to support and expand ambulatory clinic models. The group developed an ambulatory care practice model survey, with results to be published in 2011, and developed a live networking session at the 2010 MCM on ambulatory care practice models, where the results of the survey were discussed. The group is also working on an FAQ for hospital-based clinics that pharmacists can use to determine best reimbursement models and how to comply with Centers for Medicare & Medicaid Services (CMS) requirements.

#### Advisory Group on Cognitive Reimbursement Resources.

The Section Advisory Group on Cognitive Reimbursement Resources developed the 2010 MCM Ambulatory Care Learning Community: Building Ambulatory Services: Convincing Your Institution to Charge for Pharmacist Services. The advisory group also developed the 2010 MCM Networking Session on Billing for Pharmacy Services, and provided a live networking session webinar, *Collaborative Practice Boot Camp: Part II.* The advisory group continues to support members in clarifying proper methods for receiving payment for cognitive services.

**Advisory Group on Home Infusion.** The Section Advisory Group on Home Infusion is working with ASHP on updating the two ASHP guidelines on home infusion. The advisory group also coordinated a 2010 MCM networking session for home infusion practitioners.

#### Advisory Group on Pain Management and Palliative Care.

The Section Advisory Group on Pain Management and Palliative Care created a 2010 MCM workshop titled A Pain and Palliative Case Study: A Journey Across the Continuum of Care, and also provided a Pain Management and Palliative Care webinar, Patient Controlled Analgesia: Implementing the Smart Pump Generation. The advisory group collaborated with the Commission on Credentialing and ASHP to create the new PGY2 Palliative Care/Pain Management residency standards.

Membership and Marketing Committee. The Section established the Membership and Marketing Committee in 2009 to facilitate and lead the efforts of the Section in raising awareness of the Section's work, provide opportunities for ASHP members to participate, and grow the Section's membership. The advisory group started its work by developing the Section's communication plan and evaluating the different mechanisms the Section could use to recruit members. The group is focused on continued quality improvement for membership experience with the Section, has operationalized the drafting of a monthly "Members Spotlight" for the Section's website, and is developing a process for the section advisory groups to develop a "Tip of the Month" to be included in the Section's monthly NewsLink.

#### **Advisory Group on Clinical Business Development**

Gloria Sachdev, Chair (Indiana); Mary Ann Kliethermes, Vice Chair (Illinois); Jeffrey M. Brewer, (New York); Kathy Donley (Ohio); Santhi Masilamani (Texas); Jeffrey Rapp (Illinois); Steven M. Riddle (Washington); Erika E. Smith (Wisconsin); Jeffrey Steffey (Michigan); Mark D. Triboletti (Indiana); Tim R. Brown, Executive Committee Liaison (Ohio)

#### **Advisory Group on Cognitive Reimbursement Resources**

Amy L. Stump, Chair (Wyoming); Sandra Leal, Vice Chair (Arizona); Becky L. Armor (Oklahoma), Laura Roller Britton (Utah); Kristina (Kristy) Butler (Oregon); Amy Dill (Ohio); Kelly T. Epplen (Ohio); Amy M. Lugo (Texas); Betsy Bryant-Shilliday (North Carolina); Richard L. Stambaugh (Minnesota); Jennifer Anne Taylor (Washington); Laura Traynor (Wisconsin); Seena Haines, Executive Committee Liaison (Florida)

#### **Advisory Group on Home Infusion**

Donald J. Filibeck, Chair (Ohio); Barbara Petroff, Vice Chair (Michigan); Jeanie Barkett (Oregon); Daniel B. Dobson (Alaska); Kim Ehlert (Minnesota); Cathy Johnson (Ohio); Allen David Knee (Florida); Douglas R. Lang (Missouri); Steve Olsen (Idaho); Steven M. Pate (Tennessee); Carol J. Rollins (Arizona); Anthony Sardone (New Jersey); Anna Nowobilski-Vasilios, Executive Committee Liaison (Illinois)

### Advisory Group on Pain Management and Palliative Care

Virginia Ghafoor, Chair (Minnesota); Christopher Herndon, Vice Chair (Illinois); Sondra Adkinson (Florida); David Craig (Florida); Ernest Dole (New Mexico); Victoria Ferraresi (California); Lee Kral (Iowa); Mary Lynn McPherson (Maryland); Pamela S. Moore (Ohio); Mitchell Nazario (Florida); Douglas Nee (California); Suzanne A. Nesbit (Maryland); Lori Reisner (California); Scott Strassels (Texas); Jennifer Strickland (Florida); Emily Weidman-Evans (Louisiana); Pamela L. Stamm, Executive Committee Liaison (Alabama)

#### **Committee on Nominations**

Tim R. Brown, Chair (Ohio); Marc Stranz (Pennsylvania); Ernest Dole (New Mexico); Steven M. Riddle (Washington); Jennifer A. Buxton (North Carolina); Richard L. Stambaugh (Minnesota); Anthony Sardone (New Jersey)

#### **Educational Steering Committee**

Michele L. Matthews, Chair (Massachusetts); Jennifer A. Buxton, Vice Chair (North Carolina); Jennifer Lynn Clemente (Michigan); Michelle Cudnik (Ohio); Michelle A. Fritsch (Maryland); Richard Greene (Pennsylvania); Katie V. Lai (Washington); Jeannie Kim Lee (Arizona); Kimberly Braxton Lloyd (Alabama); Tracy A. Martinez (Michigan); Pamela Stamm (Alabama); Anne Teichman (Maine); Roger S. Klotz, Executive Committee Liaison (California)

#### **Membership and Marketing Committee**

Pam Letzkus, Chair (California); Binita Patel (Naik), Vice Chair (Wisconsin); Jenny Van Amburgh (Massachusetts); Kevin D. Burns (Minnesota); John Clark (Florida); Starlin Haydon-Greatting (Illinois); Rupal P. Patel, (New Jersey); Anthony Sardone (New Jersey); Lindsay Snyder (Indiana); Tim R. Brown, Executive Committee Liaison (Ohio)

# ASHP Section of Clinical Specialists and Scientists

The mission of the Section of Clinical Specialists and Scientists is to advocate for practice advancement and improvement in patient care by creating and translating scientific advances into practice. The Section Executive Committee has developed a strategic plan linked to the Section's mission and goals. These goals are to (1) create member value by developing and providing education, creating tools and resources, providing networking opportunities, and creating a "home' for faculty and preceptors; (2) participate in advocacy by creating timely groups to address key issues affecting Section members; seeking greater input in policy and advocacy efforts, including practice initiatives; increasing participation in policy implementation and ASHP initiatives; and collaborating with internal and external organizations to communicate and advocate the interests of the Section: (3) promote member involvement by developing a process to simplify the path for involvement; increasing diversity of member involvement with educational sessions, network facilitators, committees, advisory groups, and policy development; encouraging Section members to run for Executive Committee office; and encouraging and facilitating recommendations of Section members for ASHP office; (4) communicating the value of the Section and ASHP by increasing recognition of Section activities and advocacy, communicating ASHP advocacy activities, and recognizing member contributions to ASHP and the profession. The Section offers members a sense of identity within ASHP and an organizational home dedicated to meeting their specialized practice, scientific, and research needs. The Section will continue to grow and expand its activities largely because of the efforts of its enthusiastic members and dedicated leaders.

**2010–2011 Section Highlights.** Section membership increased by 4.4% during 2010, to almost 13,500 members. Approximately 42% of the Section's members have selected the Section as their primary membership group. There still is strong interest in the Section among students and new practitioners. Section members elected Erin Fox as Chair and Tricia Meyer as a Director-at-Large; both will be installed at the 2011 Summer Meeting.

The Section selected Rita Jew as the winner of the Section of Clinical Specialists and Scientists Distinguished Service Award. Established in 2007, the ASHP Pharmacy Practice Sections Distinguished Service Award recognizes a member of each section whose volunteer activities have supported the section's mission and helped advance the profession. The award was presented at the 2010 Midyear Clinical Meeting (MCM).

In addition, a number of Section leaders were very active in the Pharmacy Practice Model Initiative (PPMI) Summit as participants, document authors, and presenters. The Section will continue to provide support with ASHP and ASHP Foundation education and advocacy efforts related to the PPMI.

Educational and Networking Opportunities. The Section's Educational Steering Committee is charged with developing programming at an advanced level that will be of interest to clinical specialists and scientists. Cherry Jackson served as the 2009-2010 Committee Chair. The 2009–2010 Committee developed more than 47 hours of educational programming on current issues in antimicrobial stewardship, infectious diseases, critical care, and Risk Evaluation and Mitigation Strategies (REMS). The committee also planned a session devoted to debates in areas of therapeutic controversy and coordinated the Clinical and Emergency Pharmacy Clinical Pearls sessions. The 2010-2011 Committee has identified Section member educational needs for the 2011 MCM, which will include cardiovascular and critical care updates; medical use of marijuana; update on anticoagulation management; pain, sedation, and delirium in the ICU; sepsis management; review of opiates and safety profile; metrics in antimicrobial stewardship; off-label use of biologic agents; update on rheumatoid arthritis; pharmacogenomics; transitions of care; trauma resuscitation; infectious diseases in the immunocompromised patient; antibiotic susceptibility testing;

#### **Executive Committee**

Mary M. Hess, Chair (Pennsylvania) Erin R. Fox, Chair-elect (Utah) James A. Trovato, Immediate Past Chair (Maryland) Lea S. Eiland (Alabama) Heath R. Jennings (Illinois) Tricia Meyer (Texas) Gerald E. Meyer, Board Liaison (Pennsylvania) Sandra Oh Clarke, Secretary

anti-platelet agents; health literacy; biosimilars; and emerging roles in clinical pharmacy. Committee members were charged with developing proposals or seeking out individuals to submit proposals for MCM consideration. A number of the program topics align with educational suggestions from the Council on Therapeutics.

The Section's electronic NewsLink is distributed once a month to almost 12,750 ASHP members, providing news and current information on medical research, regulatory and health policy issues, health care, clinical leadership, preceptor skills development, emergency care, and therapeutics. The Section Chair's Message is also distributed once a month to NewsLink subscribers and provides news on Section and ASHP programs and initiatives. The Section's electronic discussion group provides a forum for Section members to exchange information and ideas on a wide variety of topics related to clinical practice; currently, more than 4,900 members participate. In addition, the Section provides an electronic discussion group in emergency care with over 2,280 subscribers. The discussion groups are also used to communicate urgent information on clinical specialty practice.

The Section has 16 specialty networks encompassing most areas of specialty pharmacy practice. Women's health was added as a new specialty area in 2010. The networks meet regularly at the MCM, with over 1,620 meeting attendees participating. In addition, the Advisory Groups on Preceptor Skills Development and Clinical Leadership held networking sessions to discuss issues in their interest areas. Facilitators are appointed for a two-year period in each network by the Section's Chair. The network facilitators monitor developments and trends in their therapeutic areas and advise ASHP and the Section's membership of these developments through the Section's electronic discussion group, NewsLink, networking meetings, and other avenues. The facilitators also serve ASHP and its members as therapeutic experts and contribute to ASHP advocacy and educational efforts.

**Specialty Certification.** The Executive Committee discussed ASHP's past role as a petitioning organization for specialty practice. It was noted that ASHP has been involved with four of the six currently approved specialty areas (ambulatory, nutrition support, oncology, and psychiatry). ASHP has been the sole petitioning organization for two specialties and has worked jointly with other organizations in two other areas. The Executive Committee expressed its opinion that there should be a standardization of credentialing eligibility and recertification requirements that align with residency training and practice model.

The Committee discussed the merits of being a petitioning organization and agreed that ASHP should continue to support and selectively lead specialty petitions that represent ASHP membership as long as the current petition process and specialty council model is in place. Continuing to support the petitioning and specialty recognition process is a way to keep high-level clinical practitioners engaged with the organization by making appointments to specialty councils and development of examination review course and recertification materials. At the same time, the Committee noted the substantial financial and time commitment for a petitioning organization and suggested that ASHP prioritize involvement in the petitioning process based on the number of practitioners and PGY2 residency programs in the specialty. This prioritization will help identify the largest areas of practice and training, determine current pressing needs in caring for patients, and help establish credibility and authority in the practice area outside of the profession.

