Government, Law, and Regulation

Drug Product Supply Chain Integrity (1602)
Source: Council on Pharmacy Management
To encourage the Food and Drug Administration (FDA) and relevant state authorities to take the steps necessary to ensure that (1) all drug products entering the supply chain are thoroughly inspected and tested to establish that they have not been adulterated or misbranded and (2) patients will not receive improperly labeled and packaged, deteriorated, outdated, counterfeit, adulterated, or unapproved drug products; further,

To encourage FDA and relevant state authorities to develop and implement regulations to (1) restrict or prohibit licensed drug distributors (drug wholesalers, repackagers, and manufacturers) from purchasing legend drugs from unlicensed entities and (2) ensure accurate documentation at any point in the distribution chain of the original source of drug products and chain of custody from the manufacturer to the pharmacy; further,

To advocate for the establishment of meaningful penalties for companies that violate current good manufacturing practices (cGMPs) intended to ensure the quality, identity, strength, and purity of their marketed drug product(s) and raw materials; further,

To advocate for improved transparency so that drug product labeling include a readily available means to retrieve the name and location of the facility that manufactured the specific lot of the product; further,

To advocate that this readily retrievable manufacturing information be available prospectively to aid purchasers in determining the quality of a drug product and its raw materials; further,

To foster increased pharmacist and public awareness of drug product supply chain integrity; further,

To urge Congress and state legislatures to provide adequate funding, or authority to impose user fees, to accomplish these objectives.

This policy supersedes ASHP policy 1503.

Timely Board of Pharmacy Licensing (1621)
Source: Council on Public Policy
To advocate that the National Association of Boards of Pharmacy (NABP) collaborate with boards of pharmacy to streamline the licensure process through standardization and improve the timeliness of application approval; further,

To advocate that NABP collaborate with boards of pharmacy and third-party vendors to streamline the licensure transfer or reciprocity process; further,

To advocate that boards of pharmacy grant licensed pharmacists in good standing temporary licensure, permitting them to engage in practice, while their application for licensure transfer or reciprocity is being processed.

This policy supersedes ASHP policy 0612.

Inclusion of Drug Product Shortages in State Price-gouging Laws (1622)
Source: Council on Public Policy
To urge state attorneys general to consider including shortages of lifesaving drug products within the definition of events that trigger application of state price-gouging laws.

Pharmacist Participation in Health Policy Development (1501)
Source: Council on Public Policy
To advocate that pharmacists participate with policymakers and stakeholders in the development of health-related policies at the national, state, and community levels; further,

To develop tools and resources to assist pharmacists in fully participating in health policy development at all levels.

Pharmacist Recognition as a Healthcare Provider (1502)
Source: Council on Public Policy
To advocate for changes in federal (e.g., Social Security Act), state, and third-party payment programs to define pharmacists as healthcare providers; further,

To affirm that pharmacists, as medication-use experts, provide safe, accessible, high-quality care that is cost effective, resulting in improved patient outcomes; further,

To recognize that pharmacists, as healthcare providers, improve access to patient care and bridge existing gaps in healthcare; further,

To collaborate with key stakeholders to describe the covered direct patient-care services provided by pharmacists; further,

To advocate for sustainable compensation and standardized billing processes used by payers for pharmacist services by all available payment programs.

This policy supersedes ASHP policy 1307.

Premarketing Comparative Clinical Studies (1506)
Source: Council on Public Policy
To advocate that the Food and Drug Administration have the authority to impose a requirement for comparative clinical trials.

This policy supersedes ASHP policy 0514.

Funding, Expertise, and Oversight of State Boards of Pharmacy (1507)
Source: Council on Public Policy
To advocate appropriate oversight of pharmacy practice and the pharmaceutical supply chain through coordination and cooperation of state boards of pharmacy and other state and federal agencies whose mission it is to protect the public health; further,

To advocate adequate representation on state boards of pharmacy and related agencies by pharmacists who are knowledgeable about all areas of pharmacy practice (e.g., hospitals, health systems, clinics, and nontraditional settings) to ensure appropriate oversight; further,

To advocate for dedicated funds for the exclusive use by state boards of pharmacy and related agencies including funding for the training of state board of pharmacy inspectors and the implementation of adequate inspection schedules to ensure the effective oversight and regulation of pharmacy practice, the integrity of the pharmaceutical supply chain, and protection of the public; further,

To advocate that inspections be performed only by pharmacists competent about the applicable area of practice.