Resources for Clinical Specialists and Scientists. The Section continues to enhance its resources for pharmacy practitioners in different specialty areas and to use multiple communication pathways to notify Section members of new resources. The "Clinical Consultation" column in the *American Journal of Health-System Pharmacy (AJHP)*, created by the Section, continues to be a popular resource for members. This column covers therapeutic controversies and provides recommendations for handling specific pharmacotherapeutic problems. The Section continues to host an anticoagulation resource center on the ASHP website, the *ASHP Anticoagulation Initiative: Promoting Patient Safety through Education, Practice, Policy, and Advocacy.* The site is a compilation of educational materials, policies, best practices, and links to other organizations for practitioners looking for resources in the area of anticoagulation management. Updates to this site occur on a quarterly basis.

The Section continues to coordinate ASHP's efforts in the development of the *PharmGenEd* educational programs, live and web versions. This series of programs was developed by the University of California, San Diego, Skaags School of Pharmacy and Pharmaceutical Sciences. The goal of the program is to educate pharmacists and other health care professionals in the basic science and clinical application of pharmacogenomics.

The Section has taken a lead role in the planning of the Ambulatory Care Pharmacy Specialty Examination Review Course to assist ambulatory care practitioners prepare for the specialty examination. This two-day review course was held on December 3–4, 2010, prior to the MCM in Anaheim. The review course is also scheduled for March 24–25, 2011, at the American Pharmacists Association meeting in Seattle, and June 11–12, 2011, at the 2011 ASHP Summer Meeting in Denver. The first examination will be administered on October 1, 2011.

**Advocacy.** The Section advocates for recognition and development of specialty pharmacy practice areas, development of clinical practitioners into pharmacy clinical leaders, and the application of evidence-based therapeutic guidelines and medication use in patient care as a responsibility of all pharmacists and pharmacy departments.

**Advisory Group on Clinical Leadership.** The advisory group conducted networking sessions at the 2010 Summer Meeting and 2010 MCM to gather ideas and identify needs of Section members. Ideas and needs discussed during these sessions were summarized for Executive Committee members during meetings. The group has prioritized project initiatives and work has begun on the various projects. Advisory group members also provided input to the *Clinical Leaders Boot Camp: Practical Tools for Promoting and Establishing New Services*, held on Sunday, December 5, prior to the MCM. This workshop was developed based on member needs identified through the Section Needs Assessment Survey and listserver postings.

Advisory Group on Emergency Care. As a follow-up to the ASHP Statement on Pharmacy Services to the Emergency Department, the group drafted ASHP guidelines on emergency care clinical pharmacist services. This document has been sent out for member and external review, with plans to finalize drafting in June. The group also hosted a successful emergency care networking session at the MCM that drew more than 150 participants. Practitioners in this field also network through the ASHP Emergency Care electronic discussion group, which has close to 2,280 subscribers. This electronic discussion group, when first started, was open to members and non-members. In August 2010, the discussion group was made available only to members. ASHP gained approximately 120 new members who joined because of this valuable resource. In addition, the group developed two webinars to meet the needs of emergency care practitioners: FAQs in Developing an Emergency Care Service and Thrombolytics in Cardiac Arrest: Life-Saving, Life-Changing, or Disappointing?; planned two educational sessions at the 2010 MCM: The Role of the Pharmacist in the Management of Acute Ischemic Stroke and ID in the ED: Challenges in the Treatment of Infectious Diseases in the Emergency Department; and are currently developing a resource center in emergency care. Committee members are also writing articles for submission to AJHP pertinent to emergency care practitioners.

**Advisory Group on Emerging Sciences.** The group is charged with advising the Section and ASHP on the emerging sciences and/ or implementing recommendations of the 2008 Task Force on Science. This group is just convening and is outlining top priorities. The group has submitted two proposals for 2011 MCM consideration, a pharmacogenomics primer and strategies for successful practice implementation of pharmacogenomics. In addition, there are plans for a resource center in the emerging sciences to include such topics pharmacogenomics, nanomedicine, gene therapy, biosimilars, translational research. Results from the gene therapy survey conducted by the Advisory Group on Gene Therapy will be available on the resource center.

**Advisory Group on Preceptor Skills Development.** This group has developed a webinar to help residency programs develop a preceptor development program: *Practical Approaches to Developing Residency Preceptors*; planned and presented an educational session at the 2010 MCM: *Delivering Effective Resident & Student Performance Evaluations*; planned a networking session at 2010 MCM that attracted 65 attendees; and are currently developing a resource center in preceptor skills development.

#### **Advisory Group on Clinical Leadership**

Linda S. Tyler, Chair (Utah); Teresa H. Seo, Vice Chair (Connecticut); Kimberly Binaso (New Jersey); John Clark (Michigan); Susan E. Conway (Oklahoma); Lynn Eschenbacher (North Carolina); Kelly M. Smith (Kentucky); Robert Talbert (Texas); Tate Trujillo (Indiana); Mary M. Hess, Executive Committee Liaison (Pennsylvania)

#### **Advisory Group on Emergency Care**

Heather Draper Eppert, Chair (Tennessee); Patrick Bridgeman, Vice Chair (New Jersey); Tony Casanova (Washington); Alison Jennett (Michigan); Deborah J. Larison (Florida); Jennifer Denise Mando-Vandrick (North Carolina); Shannon Manzi (Massachussetts); Melinda J. Ortmann (Maryland); Asad (Sid) Patanwala (Arizona); Renee M. Petzel (Illinois); Katharine A. Reisbig (Nebraska); Aaron L. Steffenhagen (Wisconsin); Michael C. Thomas (Georgia); Richard Thomas (Utah); Joanne Witsil (Illinois); Lea S. Eiland, Executive Committee Liaison (Alabama)

#### **Advisory Group on Emerging Sciences**

Carla Frye, Chair (Illinois); Kiran Kumar V. Avancha (New Jersey); Wesley G. Byerly (North Carolina); Mark Klang (New York); John Valgus (North Carolina); James A. Trovato, Executive Committee Liaison (Maryland)

#### **Advisory Group on Preceptor Skills Development**

Carol J. Rollins, Chair (Arizona); Allison Jun, Vice Chair (California); George Phillip (Phil) Ayers (Mississippi); Teresa M. Cavanaugh (Ohio); Dale English (Ohio); Sharon E. Jones (West Virginia); Holly Philips (Colorado); Charlotte A. Ricchetti (Colorado); Cathy L. Walker (Maryland); Samaneh T. Wilkinson (Kansas); Heath R. Jennings, Executive Committee Liaison (Illinois)

#### **Committee on Nominations**

James A. Trovato, Chair (Maryland); Kate Farthing (Oregon); Kimberly A. Galt (Nebraska); Michael W. Kelly (Iowa); Jean M. Scholtz (Pennsylvania); Teresa Seo (Connecticut); Kelly M. Smith (Kentucky)

#### **Educational Steering Committee**

Michelle D. Wiest, Chair (Ohio); Paul M. Szumita, Vice Chair (Massachusetts); Kimberly Benner (Alabama); Ryan J. Bickel (Michigan); Ericka L. Breden (Virginia); Kimberli Burgner (Virginia); Daniel P. Hays (Arizona); Bob Lobo (Tennessee); Joel C. Marrs (Colorado); Kamakshi V. Rao (North Carolina); Douglas Slain (West Virginia); Kimberly Rashelle Watson (Arkansas); Erin R. Fox, Executive Committee Liaison (Utah)

#### **Network Facilitators**

Anticoagulation: Daniel A. Lewis (Kentucky) Cardiology: Orly Vardeny (Wisconsin)

Critical Care: Steven Pass (Texas)

Emergency Care: Deborah J. Larison (Florida)

Geriatrics: Donna Adkins (Virginia)

Hematology/Oncology: Susannah E. Koontz (Texas)
Immunology/Transplant: Lonnie Smith (Utah)
Infectious Diseases: Andrew DeRyke (Florida)
Nutrition Support: Vivian Zhao (Georgia)

Pain Management: Mitchell Nazario (Florida) Pediatrics/Neonatal: Melissa Heigham (Missouri)

Pharmacoeconomics and Drug Policy Development: Julie P. Karpinski

(Florida)

Pharmacokinetics: Julie Dumond (North Carolina)

Primary Care/Pharmacotherapy: Beth Bryles Phillips (Georgia)

Psychopharmacy/Neurology: Troy A. Moore (Texas) Women's Health: Gayle A. Cotchen (Pennsylvania)

## ASHP Section of Inpatient Care Practitioners

The Section of Inpatient Care Practitioners was launched in September 2003 to meet the needs of the frontline pharmacist. The Section dedicates itself to achieving a vision of pharmacy practice in which pharmacists practicing in an inpatient setting safely integrate clinical (direct patient care or indirect patient care), distributive, and operational functions and are focused on improving inpatient care. To achieve this vision, the Section will (1) serve as a voice for inpatient care practitioners and members of the Section within ASHP, including ASHP governance and integration of Section policy development within ASHP; (2) facilitate the integration of drug distribution and clinical practice for inpatient care practitioners and members of the Section; (3) assist in a concerted rural health care strategy that will strengthen ASHP's rural health care advocacy efforts, facilitate promotion of ASHP's policies and agenda in rural and frontier America, and elevate ASHP's standing in rural communities; (4) promote the professional development of inpatient care practitioners and members of the Section through education and skills development; (5) increase communication with Section members on key issues for both the Section and the profession; (6) encourage, facilitate, and educate on the application of ASHP best practices and evidence-based guidelines at the inpatient care practitioner level; and (7) identify and promote the development of inpatient care leaders and preceptors within the Section and mentor students by encouraging their active participation on Section advisory groups.

2010-2011 Section Highlights. Now in its seventh year, the Section has grown to well over 9000 members. Through educational programming, networking, advocacy, and volunteer opportunities, the Section Executive Committee has worked to develop member services that support the needs of the Section's membership component: frontline pharmacists, inpatient care practitioners, investigational drug service pharmacists, medication safety officers, operating room (OR)/anesthesiology pharmacists, and rural health care practitioners. Advocacy efforts for rural health care initiatives have been enhanced, and collaborative partnerships have been expanded. The mentoring of students, one of the Section's strategic goals, was enhanced by increasing student representation on all four of the Section's advisory groups. For the second consecutive year, the Section's Executive Committee hosted a networking session at the 2010 Midyear Clinical Meeting (MCM). Participants at this session discussed ASHP's current communication vehicles and the upcoming launch of ASHP's newly enhanced social media network, ASHP Connect. The Committee successfully developed educational content as well through its session focused on pharmacist liability resulting from increased clinical responsibilities. The Section is also responsible for developing an unprecedented medication safety series for the 2011 Summer Meeting; no previous Summer Meeting has provided an entire track devoted solely to medication safety. Several Section leaders were very active in the Pharmacy Practice Model Initiative (PPMI) Summit as participants, document authors, and presenters. The Section will continue to provide support to ASHP and the ASHP Foundation through education and advocacy efforts related to the PPMI. Section members elected Dr. Edwards as Chair and Ms. Kowiatek as Director-at-Large; both will be installed at the 2011 Summer Meeting. The Section's Committee on Nominations works to aggressively recruit qualified candidates for nomination and develop a slate of candidates that will serve as officers to fulfill Section initiatives. The committee typically begins its work in late February or early March and will present a slate of candidates for the Chair and Director-at-Large. The Executive Committee selected Paul Moore as the fourth winner of the Section's Distinguished Service Award. Dr. Moore received his award at the Distinguished Service Award Reception during the 2010 MCM.

**Educational Programming.** The Section conducted 21 hours of successful educational sessions at the 2010 MCM. For the fifth

#### **Executive Committee**

Brian Benson, Chair (Iowa)

Jennifer M. Edwards, Chair-elect (Montana)

Debby Lynn Painter Cowan, Immediate Past Chair (North Carolina)

Noelle R. M. Chapman (Illinois)

Joanne G. Kowiatek (Pennsylvania)

Richard J. Pacitti (Pennsylvania)

Christene M. Jolowsky, Board Liaison (Minnesota)

Anthea V. Francis, Secretary

consecutive year, a day of programming for pharmacists working in small and rural hospitals was offered. This programming, coordinated by the Section Advisory Group on Small and Rural Hospitals and entitled Programming for Small and Rural Hospitals, featured as its opening speaker Brock Slabach, Senior Vice President of Member Services for the National Rural Health Association (NRHA). Other rural program topics included High-Tech in the Country, CMS to Save the Day? How to Get Reimbursed for Cognitive Services and Other Quandaries, Anticoagulation National Patient Safety Goal: Ensuring Safe Use in Small/ Rural Institutions, A Hitchhiker's Guide to Telepharmacy, and The ABCs of 340B for Small and Rural Hospitals. Organizations represented on the program's speaker panel included the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA) as well as the Institute for Safe Medication Practices (ISMP). Additional MCM programming of interest to Section members addressed assuring safe technology implementation in specialty areas, meaningful metrics and adverse drug events, anaphylaxis and desensitization, and preparing for adult and pediatric codes. Section-branded programs were also featured and included the ever-popular Pediatrics for the Non-Pediatric Specialist series (now in its third year), and for the second year, Catheters, Pumps and Bands, Oh My! The Section's Educational Steering Committee met during the  $2010\,\mathrm{MCM}$  to discuss and select topics for Section programming for the 2011 MCM. The committee utilized the Section's Needs Assessment Survey, electronic discussion group reports, networking session discussions, and conversations with peers to guide them in the topic selections. The new charge for this committee has been expanded to include providing suggestions for Summer Meeting programming content, developing innovative webinars, seeking publication opportunities, and channeling articles for publication in the American Journal of Health-System Pharmacy (AJHP) and the Section's website. The group successfully organized a webinar entitled Update on Federal Regulation Regarding Treatment INDs and the Potential Financial Impact on Hospitals. Members of this committee have assisted with the Section's publication goals through contribution to ASHP's consumer drug information website (www.safemedication. com) and being successful in the publication of committee member Gina Ryan's Mar. 15, 2010, article, Overcoming insulin "resistance": Assisting patients in transitioning to insulin therapy in the Section's AJHP column, "Frontline Pharmacist." Other recent articles published in AJHP by current and former section leaders include: Have You Ever Thought About a Career in Small and Rural Hospitals? (Paul Driver and Timothy Stratton Dec. 1, 2010), Open Letter to Administrators of Small and Rural Hospitals (Timothy Stratton, Dec. 1, 2010), Health Reform Means Challenges, Opportunities in Rural Areas (Jan. 15, 2011), and Job Satisfaction in Hospital Pharmacists (Randy Kuiper, Debby Cowan and Richard Pacitti, Jan 15, 2011).

**Resources for Inpatient Care Practitioners.** The Section's page on the ASHP website features information pertinent to the needs of frontline pharmacists. The information includes recent news, practical tools, webinars, and member spotlights. All Section members receive a monthly Chair's Message and electronic NewsLink containing information of interest to the Section's membership. These communication vehicles also serve to notify members of opportunities within the Section and ASHP. The Section has three electronic discussion groups: inpatient, investigational drug service, and rural hospitals. These listservers and discussion boards continue to be an effective networking mechanism and serve as a necessary resource for these component groups.

**Advocacy.** Through presentations at senior citizen nursing homes and senior citizen organizations, the Section continues to embrace opportunities to reach out to this segment of the population and educate them about safe medication practices and adverse drug reactions. Furthermore, these presentations demonstrate the value of pharmacists, encourage seniors to develop meaningful relationships with each of their health care providers, and promote the roles of hospital and health-system pharmacists to the public. To further enhance its reach to the segment of the population, the Section is exploring opportunities for collaboration with various federal agencies on aging through its contact in the Maryland Department of Aging.

The Section Advisory Group on Medication Safety has been a constant advocate for providing robust and rigorous education and training for medication safety officers. The Section, through this advisory group, and in conjunction with ASHP's Educational Services Division, will be responsible for a medication safety series at the 2011 Summer Meeting. This track will constitute the Section's first learning series at an ASHP Summer Meeting. The medication safety series will provide 18 hours of pharmacist CE and will bring speakers from diverse disciplines: pharmacy, medicine, nursing, and law. This group makes a concerted effort to demonstrate the importance of ASHP assuming a lead role in the area of medication safety. The advisory group considers it important that ASHP continue its collaboration with reputable safety organizations and associations to develop relevant and meaningful education and training materials for medication safety officers, and will continue exploring the business case for having ASHP's Summer Meeting serve as a venue for providing medication safety officers with current information on safe medication policies and practices for this evolving area of health care.

Upon the recommendation of the Section Advisory Group on Small and Rural Hospitals, the Executive Committee has sought ways to expand ASHP's network with rural health care organizations and agencies. The Section has initiated building relationships with the Centers for Medicare & Medicaid Services (CMS), National Organization of State Offices of Rural Health (NOSORH), United States Department of Agriculture, and the Center for Health Literacy within the University of Maryland School of Public Health. Section staff has helped lead efforts to strengthen ASHP's relationship with NRHA, OPA, ORHP, Institute of Healthcare Initiatives (IHI), and ISMP. The Section Advisory Group on Small and Rural Hospitals has used its MCM Sunday Programming for Small and Rural Hospitals and the Section webpage to help communicate efforts of the HRSA/OPA Patient Safety Pharmacy Collaborative and the IHI 5 Million Lives Campaign. Partnership with ISMP has included appointing ISMP staff representatives to the Section Advisory Group on Medication Safety and the Section Advisory Group on Small and Rural Hospitals. ASHP has served as a major sponsor for NRHA's three annual Medication Use in Rural America conferences, and the Section is directly involved in the conference planning for the fourth conference, which will convene July 20-22, 2011, in Rapid City, Iowa. It is the Executive Committee's belief that a concerted rural health care strategy will strengthen ASHP's rural health care advocacy efforts, facilitate promotion of ASHP's policies and agenda in rural and frontier America, and elevate ASHP's standing in rural health care centers, organizations, and communities.

Advisory Group on Medication Safety. This advisory group, formed in August 2006, is charged with providing tools and resources for medication safety officers or pharmacists who have medication safety responsibility as a component of their positions. The group provided educational content for the 2010 MCM in the form of its fourth Safety and Quality Pearls session. In response to the nation's drug shortage crisis, the advisory group sponsored a webinar, The Long of Short of It: Strategic Solutions for Managing Drug Shortages. This was the third in the advisory group's annual medication safety webinar series. The panel of presenters hailed from WakeMed Health & Hospitals, University of Utah Hospital & Clinics, University of Pittsburgh Medical Center, FDA, and ISMP. The webinar drew more than 600 participants and is posted on the Section's webpage. Additionally, the group continues to conduct successful networking sessions at the Summer Meeting and MCM and has played a major role in the educational content development of 18.5 hours of pharmacist and nursing CE and physician CME credits for the Summer Meeting Medication Safety Series, June 13–15, 2011, in Denver.

**Advisory Group on Pharmacy Practice Experiences.** This advisory group was formed to provide tools and resources for frontline pharmacist preceptors and potential preceptors that foster favorable student experiences as students matriculate through their pharmacy rotations. The group maintains its resources, *How to Start a New Student Rotation* and *ASHP Preceptor Tool Kit.* Both are posted on the Section's webpage. The advisory group hosted a successful webinar, *Precepting from the Trenches: Tools and Tips for the Frontline Pharmacist.* Efforts are underway to organize the group's networking session for the 2011 MCM in New Orleans. The group hopes to collaborate with the Student Forum to address Introductory Pharmaceutical Practice Experiences (IPPEs). The advisory group plans to use results from the networking session to inform the development of future educational programs and additional resources.

**Advisory Group on Pharmacy Support Services.** This advisory group was formed in 2009. During its first year, the group's focus was to develop its goals and objectives. Currently, the group seeks to reap tangible outcomes and start producing resources for its membership component. Ultimately, the group's efforts will be directed toward assisting and supporting ASHP's Pharmacy Technician Initiative (PTI) and working with ASHP state affiliates to provide quality continuing education for certified pharmacy technicians. The advisory group recognizes the importance of conducting surveys and gap analyses that address the value of pharmacy technicians and the needed practice resources for pharmacy support personnel and their supervisors. The advisory group has a desire to investigate innovative roles for pharmacy support personnel and recommend approaches for incorporation of these roles into the PPMI.

Advisory Group on Small and Rural Hospitals. The Section Advisory Group on Small and Rural Hospitals maintains an active electronic discussion group and planned a successful educational track featuring eight hours of pharmacist continuing education credits for its fifth Programming for Small and Rural Hospitals during ASHP's 2010 MCM in Anaheim. Members of ASHP's Board of Directors, corporate leadership, and past presidents were among the attendees. Additionally, the advisory group organized a successful and well-attended networking session for the 2010 MCM. Planning for content for the 2011 MCM Programming for Small and Rural Hospitals is currently under way. This advisory group has been very active in the area of advocacy, educational programming, publications, and health policy. The group convened its first Rural Caucus during the 2010 Summer Meeting and keeps its members informed through its Small and Rural Hospital Resource Center. Due to the wide range of issues this advisory group addresses and advocates on behalf of, the considerable contributions the group has made to rural health care practice, and the percentage of ASHP members that practice in rural and frontier America, the Executive Committee has prompted ASHP to enhance its efforts related to rural health care policy, advocacy, education, and training as part of the Society's Leadership Agenda. The Executive Committee will continue to help ASHP recognize the role that small and rural hospitals, critical access hospitals, and other rural health care institutions play in the health care reform debate and the unique needs of these institutions. Furthermore, the Executive Committee will continue to stress the importance of expanding the advisory group's efforts to collaborate and engage with rural health care stakeholders.

#### **Educational Steering Committee**

Angela Turner Cassano, Chair (Virginia); Lois F. Parker, Vice Chair (Massachusetts); Catherine Christen (Michigan); Darlette G. Luke (Minnesota); Jacqueline L. Olin (North Carolina); Kimberly Pesaturo (Massachusetts); Wes Pitts (Mississippi); Gina Ryan (Georgia); Ronald Seto (Canada); Susan Jean Skledar (Pennsylvania); Linda Spooner (Massachusetts); Richard Pacitti, Executive Committee Liaison (Pennsylvania)

#### **Advisory Group on Medication Safety**

Lynn Eschenbacher, Chair (North Carolina); Janice L. Hoyt, Vice Chair (Washington); May Alomari (Michigan); Jorge D. Carrillo (Texas); Dan Degnan (Indiana); Christian A. Hartman (Massachusetts); Constance D. Hogrefe (Florida); Molly Billstein Leber (Connecticut); Jeannell M. Mansur (Illinois); Jason F. Nickisch (Montana); Victoria (Vicki) Tamis (Washington); Allen Vaida, ISMP Liaison (Pennsylvania); Deborah Wagner (Michigan); Ashleigh Vines, Student Member, Class of 2011 (Maryland); Joanne Kowiatek, Executive Committee Liaison (Pennsylvania)

#### **Advisory Group on Pharmacy Support Services**

Aubrey Booth Wynn III, Chair (Texas); Helen M. Calmes, Vice Chair (Louisiana); Sylvia Q. Banzon (California); Delia M. Charest (Maryland); Madeline F. Jensen Grauel (Texas); Cynthia (Cindy) Jeter (Minnesota); Barbara E. Lacher (North Dakota); Scott A. Meyers (Illinois); Terri K. Mundy (Louisiana); Robert M. Parsons (Ohio); Liesl Smith (Tennessee); Robert Sobolik (Montana); Winona T. Thomas (Louisiana); Trish Wegner (Illinois); Brian D. Benson, Executive Committee Liaison (Iowa)

#### **Advisory Group on Small and Rural Hospitals**

Todd Lemke, Chair (Minnesota); Robert David Long, Vice Chair (Nevada); Emily Alexander (Texas); Todd F. Biederman, NRHA Liaison (Texas); Navy Chaay (Wisconsin); Paul S. Driver (Idaho); Matthew P. Fricker, Jr, ISMP Liaison (Pennsylvania); Angela George (Minnesota); Jeffrey Brent Greer (Florida); Amanda J. Hays (Alaska); Pamela Milbern (Texas); Sal Morana (Vermont); Aaron Wayne Nash (Louisiana); Ann Marie B. Prazak (Utah); Jim Rorstrom (Kansas); Timothy S. Seeley (Wyoming); William R. Simpson (Pennsylvania); Debbie Sisson (Minnesota); Debra L. Cowan, Executive Committee Liaison (North Carolina)

#### **Advisory Group on Pharmacy Practice Experiences**

Beth D. Ferguson, Chair (Minnesota); Rony Zeenny, Vice Chair (Lebanon); Lijian "Leo" Cai (Illinois); Dale E. English II (Ohio); Scott D. Greene (Pennsylvania); Laura F. Hamilton, Student Member (Alabama); Thomas P. Lombardi (New York); Patrick McDonnell (Pennsylvania); Nancy R. Smestad (North Dakota); Stephanie Thomas (Pennsylvania); Laura C. Wachter (Maryland); Noelle RM Chapman, Executive Committee Liaison (Illinois)