This policy supersedes ASHP policy 0518.

Support for FDA Expanded Access (Compassionate Use) Program (1508)

Source: Council on Public Policy

To advocate that the Food and Drug Administration (FDA) Expanded Access (Compassionate Use) Program be the sole mechanism for patient access to drugs for which an investigational new drug application (IND) has been filed, in order to preserve the integrity of the drug approval process and assure patient safety; further,

To advocate for broader patient access to such drugs under the FDA Expanded Access Program; further,

To advocate that IND applicants expedite review and release of drugs for patients who qualify for the program; further,

To advocate that the drug therapy be recommended by a physician and reviewed and monitored by a pharmacist to assure safe patient care; further,

To advocate for the patient's right to be informed of the potential benefits and risks via an informed consent process, and the responsibility of an institutional review board to review and approve the informed consent and the drug therapy protocol.

Approval of Biosimilar Medications (1509)

Source: Council on Public Policy

To encourage the development of safe and effective biosimilar medications in order to make such medications more affordable and accessible; further,

To encourage research on the safety, effectiveness, and interchangeability of biosimilar medications; further,

To support legislation and regulation to allow Food and Drug Administration (FDA) approval of biosimilar medications; further,

To support legislation and regulation to allow FDA approval of biosimilar medications that are also determined by the FDA to be interchangeable and therefore may be substituted for the reference product without the intervention of the prescriber; further,

To oppose the implementation of any state laws regarding biosimilar interchangeability prior to finalization of FDA guidance; further,

To oppose any state legislation that would require a pharmacist to notify a prescriber when a biosimilar deemed to be interchangeable by the FDA is dispensed; further,

To require postmarketing surveillance for all biosimilar medications to ensure their continued safety, effectiveness, purity, quality, identity, and strength; further,

To advocate for adequate reimbursement for biosimilar medications that are deemed interchangeable; further,

To promote and develop ASHP-directed education of pharmacists about biosimilar medications and their appropriate use within hospitals and health systems; further,

To advocate and encourage pharmacist evaluation and the application of the formulary system before biosimilar medications are used in hospitals and health systems.

This policy supersedes ASHP policy 1409.

Development of Abuse-Resistant Narcotics (1512)

Source: Council on Therapeutics

To advocate that the Food and Drug Administration investigate the efficacy of abuse-resistant formulations in preventing prescription drug abuse.

Quality Patient Medication Information (1513)

Source: Council on Therapeutics

To support efforts by the Food and Drug Administration (FDA) and other stakeholders to improve the quality, consistency, and simplicity of written patient medication information (PMI); further,

To encourage 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 PMI; further,

To advocate that research be conducted to validate these models in actual-use studies in pertinent patient populations; further,

To advocate that FDA explore alternative models of PMI content development and maintenance that will ensure the highest level of accuracy, consistency, and currency; further,

To advocate that the FDA engage a single third-party author to provide editorial control of a highly structured, publicly accessible central repository of PMI in a format that is suitable for ready export; further,

To advocate for laws and regulations that would require all dispensers of medications to comply with FDA-established standards for unalterable content, format, and distribution of PMI.

This policy supersedes ASHP policy 1012.

Automatic Stop Orders (1405)

Source: Council on Pharmacy Practice

To advocate that the Centers for Medicare & Medicaid Services (1) remove the requirement in the Hospital Conditions of Participation that all medication orders automatically stop after an arbitrarily assigned period to include other options to protect patients from indefinite, open-ended medication orders, and (2) revise the remainder of the medication management regulations and interpretive guidelines to be consistent with this practice; further,

To affirm that the requirement for automatic stop orders for all medications is a potential source of medication errors and patient harm; further,

To encourage pharmacists to participate in interprofessional efforts to establish standardized methods to assure appropriate duration of therapy.

This policy supersedes ASHP policy 0904.