#### **Committee on Nominations**

Helen Calmes, Chair (Louisiana); Debra Cowan, Vice Chair (North Carolina); Dale E. English II (Ohio); Megan K. McMurray (Washington)

#### **2010 Networking Session Facilitators**

Peggy Bickham (Illinois); Jorge Carillo (Texas); Todd Lemke(Minnesota); Section Executive Committee: Brian Benson, Noelle Chapman, Debra Cowan, Jennifer Edwards, Joanne Kowiatek, and Richard Pacitti; Ron Seto (Canada); Helen Tamer (Michigan); Victoria Tamis (Washington)

## ASHP Section of Pharmacy Informatics and Technology

The mission of the Section of Pharmacy Informatics and Technology is to improve health outcomes through the use and integration of data, information, knowledge, technology, and automation in the medication-use process. In that role, the Section continually seeks to define and promote the optimal synergy between technology and the pharmacy professional in an effort to enhance and support practice models that bring the full benefit of the pharmacist's training and experience to the medication-use process. The Section is dedicated to achieving a vision in which members will (1) be enabled by technology to focus on providing optimal pharmaceutical care to each patient; (2) participate in all aspects of medical informatics that support the medication-use process through multidisciplinary collaboration across the entire health care system; (3) collaborate domestically and internationally with other organizations and governmental agencies to promote the use of medical informatics in the provision of quality health care; (4) take a leadership role in medical informatics, at all levels of health care, to ensure that health information technology (HIT) supports safe medication use; (5) promote the development of a set of practical medical informatics competencies to manage medication-related data and information challenges across the continuum of care; and (6) stimulate an environment that focuses on setting the agenda for designing and conducting research to expand medical informatics knowledge and its use in supporting patient care. The Section is dedicated to improving health outcomes through the use and integration of data, information, knowledge, technology, and automation in the medication-use process. The Section has focused its goals and objectives to support the ASHP Leadership Agenda: "Influence the development and implementation of health information technologies and standards that help improve patientcare outcomes through the leadership of pharmacists."

2010–2011 Section Highlights. During 2010, the Section added more than 5200 members. About 20% of the Section's members have selected this group as their primary membership group. Total Section membership has increased by 24.4% from the previous year. Nearly one quarter of the Section membership is student members. In the 2010 elections, the Section's membership elected Allen J. Flynn as Chair-elect. Dr. Sylvia Thomley was elected as a Director-at-Large; both will be installed at the 2011 Summer Meeting. The Section also selected Mark H. Siska as the winner of the Section of Pharmacy Informatics and Technology Distinguished Service Award. Established in 2007, the ASHP Pharmacy Practice Sections Distinguished Service Award recognizes a member of a section whose volunteer activities have supported the mission of the section and helped advance the profession. The award was presented at the 2010 Midyear Clinical Meeting (MCM). In addition, a number of Section leaders were very active in the Pharmacy Practice Model Initiative (PPMI) Summit as participants, document authors, and presenters. The Section will continue to provide support to ASHP and ASHP Foundation education and advocacy efforts related to the PPMI.

ASHP is participating with the new Pharmacy e-Health Information Technology Collaborative. The Collaborative was formed by the Academy of Managed Care Pharmacy (AMCP), American Pharmacists Association (APhA), ASHP, and the National Community Pharmacists Association (NCPA). These four organizations will be the steering committee for the Collaborative, and they will work with the other organizations to meet the objectives of the Collaborative. The other organizations that will participate in the Collaborative are the American Association of Colleges of Pharmacy (AACP), American College of Clinical Pharmacy (ACCP), American Society of Consultant Pharmacists (ASCP), and the National Alliance of State Pharmacy Associations (NASPA). The expected outcomes of the Collaborative are to:

Identify (through the consensus work of expert panelists) the minimum data set and functional electronic health record (EHR) requirements for the delivery, documentation, and billing of pharmacist-

#### **Executive Committee**

Christopher J. Urbanski, Chair (Indiana) Allen Flynn, Chair-elect (Michigan) J. Chad Hardy, Immediate Past Chair (Texas) Anne M. Bobb, Director-at-Large (Illinois) Leslie R. Mackowiak, Director-at-Large (Tennessee) Sylvia M. Thomley, Director-at-Large-elect (South Dakota) John A. Armitstead, Board Liaison (Florida) Karl F. Gumpper, Secretary

provided medication management services. Such requirements include access to key medical information, such as laboratory data, and bidirectional communication flow among all practitioners.

- Structure and support implementation of a Pharmacy Practitioner HIT roadmap (Roadmap). The Roadmap is a document that directs and establishes benchmarks. These benchmarks will describe the development, implementation, and application of technology in an efficient and effective manner for pharmacists to affect improved medication use.
- Build cooperative relationships within pharmacy and among pharmacy and other stakeholders to communicate and advocate for the Pharmacy Practitioner minimum data set and Roadmap leading to a certified EHR as defined in the Federal Register.
- Ensure pharmacy representation on key HIT-related committees and workgroups.

The collaborative has accomplished the following activities since September 2010:

- Defined the structure of the Collaborative.
- Developed membership structure of the Collaborative.
- Appointed ASHP members to Collaborative's Advisory Work Group (six members).
- Working with Pharmacist Services Technical Advisory Coalition (PSTAC) on a medication therapy management (MTM) value set.
- Pharmacist Provider—Electronic Health Record (PP-EHR) functional profile approved by Health Level 7 (HL7) and National Council for Prescription Drug Programs (NCPDP).

**Educational Programming.** The Section's programming for the 2010 MCM consisted of over 15 hours of continuing education. Topics that were presented included electronic prescribing, clinical rule development, BCMA research (ASHP Foundation-supported grants), EHR implementation, safe technology implementation, pharmacy IT team structures, and mobile health applications. Lynn Sanders of the Section's Educational Steering Committee coordinated the Informatics Bytes: Pearls Session. Maritza Lew was the Chair of the Section's 2010–2011 Educational Steering Committee.

Planning for the 2011 MCM is currently in progress. The Educational Steering Committee is searching for proposals that include "meaningful use" of electronic health records, advanced clinical decision support, closed-loop medication practices, pharmacy practice models enabled by technology, and mechanisms for training end users on technology use. Armen Simonian of the Section's Educational Steering Committee will coordinate the Informatics Bytes: Pearls Session.

Drs. Fox and Fortier worked with the ASHP Educational Services Division to plan an informatics series at the 2010 Summer Meeting. An informatics session was scheduled during all six of the meeting's educational opportunities. Topics that were presented included the American Reinvestment and Recovery Act (ARRA), "meaningful use" of electronic health records, project management of technologies, applying technology to facilitate error reporting, maximizing operational efficiencies, and oncology informatics applications.

Drs. Fox and Fortier planned an Informatics Series for the 2011 Summer Meeting, whose topics include an update on meaningful use and the EHR, PPMI, optimizing automation, credentialing for informatics, mobile devices and social media, and order set development and maintenance.

The Section also planned and implemented four networking sessions at the 2010 MCM. Each of the Section's advisory groups planned a thematic program related to its primary charge. A networking session is planned for the 2011 Summer Meeting to be facilitated by the Executive Committee.

Electronic Networking Opportunities. The Section's electronic NewsLink is distributed monthly to more than 4400 ASHP members. The NewsLink provides information on current issues relating to informatics and technology, research, legislative and regulatory facts, and health policy and health care news. The Section's electronic discussion group, which includes 2700 participants, provides a forum for Section members to exchange information and ideas on a wide variety of topics related to pharmacy informatics and technology. The most visited web sites of the Section were Pharmacy Informatics Job Descriptions, Pharmacy Informatics Career Development, and Bar Code Medication Administration Resources. The Section will continue to monitor the use of the Section's web site and promote its available resources to members. The Executive Committee is interested in expanding the Section's presence utilizing existing social media tools (e.g., Twitter, FaceBook, LinkedIn, etc.) and developing new tools and strategies.

Revised Charges for Section Advisory Groups. During the Section's June 2009 Executive Committee meeting, the Executive Committee formalized and standardized the charge of each of the four advisory groups. Each advisory group will share eight common charges: (1) contribute to the "Informatics Interchange" column in the American Journal of Health-System Pharmacy (AJHP), (2) coordinate a webinar for the Section membership on a related topic area, (3) review the relevant content area on the Section's website on an annual basis, (4) develop programming for the MCM, (5) appoint a working group to manage the frequent call for comments for various government and regulatory groups, (6) encourage members to contribute and post to the Section's listserver and ASHP Connect, (7) coordinate a networking session at the MCM on a topic relevant to the advisory group's purview, and (8) coordinate a spotlight on a member's contribution to the Section for the Section's website. Each Section advisory group and committee will further have projects and deliverables focused on the group's scope and content knowledge.

Advisory Group on Ambulatory Care Informatics. Activities of the Section Advisory Group on Ambulatory Care Informatics includes developing resources for members on electronic prescribing (ePrescribing), personal health records (PHRs), medication reconciliation, and electronic reimbursement issues (MTM clinical services documentation and billing for medications). The advisory group is still reviewing survey results on drug-drug interactions (DDI) to direct its efforts on developing recommendations concerning DDIs in pharmacy and integrated electronic systems. A plan is being developed to share the survey results and develop a commentary/editorial for AJHP. The advisory group conducted its first webinar networking session, It Is Not Just a List: The Complexities of Med Reconciliation, facilitated by HIT in April 2010. The advisory group is continuing work to educate health-system pharmacists on ambulatory care informatics issues such as electronic prescribing, electronic medication reconciliation, and Risk Evaluation and Mitigation Strategies (REMS) programs. The networking session that was developed by the advisory group at the MCM was related to the use of electronic prescribing in hospitals and health systems.

Advisory Group on Clinical Information Systems. Activities of the Section Advisory Group on Clinical Information Systems include the development of computerized provider order entry (CPOE) guidelines and clinical decision support systems (CDSS). The ASHP Guidelines on Pharmacy Planning for Implementation of Computerized Provider Order Entry (CPOE) Systems in Hospitals and Health Systems were approved by the ASHP Board of Directors during summer 2010 and published in the March 15, 2011, issue of AJHP. CDS alerts and alert fatigue is a priority issue with the advisory group for the coming year. The advisory group is interested in assessing the pharmacy resources required to manage and implement clinical information systems within hospitals and health systems. In supporting the federal government's requirements for "meaningful use" of the EHR, the advisory group will focus on quality outcomes and measure reporting. The networking session at the MCM that the advisory group identified has as its topic the pharmacy technician role in information technology to reduce medication errors and enhance patient quality and safety. The advisory group is interested in working further on the role of the pharmacy technician in informatics.

Advisory Group on Pharmacy Informatics Education. Activities of the Section Advisory Group on Pharmacy Informatics Education include updating and maintaining the Section's website and resource centers; supporting the development of informatics residency programs and other educational opportunities for pharmacists, students, technicians, and vendors; and facilitating a column in AJHP. With the establishment of the "Informatics Interchange" column in AJHP, there have been over 17 publications since June 2008. With the changing responsibilities of pharmacy informatics practitioners, the advisory group will be revising the ASHP Statement on the Role of the Pharmacist in Informatics during the upcoming year. This advisory group is developing strategies to engage practitioners in informatics to support the clinical role of the pharmacist. Educational needs of students, residents, practitioners, and pharmacy technicians are a concern for members of the Section. The advisory group is investigating the need for a certification in pharmacy informatics for pharmacists. The networking session that was developed by the advisory group at the MCM was related to the required competencies and the need for certification of pharmacists.

**Advisory Group on Pharmacy Operations Automation.** Activities of the Section Advisory Group on Automation and Documentation include electronic/automated management of the

Documentation include electronic/automated management of the medication supply chain process, preparation of medications and dispensing of medications with robotics, medication administration with bar code medication technologies and smart pumps, and formulary management with multiple applications within multiple hospital settings. With the completion of the ASHP Statement on Bar-Code Verification During Inventory, Preparation, and Dispensing of Medications, the advisory group will work on developing a communication plan to members and other stakeholders around ASHP policy on bar-code medication management. The statement was published in the March 1, 2011, issue of AJHP. The advisory group is developing resources on many important areas of automation and pharmacy devices; some of its work groups are looking at the following: measuring quality of automation and technology; developing policy and procedure templates; updating resources on intelligent infusion devices; establishing the standard reports required for any system; defining interoperability, interface, and integration; and creating resources on robotics. The networking session at the MCM will provide guidance on reviewing contacts for automation and software vendors for IT pharmacists and directors.

#### **Advisory Group on Ambulatory Care Informatics**

Helen L. Figge, Chair (New York); Shobha Phansalkar, Vice Chair (Massachusetts); Mary E. Burkhardt (Michigan); Gaurang Gandhi (Florida); John Horn (Washington); Tom Jurewitz (California); Kevin Marvin (Vermont); Barry McClain (Wisconsin); Paul G. Miller (Michigan); Navin B. Philips (New Jersey); George A. Robinson (Indiana); Bob Rocho (Colorado); James Russell (Wisconsin); Mark H. Siska (Minnesota); Douglas R. Smith (Texas); Robert L. Stein (California); Kathleen Vieson (Florida); Marc Young (Texas); Ruth Serrano, Informatics Resident (Florida); Patrick McDonnell, Council on Therapeutics Liaison (Pennsylvania); Ronald J. Campbell, Jr., Council on Therapeutics Liaison (Pennsylvania)

#### **Advisory Group on Clinical Information Systems**

Nancy R. Smestad, Chair (North Dakota); W. Lynn Ethridge, Vice Chair (South Carolina); Dawn Biller (Indiana); Lynn Boecler (Illinois); Denny C. Briley (Kansas); Christine M. Beuning (Washington); James Carpenter (Oregon); Bruce Chaffee (Michigan); Raymond Chan (Virginia); Janet Crawford (Missouri); Franklin Crownover (Massachusetts); Kelly Duarte (West Virginia); P. Neil L. Edillo (Oregon); Krista

Engelmann (Illinois); Maren Everton (Utah); Allen Flynn (Michigan); Randy Herring (Georgia); Richard S. Jacobs (Washington); Tara K. Jellison (Indiana); Michael A. Jones (Colorado); Joan E. Kapusnik-Uner (California); Andrew Laegeler (Texas); Trinh Le (North Carolina); Te Jung Lin (Texas); Adam Lisi (New Jersey); Mark Mahoney (Ohio); Tommy Mannino (Louisiana); Gregory Matsuura (Washington); Joseph T. Moss (Ohio); Stanley L. Pestotnik (Utah); Adelaide Quansah-Arku, Technician Member (District of Columbia); Brendan Reichert (Maryland); Mohammad Aslam Siddiqui (Kentucky); Kirby Stiening (Virginia); Lisa S. Stump (Connecticut); Sylvia Thomley (South Dakota); David L. Troiano (Texas); Laura L. Tyndall (Pennsylvania); Karen Umali (Connecticut); DeWayne A. Davidson, Student Representative (Texas); Lisa Starost, Informatics Resident (Indiana)

#### **Advisory Group on Pharmacy Informatics Education**

Louis Barone, Chair (Ohio); Elizabeth Ann Breeden, Vice Chair (Tennessee); Jennifer Boehne (Massachusetts); Willie Capers II (Arkansas); Kevin Clauson (Florida); Amy P. Davis (Florida); Jerry Fahrni (California); Stephanie M. Ferrell (California); Brent Fox (Alabama); Carol Hope (Utah); Douglas B. Kent (Pennsylvania); Cheryl Krempa (New Jersey); Joseph Lassiter (Oregon); John Paul Marcus (Illinois); Scott McCreadie (Michigan); Sharon K. Park (Maryland); Pamela Schindler (Alabama); Beju Shah (South Carolina); Jonna Smith (Illinois); Phillip W. Stewart (Tennessee); Allison D. Woods, Informatics Resident (Michigan); Michael Schroeder, Student Representative (New Jersey)

#### **Advisory Group on Pharmacy Operations Automation**

Gwen Volpe, Chair (Indiana); Barbara Lane Giacomelli, Vice Chair (New Jersey); Leslie Brookins (Missouri); Ron Burnette (Florida); Richard Capps III (South Carolina); Kavish J. Choudhary (Utah); William Coffey (Texas); Seth Aaron Cohen (Maryland); Thomas W. Cooley (Massachusetts); Charles De la Torre (Florida); Doina Dumitru (Texas); Darren S. Ferer (New York); Christopher Fortier (South Carolina); LeAnn Graham (Oklahoma); Staci Hermann (Kansas); Jennifer J. Howard (California); Isha S. John (Maryland); Seth A. Kuiper (Ohio); Louis Levenson (Delaware); Robert Locke (New York); Mick Lowry (Texas); Silvia Maranian (Colorado); Rhonda B. McManus (South Carolina); Eric Nemec (Massachusetts); Nancy A. Nickman (Utah); Beth Prier (Ohio); Brad Rognrud (Minnesota); Kevin A. Scheckelhoff (Ohio); Ronald Schneider (District of Columbia); Steven Silverstein (Illinois); Chad S. Stashek (Massachusetts); David A. Tjhio (Illinois); Dennis A. Tribble (Florida); Thuy Vo (Washington); Robynn P. Wolfschlag (Colorado); Aaron Speak, Resident Representative (Kentucky)

#### **Committee on Nominations**

J. Chad Hardy, Chair (Texas); Brent Fox (Alabama); Scott R. McCreadie (Michigan); Kevin A. Scheckelhoff (Ohio); Dennis A. Tribble (Florida)

#### **Educational Steering Committee**

Maritza Lew, Chair (California); Robert Christiansen, Vice Chair (Pennsylvania); Alan Chung (District of Columbia); John Manzo (New York); Lynn C. Sanders (District of Columbia); Michael D. Schlesselman (Connecticut); Armen Simonian (California); Lolita White (Maryland)

# ASHP Section of Pharmacy Practice Managers

The mission of the Section of Pharmacy Practice Managers is to help members manage pharmacy resources, maximize the safety of medication-use systems, develop future leaders, and promote the pharmacist's role in patient care. The Section Executive Committee has developed a strategic plan linked to the mission and goals of the Section. These goals are (1) maximize communications and interactions with and among Section members; (2) enhance effectiveness of managers and leaders through development of education, training, and cultivating mentoring relationships; (3) recommend professional policy and advocacy on issues of importance to Section members; (4) define strategies to enhance the stature of the pharmacy enterprise within the health care delivery system and demonstrate the value of the profession; and (5) drive the advancement of the future practice model to support health care reform. The ASHP Section of Pharmacy Practice Managers represents ASHP's continued commitment to meeting the needs of pharmacists who lead and manage departments of pharmacy. The Section provides pharmacy directors and managers with a sense of identity within ASHP and an organizational home dedicated to meeting their special needs.

**2010–2011 Section Highlights.** The Section has 8564 members, with approximately 44% of the Section's members having selected the Section as their primary membership group. Section members elected Michael Powell as Chair and Laura Mark as a Director-at-Large; both will be installed at the 2011 Summer Meeting. The Section recognized Steve Rough as the winner of the Section of Pharmacy Practice Managers Distinguished Service Award. Established in 2007, the ASHP Pharmacy Practice Sections Distinguished Service Award recognizes a member of each section whose volunteer activities have supported the Section's mission and helped advance the profession. The award was presented at the 2010 Midyear Clinical Meeting (MCM).

In addition, a number of Section leaders were very active in the Pharmacy Practice Model Initiative (PPMI) Summit as participants, document authors, and presenters. The Section will continue to provide support to ASHP and ASHP Foundation education and advocacy efforts related to the PPMI. The Section is planning to establish an advisory group to facilitate the Section role in translating the reccomendations of the Summit into practice.

Educational and Networking Opportunities. Under the leadership of John Pastor, the 2009-2010 Educational Steering Committee designed educational sessions for pharmacy managers and directors that were presented at the 2010 MCM. Topics included inpatient and outpatient prospective payment system rules and regulations, succession planning, strategic planning, human resource management, drug diversion, leadership, medication safety, C-suite communication, and management pearls. All of these sessions were recorded and synchronized with the presentation slides so that they can be made available to members. For the 2011 MCM, the committee is planning sessions on inpatient and outpatient prospective payment system rules and regulations, managing practice model change, working with consultants, accountable care organizations, leadership challenges for multi-hospital pharmacy leaders, dashboards and score cards, and revenue cycle management and compliance. The Section also planned and implemented networking sessions at the 2010 MCM addressing issues and opportunities with administrative residencies, risk evaluation and mitigation strategies (REMS), human resource management, workload and productivity, and multi-hospital pharmacy leaders.

The Section continues to distribute a monthly electronic NewsLink that serves over 8000 ASHP members. The NewsLink provides Section information, business information, leadership and management information, relevant research, legislative updates, regulatory alerts, and health policy/health care news. The Section also continues to facilitate an electronic discussion group with

#### **Executive Committee**

Scott J. Knoer, Chair (Ohio)
Michael F. Powell, Chair-elect (Nebraska)
Kathleen S. Pawlicki, Immediate Past Chair (Michigan)
Todd A. Karpinski (Wisconsin)
Patricia J. Killingsworth (Idaho)
Laura K. Mark (Pennsylvania)
Michael D. Sanborn, Board Liaison (Texas)
David F. Chen, Secretary

approximately 3000 participants. The electronic discussion group provides a forum for Section members to exchange information and ideas on a wide variety of topics related to pharmacy management and leadership.

Conference for Leaders in Health-System Pharmacy. The Section, in collaboration with ASHP Advantage, planned and implemented another successful leadership conference. This event reached capacity in 2010 with over 400 participants, included key programs in areas such as human factors, leading a just culture, health reform, and the future practice model. In addition, a preconference Managers' Boot Camp was conducted for its third year as a free-standing workshop focusing on key drivers for the C-suite, financial management skills for the future, executing change, and developing teams. In addition, 10 section leaders provided facilitation for networking tables on hot topics. As part of the conference proceedings, the John W. Webb Lecture Award was presented to James Stevenson.

**Multi-hospital Health-System Pharmacy Leaders.** This group of Section members is a growing area of membership. For the second year the Section organized a networking session at the 2010 MCM for these practitioners. Future plans include providing education and networking session addressing the specific needs of these leaders. The Section is considering conducting a survey on pharmacy service characteristics of these evolving multi-hospital health systems.

**Advocacy.** The Section continues to be very active in advocacy in the areas of workload and productivity measures, the expansion of restricted drug distribution systems, the affordability of drugs, and reimbursement. In addition, the Section will continue to be engaged in promoting, fostering, and expanding the opportunities for pharmacy leadership and the benefits of pharmacist leadership in improving the medication use system.

### **Advisory Group on Communications and Publications.** This advisory group has worked steadily to improve communications.

This advisory group has worked steadily to improve communication of the Section's activities and the completion of publications focused on the needs of pharmacy practice managers. The group finalized the Section's communication and marketing plan. Members of this group have facilitated submissions for the the "Manager's Consultation" column in the *American Journal of Health-System Pharmacy (AJHP)*, with two publications on leadership and workflow design. The advisory group has completed seven Member Spotlights for the Section webpage to recognize Section members that have been active in the success of Section goals.

**Advisory Group on Leadership Development.** This advisory group was successful in completing a webinar focused on succession planning and a well-attended program at the 2010 MCM on talent mapping and employee portfolio management for leadership development. The group also provided educational programming on leadership in turbulent times at the 2010 MCM. Another significant accomplishment of the Section coordinated through the advisory group is the Student Leadership Development (SLD) Workshop. This workshop is a three-hour program to introduce students to leadership opportunities and to facilitate networking with other students interested in leadership. The program has been incorporated into

the last two Summer Meetings and has been implemented at 16 ASHP state affiliates and one college of pharmacy. The advisory group is working in collaboration with the ASHP Affiliate Relations Division and the Center for Health-System Pharmacy Leadership to continue the expansion of the program. The advisory group has organized networking sessions to promote administrative residencies and the benefits of residency training the past three MCMs. A number of the advisory group's members also participated in the Health-System Pharmacy Practice Administration residents networking session at the annual Conference for Leaders in Health-System Pharmacy. The group has also been engaged with the ASHP Foundation and its efforts on identifying opportunities for new practitioner and student leadership development.

**Advisory Group on Manager Development.** This advisory group focused on tools and education to support health-system pharmacy manager development. The group completed and launched the web-based Managers Continuous Professional Development Resource Center, which is a curriculum utilizing key management and leadership textbooks that are organized around 11 domains of manager competencies. Two very successful networking sessions were organized by the group dealing with human resource management, with a session at 2010 Summer Meeting and MCM. In addition, the advisory group coordinated the third annual Managers' Boot Camp held prior to the Conference for Leaders in Health-System Pharmacy.

#### Advisory Group on Pharmacy Business Development.

This advisory group finalized its Financial Management Self-Assessment Tool and Web Resource. This tool is a comprehensive self-assessment instrument for members to determine their level of accomplishing over 80 different financial management strategies. The group also collected and posted as a web resource three returnon-investment models for members to utilize. The group has as a priority workload and productivity metrics, and *AJHP* published the two-part paper, "Effective use of workload and productivity monitoring tools in health-system pharmacy" in February and March 2010. The group continues to focus on this important issue and led a network session on the topic at the 2010 MCM and is working on a standard slide presentation to provide as a resource for members with information to present to hospital administrators.

Advisory Group on Quality and Compliance. This advisory group was very active with issues surrounding REMS, reimbursement compliance, and CMS Conditions of Participation (CoP) challenges. The group provided a webinar on inpatient and outpatient prospective payment system rules and regulations and one on strategies to manage REMS. At the 2010 MCM an education session on reimbursement compliance and the new inpatient and outpatient prospective payment systems (IPPS and OPPS) rules was provided for the second year. The advisory group was also part of a 2010 MCM education program on REMS, followed by a network session organized by the group. The advisory group is continuing work on creating a "Tip of the Month" that will provide members with ideas and resources on how to improve their compliance and success with quality and regulatory goals. The group is continuing to work with ASHP's staff on seeking more patient safe interpretation of CMS's medication administration CoPs surrounding the "30-minute" rule.

#### **Advisory Group on Communications and Publications**

Audrey Nakamura, Chair (California); Rabiah Dys, Vice Chair (Massachusetts); John S. Clark, Immediate Past Chair (Michigan); Steven Dzierba (Texas); Matthew W. Eberts (Pennsylvania); John P. Gray (Wisconsin); Kristi Gullickson (Minnesota); Trinh Le (North Carolina); Jacob D. Spangler (Wisconsin); Mark Sullivan (Tennessee)

#### **Advisory Group on Leadership Development**

Edward Nold, Chair (Florida); Karol Wollenburg, Vice Chair (New York); Cynthia A. Clegg, Immediate Past Chair (Washington); Richard Burnett (Texas); Jennifer Cimoch (California); Arash Dabestani (California); Michael A. DeCoske (North Carolina); Lori J. Golterman (District of Columbia); Justin Paul Konkol (Wisconsin); Richard Montgomery (Florida); David B. Moore (Florida); Veena Rajanna (Minnesota); Jerome Wohleb (Utah); David Wolfrath (Florida)

#### **Advisory Group on Managers Development**

Rick Couldry, Chair (Kansas); Lindsey R. Kelley, Vice Chair (Pennsylvania); Jennifer Tryon, Immediate Past Chair (Washington); Trent A. Beach (Delaware); Osmel Delgado (Florida); Marilyn Farinre (District of Columbia); Robert Granko (North Carolina); Karl Kappeler (Ohio); Timothy W. Lynch (Washington); Carolyn (Carrie) S. Morton (Indiana); Michael C. Nnadi (North Carolina); Adam Orsborn (North Carolina); Kate Schaafsma (Wisconsin); Andrew J. Wilcox (Wisconsin)

#### **Advisory Group on Pharmacy Business Management**

Laura Mark, Chair (Pennsylvania); Philip Brummond, Vice Chair (Michigan); Dave A. Ehlert, Immediate Past Chair (Minnesota); Edward H. Eiland III (Alabama); Erin Hendrick (Wisconsin); Russell K. Hulse (Utah); Alexander Thomas Jenkins (North Carolina); Paul R. Krogh (Minnesota); Michael McGregory (Indiana); Brian Paul Romig (North Carolina); Rafael Saenz (Pennsylvania); Armando Soto (Florida); Chad S. Stashek (Massachussetts); Kimberly R. Watson (Arkansas); John Worden (Kansas)

#### **Advisory Group on Quality and Compliance**

James M. Hoffman, Chair (Tennessee); Margaret A. Huwer, Vice Chair (Ohio); Greg Polk, Immediate Past Chair (Michigan); Jennifer Burgess (North Carolina); Brian M. Cotter (Maryland); Tara K. Jellison (Indiana); Bonnie Kirschenbaum (Colorado); Ben Lopez (Ohio); Joel Thomas Melroy (South Carolina); Robert James Moura (Massachussetts); Stephen Novak (North Carolina); Kuldip R. Patel (North Carolina); Dianna Pimlott (Oregon); Cynthia Williams (Virginia); Samaneh Wilkinson (Kansas); Doris Wong (California)

#### **Educational Steering Committee**

Ryan Forrey, Chair (Ohio); Thomas E. Kirschling, Vice Chair (Pennsylvania); John D. Pastor III, Immediate Past Chair (Minnesota); Tammy Cohen (Texas); Doina Dumitru (Texas); Mary Foss (Minnesota); Nancy A. Huff (Massachusetts); Jennifer Jastrzembski (Florida); Susan Kleppin (Wisconsin); James T. Lund (Illinois); Stephanie Peshek (Florida); Carol Welch-Plaskey (Michigan); Jay P. Rho (California)

#### **Committee on Nominations**

Kathleen S. Pawlicki, Chair (Michigan); David A. Kvancz (California); James R. Rinehart (Nebraska); Steve Rough (Wisconsin); Andrew L. Wilson (Virginia)

## ASHP New Practitioners Forum

The New Practitioners Forum is led by a five-member Executive Committee appointed each year by the ASHP President-elect and approved by the Board of Directors. The Executive Committee is responsible for advising the Board and ASHP staff on the overall direction of the Forum, including member services, programs, and resources. The Executive Committee Chair participates in ASHP's strategic planning process and serves as a voting new practitioner member in the ASHP House of Delegates. Each Executive Committee member serves as a liaison to one of the Forum's six advisory groups.

The Executive Committee updated and approved a new Mission and Vision for the New Practitioners Forum this year, reflecting the ongoing growth and future direction of this membership component group.

**Forum Mission and Vision.** Recognizing that recent pharmacy graduates have unique and diverse professional needs, the ASHP New Practitioners Forum seeks to provide a community and collective voice for new practitioners as they transition into hospital and health-system pharmacy practice. Through innovative programming, educational resources, advocacy tools, networking events, and leadership opportunities, the Forum supports the integration of new practitioners into ASHP and empowers members to lead the future of pharmacy practice.

The ASHP New Practitioners Forum seeks to be the preferred organizational home for new practitioners practicing in hospitals and health systems. Through our dynamic programs and services, our knowledgeable and respected members will collaboratively develop, promote, and lead best practices supporting innovative practice models that provide optimal care to patients.

**Strategic Goals and Objectives.** The Executive Committee established four strategic goals, with accompanying objectives, to direct the Forum's operations:

- Serve the unique and evolving educational and informational needs of new practitioner members. Objectives:

   (1) Conduct continual assessment and analysis of evolving needs and the effectiveness of Forum programs to meet these needs.
   (2) Provide programs and publications that meet the educational and informational needs of new practitioner members.
   (3) Utilize social media to effectively communicate with new practitioner members.
- 2. Support the development of leadership skills and professionalism in new practitioner members. Objectives: (1) Promote leadership and engagement opportunities for new practitioner members within the Forum and ASHP. (2) Provide programs and resources that promote leadership skill development and foster professionalism in new practitioner members.
- 3. Promote membership and active involvement in the ASHP New Practitioners Forum. Objectives: (1) Recruit, retain, and promote active involvement in the Forum. (2) Enhance visibility and awareness of Forum membership benefits. (3) Expand collaboration between Forum members and others in ASHP, including section and Student Forum members. (4) Promote initiatives and accomplishments of Forum members.
- 4. Facilitate greater understanding and participation in professional policy development and advocacy by new practitioner members. Objectives: (1) Generate awareness and encourage participation of new practitioner members in professional policy development. (2) Create awareness and support involvement of new practitioner members in advocacy. (3) Support new practitioner member engagement in practice advancement initiatives.

**2010–2011 Forum Highlights.** Landmark achievements consistent with these goals and objectives in 2010–2011 included (1) fully

#### **Executive Committee**

John B. Hertig, Chair (North Carolina) Jeffrey D. Little, Vice Chair (Kansas) Linda W. Banares (California) Jordan R. Covvey (Virginia) Brandon J. Ordway (Minnesota) Lisa M. Gersema, Board Liaison Jill L. Haug, Secretary

implementing the new, multifaceted Great eXpectations eXperience program by hosting the second consecutive successful Great eXpectations Live program for new practitioners at the Midyear Clinical Meeting (MCM), holding the inaugural Great eXpectations eConference in April, and unveiling the web-based, on-demand Great eXpectations Video program; (2) awarding the fourth New Practitioners Forum Distinguished Service Award; (3) updating the Forum's Mission and Vision to more accurately reflect the continued evolution of the Forum and its members; and (4) developing member-generated, webbased video career profiles to spotlight the professional accomplishments of new practitioner members. These activities demonstrate the commitment of ASHP and the Forum to meeting the unique needs of over  $4500\,\mathrm{new}$  practitioner members. The continual creation and provision of career development tools, leadership opportunities, and practice resources, and the identification of opportunities for collaboration with the ASHP practice sections, also show support for this membership group. By meeting new practitioner needs, ASHP hopes to foster professional development in new practitioners that extends into greater involvement in ASHP and state and local health-system pharmacy organizations.

**Distinguished Service Award.** The Forum selected Lindsey Kelley as the winner of the New Practitioners Forum Distinguished Service Award. Established in 2007, the ASHP New Practitioners Forum Distinguished Service Award recognizes a member of the Forum whose volunteer activities have supported the Forum's mission and helped advance the profession. The award was presented at the 2010 MCM.

**Advisory Groups.** The Chair of the New Practitioners Forum Executive Committee appoints Forum members to advisory groups in June, placing over 60 new practitioners in leadership positions. The advisory groups are charged with providing feedback, guidance, and assistance in achieving the Forum's strategic goals. Each group is chaired by a returning advisory group member, and an Executive Committee member serves as a liaison. The Executive Committee implemented several continuing quality improvement initiatives to assess and improve members' advisory group experience, including in-person status reports at the December Executive Committee meeting and midpoint surveys assessing both advisory group chair and advisory group member satisfaction.

**Advisory Group on Communications and Technology.** This group is charged with enhancing the Forum's image and outreach using various electronic communication tools. Priorities this year included developing a new web-based video profiles program to spotlight new practitioners in various practice initiatives, providing ongoing review and feedback regarding the Forum's engagement in social media, and discussing the importance of e-professionalism and exploring ways to provide education on this topic.

**Advisory Group on Membership and Outreach.** This group is charged with advancing the objectives set forth in strategic goal 3 and focused on projects to expand collaboration between Forum members and the broader ASHP membership. Priorities this year included encouraging Forum advisory group members to volunteer and serve as student poster mentors at the MCM, creating a toolkit of best practices for state affiliates to promote new practitioner engagement, and developing a pilot program to recognize excellence

in research and practice innovation for new practitioners presenting a professional poster at the 2011 MCM.

**Advisory Group on Public Affairs and Advocacy.** This group is charged with advancing the objectives set forth in goal 4. Priorities this year included launching an advocacy video project that spotlights new practitioners from ASHP policy committees, providing feedback to enhance the Forum's web-based advocacy resources, collaborating with the ASHP Government Affairs Division to encourage new practitioner engagement with ASHP-PAC activities, and developing an advocacy program to be considered for the 2011 *Great eXpectations Live* program.

#### Advisory Group on Leadership and Career Development.

This group is charged with advancing the objectives set forth in goal 2. Priorities this year included developing a webinar on advanced practice management degrees, writing a series of mini-articles focused on various career development topics, and developing a resource that will assist new practitioners with maintaining professionalism in the era of electronic communication.

**Advisory Group on Professional Practice.** This group is charged with advancing the objectives set forth in goal 1, specific to professional practice issues. Priorities this year included developing a clinical pearls session for the Pharmacy Student Forum programming at the 2010 MCM and subsequently repurposing the content from this program into a useful web-based resource for new practitioners and exploring the development of a resource highlighting important professional transitions encountered by many new practitioners.

**Advisory Group on Science and Research.** This group is charged with advancing the objectives set forth in goal 1, specific to science and research issues. Priorities this year included collaborating with the ASHP Research and Education Foundation to identify gaps in web-based research tools, developing sample protocols and model grant applications for the Foundation's website, and initiating the development of a web-based landmark trials resource that will potentially develop further through utilization of ASHP Connect and collaboration with the Section of Clinical Specialists and Scientists.

Meetings and Programming. For the second consecutive year, Great eXpectations Live was held at the MCM and was enormously successful. High-tech, interactive, fresh, and fun, the Great X program allows new practitioners the opportunity to learn, network, and move forward in their careers. This live event offered skill-building sessions in three learning tracks: Fine Tuning Your Clinical Skills, Mentoring and Leadership, and Advancing Your Career. Attendees also had many opportunities to mix and mingle with fellow new practitioners from across the country. ASHP hosted the Great eXpectations eConference on April 1, the first virtual conference offered in the pharmacy association world. Completing the Great eXpectations eXperience portfolio, Great eXpectations Video was launched in the spring with an initial offering of two continuing education video programs focusing on effectively presenting a professional poster and influencing change as a member of the health care team. These continuing education videos are available on-demand on the New Practitioners Forum website.

The 2010 MCM offered a variety of programs and opportunities for new practitioners. New practitioners participated in the residency showcase and personnel placement service. The all-day *Great eXpectations Live* program provided fifteen hours of continuing education targeted at new practitioners. The New Practitioner Lounge was available throughout the meeting, giving new practitioners a place to meet with peers in an informal setting and discover more about the New Practitioners Forum either by reviewing information placed in the lounge or by meeting with other members actively engaged with the Forum. Executive Committee members also represented the Forum in the ASHP Experience Membership booth.

The Forum added one webinar to its online library this year, *Pharmacy Service Initiation: Steps for New Clinical Pharmacy Leaders*. Forum webinars are recorded educational sessions on relevant practice topics, available for new practitioners to view at their convenience.

**Communications.** The Forum relies on ASHP Connect for new practitioner members to communicate on practice and career development issues. ASHP Connect provides members the convenience of only participating in discussions of interest and in ways they prefer to communicate.

All Forum members receive the ASHP New Practitioners Forum NewsLink once a month. This service provides information relevant to recent graduates, communicates deadlines, and helps recruit members for greater involvement in the Forum. The NewsLink has enabled the Forum to recruit new practitioner authors, advisory group members, and volunteers for various outreach efforts and identify new practitioners to highlight on the webpage. In addition, Forum members receive an electronic message from the New Practitioners Forum Executive Committee once a month that highlights key programs and initiatives as well as provides an ongoing update of what the Executive Committee and Forum advisory groups are doing on behalf of members.

The Forum has its own area on the ASHP website where new practitioners can find information pertinent to their needs, such as updates on Forum activities, career development resources, leadership opportunities, and a personal message from the Forum Executive Committee. Efforts have focused on making the site a clearinghouse for career development, advocacy, clinical, precepting, and administrative and management resources to meet new practitioners' varying informational needs. This section of the website also highlights each member of the Executive Committee and allows Forum members to communicate directly with these leaders.

**New Practitioners Forum Column.** Members of the Forum are contributing authors for the New Practitioners Forum column in the *American Journal of Health-System Pharmacy.* The topics, pertinent to the needs of practitioners just starting their careers, have included a variety of career and professional development topics, such as residency training, legislative advocacy, and developing clinical practices. The column offers new graduates the chance to learn about writing for a professional journal and increases their awareness of opportunities for new practitioners in ASHP.

**Outreach.** Forum members desire to mentor students and share experiences with peers. To this end, Forum leaders volunteer to participate in various student outreach initiatives throughout the year to promote ASHP membership, provide information on pursuing residencies, promote the value of involvement in professional organizations, and explain how to become more engaged in professional endeavors on the local, state, and national level. Forum leaders also represented the Forum six of the regional residency conferences during the spring, promoting the Forum and encouraging peers to become involved in the many opportunities ASHP offers exclusively for new practitioners.

For the third year, the New Practitioners Forum Executive Committee charged all advisory groups to participate in a Targeted Recruitment Initiative. This initiative focuses on identifying peers who are either currently members of ASHP but not involved or who are not members of ASHP and recommending them for an involvement opportunity in the Forum. Through this endeavor, 151 new practitioners were recommended for advisory group positions, 42 were recommended for educational program coordination, and 22 were recommended for executive committee or policy committee appointments. Each nominee was sent a personalized message encouraging them to consider greater involvement in these activities at the recommendation of their peer.

**Section Collaboration.** Forum members share common professional and career development needs, but their varied practice needs are addressed through involvement in the ASHP pharmacy practice sections. Many new practitioners hold positions on section committees and advisory groups.

**ASHP Resident Visit Program.** For many years ASHP has invited residents in accredited programs to visit ASHP headquarters. These all-day visits give residents an inside glimpse of ASHP operations and an opportunity to learn about the many ways to get involved

in ASHP and the resources available to them as new practitioner members. Three visits were held this year, with approximately 100 residents participating. ASHP has redesigned this program in recent years. Now, participants not only learn but actively participate and provide feedback to ASHP on issues of importance.

**ASHP's Next Top New Practitioner Interviewer Competition.** The New Practitioners Forum held a competition for the second consecutive year to identify a new practitioner interviewer for the daily ASHP E-News Video Update at the 2010 MCM. The winner, Isha John, was selected by judges from a number of video interview submissions. The competition allowed new practitioners the opportunity to gain greater visibility and recognition in the ASHP member community, meet with key thought leaders, and further develop personal communication skills.

#### **Advisory Group on Communications and Technology**

Tegan Williams, Chair (Virginia); Jeff Little, Executive Committee Liaison (Kansas); Emily Waite (Alabama); Jessica Larva (Indiana); Andrew Laegeler (Texas); Jared Anderson (Wisconsin); Sadie Cox (Ohio); Melissa Ortega (Florida); Christina Martin (Kansas); Sara Parli (Kentucky); Lindsey Childs (Florida); Adam Harris (Alaska)

#### **Advisory Group on Membership and Outreach**

Ashley Mains, Chair (Kansas); John Hertig, Executive Committee Liaison (North Carolina); Shirley Lee (Maryland); Audrey Kennedy (Texas); Brandon Conforti (Pennsylvania); Linda Ho (Texas); Angela Bingham (Maryland); Nicole Metzger (Georgia); Lindsay Justin (Kansas); Jessica Winter (West Virginia); Brittany Warrick (Kentucky); Andrea Bishop (Indiana)

#### **Advisory Group on Public Affairs and Advocacy**

Kayla Hansen, Chair (North Carolina); Jeff Little, Executive Committee Liaison (Kansas); Matthew Jenkins (Pennsylvania); Meghan Davlin (Maryland); Lindsay Davison (New York); Nicholas Bennett (Missouri); Rachel Root (Minnesota); Sarah Phanco (North Carolina); Matt Sapko (Ohio); Jason Chou (North Carolina); Elaine Mebel (Pennsylvania); Stephanie Swain (Iowa)

#### **Advisory Group on Leadership and Career Development**

Katherine Palmer, Chair (California); Brandon Ordway, Executive Committee Liaison (Minnesota); Katie McKinney (Ohio); Rola Kaakeh (Michigan); Becky Natali (Texas); Garrett Eggers (Pennsylvania); Kristen Hillebrand (Ohio); Tara Gleason (Missouri); Stephen Davis (Pennsylvania); Eric Wombell (Missouri); Kunal Patel (Texas); Katherine Miller (Oregon)

#### **Advisory Group on Professional Practice**

Meredith Mulvanity, Chair (Florida); Jordan Covvey, Executive Committee Liaison (Virginia); Jessica Brady (Louisiana); Angela Shogbon (Georgia); Adam Pate (Arkansas); Mallory Heath (Oregon); Michael Armahizer (Pennsylvania); Paul Tran (Missouri); Janene Marshall (Illinois); Allison King (Missouri); Erin Reichert (Ohio); Joseph Woolery (Florida)

#### **Advisory Group on Science and Research**

Josh Cirulli, Chair (Pennsylvania); Linda Banares, Executive Committee Liaison (California); Danijela Stojanovic (Texas); Candace Sampson (Virginia); Cassie Barton (Vermont); Karen Berger (Florida); Andrea Nigg (Ohio); Clare Rupprecht (Illinois); John Hammer (Maryland); Jennifer Gass (Texas); Zara Risoldi Cochrane (Nebraska); Kathryn Connor (New York)

## ASHP Pharmacy Student Forum

The Pharmacy Student Forum serves to prepare the next generation of health-system pharmacists to be leaders in their schools and communities and to advance the future of the pharmacy profession. The Forum is led by a five-member Executive Committee appointed annually by the ASHP President. Each Executive Committee member serves as the chair of one of the five Forum advisory groups: Leadership Development, Education and Programming, Student Society Development, Policy and Legislative Advocacy, and Community and eCommunications. The Executive Committee is responsible for advising the ASHP Board of Directors and staff on the overall direction of the Forum, including member benefits and services. The Chair of the Executive Committee serves as the voting student representative to the ASHP House of Delegates. The Executive Committee also assists in building relationships between ASHP and schools of pharmacy by serving as liaisons, providing information to student society leaders, and helping to strengthen the student society of health-system pharmacy (SSHP) activities and programs on each campus.

**Strategic Goals.** The 2010–11 Executive Committee established a strategic plan with four core goals to direct Forum operations:

- Cultivate a community of actively engaged pharmacy students who are inspired to pursue a career in health-system practice and through the development of a strong foundation, remain lifelong, dedicated ASHP members.
- Strengthen the triad relationship between SSHPs, state affiliates, and ASHP to establish an organizational home that supports professional growth and development.
- 3. Inspire and empower students to become agents of change in the advancement of health-system pharmacy practice.
- 4. Assist in addressing the leadership gap within health-system pharmacy by increasing awareness and encouraging use of ASHP professional and leadership development resources and opportunities for students across the continuum of their education.

**2010–2011 Forum Highlights.** The past year was successful for the Pharmacy Student Forum, marked by continued growth in membership, student involvement, and the ASHP-SSHP Recognition Program. Forum membership exceeds 11,000 students, from schools of pharmacy across the nation. The consistent growth trend in the Forum is attributed to the growing number and expansion of pharmacy programs, the structure and strength of the ASHP-SSHP Recognition Program, and the wealth of valuable member benefits that help students achieve their professional goals.

The Forum continually strives to meet the needs and exceed expectations of student members. This goal was accomplished through increasing awareness of career opportunities within health-system practice; providing information regarding residencies and other postgraduate education programs; and encouraging professional development by fostering student leadership development and involvement in ASHP, state, and local health-system pharmacy organizations.

The Forum Executive Committee and advisory groups focused efforts on the strategic goals established at the start of the year and made significant progress. Some highlights include the launch of an advocacy toolkit to equip student members to become effective agents of change, a revamp of the student programming and events at the Midyear Clinical Meeting (MCM) to better meet the evolving needs of student attendees, and heightened training and investment in SSHP leaders to strengthen campus-level membership.

**ASHP-SSHP Recognition Program.** In 2007, the Forum devoted resources to advance the development of strong SSHPs. As a result of these efforts, the ASHP-SSHP Recognition Program was developed. Student societies nationwide have the opportunity to earn this official annual recognition from ASHP based on programming and activities completed each year. Criteria for recognition encourage SSHP activities that promote membership in local, state, and

#### Executive Committee

Emily C. Dotter, Chair (Maryland) Joseph A. Dikun, Vice Chair (Ohio) Stacy B. Livingston (Iowa) Debbie D. Ramirez (Texas) Brandon R. Shank (Pennsylvania) Janet L. Mighty, Board Liaison Marni D. Lun, Secretary

national health-system organizations; stimulate interest in health-system pharmacy careers; and encourage career development and professionalism among students aspiring to careers in health-system pharmacy. In 2010, 91 SSHPs met the criteria for recognition and received benefits, including a complimentary student registration to the MCM and the Summer Meeting, awards for incoming and outgoing officers, a custom SSHP logo, and a certificate of recognition.

**Outreach, Connection, and Engagement.** The Pharmacy Student Forum strives to engage students who have an interest in hospital and health-system careers. Our aim is to reach every school of pharmacy every year to inform students about member benefits, including leadership training and opportunities, educational programming, professional development resources, and career preparation tools. Our outreach efforts are multifaceted, consisting of campus visits by ASHP staff and volunteer leaders and virtual visits using web-based conferencing technology.

With the growing number of members and activity in the Forum, creating a sense of community and connection is critical to foster engagement with the organization. The Forum facilitates connections with and between students by leveraging a wide variety of communication vehicles, such as the student pages of the ASHP website, the twice-monthly NewsLink email service to provide deadline reminders and updates, and our newest resource, ASHP Connect. This tool provides students with a multitude of ways to directly connect with ASHP and with each other through the Discussion Board, Facebook Fan Page, LinkedIn, Twitter, You Tube, and more.

Meetings and Programming. ASHP offers programming designed specifically for student members at both the MCM and Summer Meeting. The 45th annual ASHP MCM in Anaheim, California attracted more than 4000 pharmacy students. This meeting offered a wealth of options for students, including the Residency Showcase, Personnel Placement Service, and research posters. In addition, students took advantage of a full day of educational programming tailored for their unique needs, with topics including residency preparation, resume writing and interviewing, and financial management. A highlight of the week was the Student Society Showcase, where a record number of schools from across the nation participated and put the spotlight on the excellent work of the SSHPs. New in 2010, a special awards ceremony was held in conjunction with the Student Society Showcase to recognize the outstanding contribution and leadership of several ASHP and SSHP student members.

The Pharmacy Student Leadership Development Program at the 2010 Summer Meeting was a success, attracting emerging pharmacy leaders from schools nationwide. The program consisted of educational programming covering topics such as the ASHP policy process and leadership development. A three-hour workshop coordinated by the Section of Pharmacy Practice Managers served as the centerpiece for the weekend activities. Students were encouraged to get involved in ASHP policy by attending key House of Delegates events and letting their voices be heard at the Student Caucus. New in 2010, each student attendee was paired up with a seasoned practitioner to help navigate the meeting activities through the Mentoring Emerging Leaders program.

**Clinical Skills Competition.** The 15th Annual ASHP Clinical Skills Competition, supported by the ASHP Research and Education Foundation, was held at the 2010 MCM. Teams from 110 schools of

pharmacy throughout the nation competed. This two-day competition offered students the opportunity to analyze patient cases; demonstrate their skills in assessing a patient's medical history; identify drug therapy problems and treatment goals; and recommend a pharmacist's care plan, including monitoring desired patient outcomes. The national title was awarded to Jennifer Murphy and Rachelle Bermingham from the University of California, San Francisco.

**ASHP Student Leadership Award Program.** The ASHP Student Leadership Award program prominently recognizes and celebrates the contributions of students who represent the very best attributes and accomplishments of ASHP student members. The highly competitive program consists of 12 annual awards to four student members in each professional year of pharmacy school, beginning with the second professional year. Award recipients receive a plaque, an ASHP drug information reference library, and a cash award provided by the ASHP Research and Education Foundation and funded through the Walter Jones Memorial Student Financial Aid Fund. The objective of the program is to encourage personal and professional development through a formal program providing well-deserved recognition to student leader role models who have demonstrated an interest in health-system practice and displayed exemplary student involvement in professional organizations.

The 2010 ASHP Student Leadership Award recipients were as

Class of 2010: Jessica Larva, Purdue University; Shirley Lee, University of Maryland; Brian Marlow, University of Tennessee; Christina Martin, University of Pittsburgh

Class of 2011: Nerissa Alday, University of Florida; Elva VanDevender, Oregon State University; Joseph Dikun, Northeastern Ohio Universities; David Kramp, University of Cincinnati; Rodney Turner, Lake Erie College of Osteopathic Medicine

Class of 2012: Soranarom Kumsaitong, Mercer University; Christine Vi Dang, University of Colorado; Matthew Wolf, University of Michigan

Experiential Education Program. ASHP offers an elective Advanced Pharmacy Practice Experience (APPE) in national association management. The purpose of the program is to provide students with an understanding of the importance of pharmacy associations to the profession and the value of participation in local, state, and national pharmacy organizations. The rotation also provides an opportunity for pharmacy students with an interest in association management to experience a professional association's practices and procedures in furthering its mission, vision, and goals. The program also identifies potential leaders in the pharmacy profession. In the 2010-11 academic year the following students were selected to participate in this program:

- Jenna Nader, University of Maryland
- Samm Anderegg, University of Iowa
- Joseph Dikun, Northeastern Ohio Universities
- Jasmine Shah, Philadelphia College of Pharmacy
- Kate McHenry, University of Maryland
- Cindy Chung, University of Maryland
- Ashley Parrott, University of Toledo
- Sali Mahmoud, University of Maryland

**Summer Internship Program.** ASHP offers a 10-week training program in national association management. The interns, students early in their pharmacy education, are introduced to the role of pharmacy associations to the profession while being exposed to ASHP's practices and procedures in furthering its mission, vision, and goals. In 2010, two interns joined ASHP in the Office of Member Relations:

- Jesni Mathew, University of Florida; focus area: Pharmacy Technician Initiative
- Diana Park, Harding University: focus area: Pharmacy Student Forum and Member Relations

Student Society Development Grant Program. ASHP offers grants to aid in the development of SSHPs. The grants are intended for use by the ASHP state affiliate and college of pharmacy partners to establish a new SSHP, or to strengthen an existing SSHP, ultimately aiding the SSHP to achieve official ASHP Recognition. In 2010, grants were awarded to the following pharmacy programs:

- California Northstate College of Pharmacy
- Chicago State University
- Howard University
- Jefferson School of Pharmacy and the Pennsylvania Society of Health-System Pharmacists
- Pacific University
- Southern Illinois University Edwardsville
- Union University and the Tennessee Society of Health-System Pharmacists
- University at Buffalo
- University of Hawaii at Hilo
- University of Illinois—Rockford and the Illinois Council of Health-System Pharmacists
- University of Michigan and the Michigan Society of Health-System Pharmacists
- University of Minnesota and the Minnesota Society of Health-System Pharmacists
- University of New England and the Maine Society of Health-System Pharmacists
- Wayne State University and the Michigan Society of Health-System Pharmacists

Student Research Award. Through the ASHP Research and Education Foundation's annual Literature Awards Program, a Student Research Award is presented to a pharmacy student for a published or unpublished paper or report of a completed research project related to pharmacy practice in a health system. The Foundation provides a plaque and an honorarium to the award recipient, as well as an expense allowance to attend the MCM to receive the award. The 2010 recipient was Brittany Traylor from the University of Arizona School of Pharmacy, as the lead author of a paper published in the American Journal of Respiratory and Critical Care Medicine, "Influence of genetic variation of B2 adrenergic receptor in patients with cystic fibrosis."

Advisory Group Appointments. The five advisory groups of the Forum serve to offer feedback to ASHP on areas of specific interest to pharmacy students, while expanding the opportunity for student leadership at the national level. For the 2010–2011 academic year, 50 students from the first through fourth professional years were appointed to these advisory groups. The groups completed their work via electronic communications, conference calls, and one in-person meeting preceding the MCM in December.

#### Advisory Group on Community and eCommunications.

The advisory group has focused efforts on continuing to leverage ASHP Connect to engage student members. A tutorial document was disseminated to SSHP leaders to encourage the development of individual SSHP Facebook pages. The advisory group provided a recommendation to ASHP to improve and add functionality to the existing smartphone application for ASHP events and resources. The group served as beta-test users of the new ASHP Connect private social network and will be providing ongoing feedback to ASHP during the testing phase to ensure a successful launch.

Advisory Group on Education and Programming. The advisory group provided detailed guidance in the preparation of programming and collateral materials for the MCM, including the student guide to highlight important activities and events for students to attend. Specific recommendations for improving the student experience at the 2010 MCM were implemented, including pre-meeting webinars to assist in meeting preparation, revisions to the student programming schedule to extend options throughout the week, and a renewed focus on the residency-related activities to ensure minimal overlap with key student-attended events. Recommended actions to improve the student experience at the Summer Meeting were also provided.

**Advisory Group on Leadership Development.** The advisory group conducted a series of journal club activities via the ASHP Connect Discussion Board centered on leadership topics. They worked with the ASHP Foundation to take action on recommendations published in the Student and New Practitioner Leadership Task Force white paper and to refresh the template presentation available for use by volunteers in the Leadership Speakers Bureau. The group reviewed and offered comment on ASHP's draft statement on leadership as a professional obligation.

**Advisory Group on Policy and Legislative Advocacy.** The advisory group made significant strides to engage student members in ASHP policy and advocacy efforts. They provided a recommendation to create a web-based toolkit for students to increase participation and interest in policy and advocacy. The toolkit included samples and suggestions for advocacy-related projects qualified to meet the criteria as a professional development project required for the ASHP-SSHP Recognition program.

Advisory Group on Student Society Development. The advisory group has made efforts to further strengthen the relationship between ASHP and the ASHP student liaisons on each campus. Prior to the start of the fall semester, the advisory group worked to provide a more robust orientation, including a webinar, for all ASHP student liaisons at the start of their term of office. In the spring semester they will be working closely with these liaisons to distribute a progress report for SSHPs to use in tracking their activities that meet the criteria for official recognition. To help SSHPs structure their leadership in line with the requirements for SSHP recognition, the group drafted suggested committees and descriptions of related responsibilities. In conjunction with the Leadership Development Advisory Group, they planned and implemented the 2010 MCM SSHP Leaders Workshop.

#### **Advisory Group on Community and eCommunications**

Brandon Shank, Chair, Philadelphia College of Pharmacy; Kathryn Elofson, University of Arizona; Michelle A. Foster, University of the Incarnate Word; Erin Gulbransen, University of Michigan; Megan Hartranft, University of North Carolina; Ryan Markham, University of Georgia; Veldana Nuhi, University of Florida; Daphne O'Hara, West Virginia University; Lisa A. Scherkenbach, University of Minnesota; Jasmine Shah, Philadelphia College of Pharmacy; Ryan Caddell, The Ohio State University

#### **Advisory Group on Education and Programming**

Stacy B. Livingston, Chair, University of Iowa; Melissa Buchanan, Campbell University; Samar Chakar, University of New England; Christine Vi Dang, University of Colorado; Lauren Davis, Philadelphia College of Pharmacy; Phuong Vyle Ho, University of Texas at Austin College; Allison Kobin, University of Maryland–Baltimore; Sherry Kwon, University of California–San Francisco; Jesni Mathew, University of Florida–Gainesville; Phuoc Anh Thi Nguyen, University of Southern California; Ashley M.F. Harbison, University of Missouri–Kansas City; Steve D. Erickson, University of Washington School of Pharmacy

#### **Advisory Group on Leadership Development**

Joseph Dikun, Chair, Northeastern Ohio Universities; Tiffany R. Bish, Virginia Commonwealth University; Sandy Chan, Washington State University; Sarah Johannes, University of North Carolina; Rebecca Lalani, University of Michigan; Diana Park, Harding University; Meenakshi Shelat, University of Michigan; Adam Sieg, South Carolina University; Alana Willman, Oregon State University; Melinda C. Stanton, University of Cincinnati; Thomas Achey, Auburn University

#### **Advisory Group on Policy and Legislative Advocacy**

Emily Dotter, Chair, University of Maryland; Krystal Canally, The Ohio State University; Ryan Fischer, Ohio Northern University; Matthew J. Guindon, University of Washington; Stephanie Kroseman, University of Minnesota; Soranarom Kumsaitong, Mercer University; Matthew J. Newman, Northeastern University; Rodney Brigg Turner, Lake Erie College of Osteopathic Medicine—Erie; Elva A. Van Devender, Oregon State University—Portland; Kenneth Worsham II, Hampton University; Henry Ho, University of Southern California

#### **Advisory Group on Student Society Development**

Debra D. Ramirez, Chair, University of Texas at Austin; Saadia Bano, Ali University of Texas at Austin; Anna C. Gehres, The Ohio State University; Elizabeth Gorski, University of Illinois at Chicago; Steven Larson, University of Washington; Luci Moore, Auburn University–Mobile; Tiffany Pon, Purdue University; Saranyu Ravi, Thomas Jefferson University; Heather Schoeneman, University of Cincinnati; Alexander Flannery, University of Kentucky; Sean Byers, Creighton University School of Pharmacy