Federal and State Regulation of Compounding (1406)

Source: Council on Public Policy

To advocate that the applicable compendial standards of the United States Pharmacopeia be included in state and federal laws and regulations that govern compounding by any health professional; further,

To advocate for mandatory state registration of compounding facilities (e.g., pharmacies, physician offices, clinics, ambulatory surgery centers) that provide products for specific patient prescriptions or in anticipation of specific patient prescriptions or medication orders; further,

To advocate for mandatory Food and Drug Administration registration and current good manufacturing practices requirements for outsourcing facilities that compound and sell products without patient-specific prescriptions across state lines; further,

To advocate for improved patient safety and care through education of regulatory inspectors, increased fre-

quency and improved effectiveness of compliance inspections, and enhancing interagency communications; further,

To advocate that state and federal agencies develop standardized definitions and nomenclature relating to sterile and nonsterile compounding, including but not limited to definitions of compounding, manufacturing, repackaging, and relabeling.

This policy supersedes ASHP policy 1308.

340B Drug Pricing Program Sustainability (1407)
Source: Council on Public Policy
To affirm the intent of the federal drug pricing program (the "340B program") to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services; further,

To advocate legislation or regulation that would optimize access to the 340B program in accordance with the intent of the program; further,

To advocate for clarification and simplification of the 340B program and any future federal discount drug pricing programs with respect to program definitions, eligibility, and compliance measures to ensure the integrity of the program; further,

To encourage pharmacy leaders to provide appropriate stewardship of the 340B program by documenting the expanded services and access created by the program; further,

To educate pharmacy leaders and health-system administrators about the internal partnerships and accountabilities and the patient-care benefits of program participation; further,

To educate health-system administrators, risk managers, and pharmacists about the resources (e.g., information technology) required to support 340B program compliance and documentation; further,

To encourage communication and education concerning expanded services and access provided by 340B participants to patients in fulfillment of its mission.

This policy supersedes ASHP policy 0506.

State Prescription Drug Monitoring Programs (1408)
Source: Council on Public Policy
To advocate for mandatory, uniform prescription drug monitoring programs that collect real-time, relevant, and standard information from all dispensing outpatient entities about controlled substances and monitored 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 full interstate integration to allow for access by prescribers, pharmacists, and other qualified designees across state lines; further,

To advocate for federal and state funding to establish and administer these programs; further,

To promote research, education, and implementation of best practices in prescription drug monitoring programs.

This policy supersedes ASHP policy 1122.

Access to Oral Contraceptives Through an Intermediate Category of Drug Products (1410)
Source: Council on Therapeutics
To advocate that oral contraceptives be provided only under conditions that ensure safe use, including the availability of counseling to ensure appropriate self-screening and product selection; further,

To support expanded access to these products through a proposed intermediate category of drug products, as described by ASHP policy, that would be available from all pharmacists and licensed health care professionals (including pharmacists) who are authorized to prescribe medications; further,

To advocate that the proposed reclassification of these products be accompanied by coverage changes by third-party payers to ensure that patient access is not compromised and that pharmacists are reimbursed for the clinical services provided.

Expedited Pathways for FDA Drug Approval (1411)
Source: Council on Therapeutics
To support the use of expedited pathways for Food and Drug Administration (FDA) approval of new drugs that expand access to innovative therapies while protecting patient safety; further,

To advocate for the development of unique labeling requirements that would be used on an interim basis to identify products approved by these pathways in order to increase awareness of data limitations and guide clinician use of these drugs until additional evidence becomes available; further,

To advocate that the FDA be diligent in enforcing postmarketing commitments for drug products approved via expedited pathways, including utilizing its existing authority to enforce penalties when these requirements are not met; further,

To encourage research to evaluate the impact of expedited pathways on drug product development and patient care, including drug development timelines and costs, overall health care costs, patient access to care, and the effectiveness and safety of these therapies.

FDA Oversight of Laboratory-Developed Tests (1412)
Source: Council on Therapeutics
To advocate that the Food and Drug Administration be granted increased authority to regulate laboratory-developed tests as medical devices, including tests used for pharmacogenetic testing; further,

To support development of a risk-based framework for regulatory oversight of laboratory-developed tests that promotes innovation while providing a mechanism to ensure that test results are reliable, reproducible, and clinically relevant; further,

To encourage expanded availability of commercially marketed pharmacogenetic tests that would be available for use by laboratory and health care professionals to guide drug therapy.

Regulation of Telepharmacy Services (1310)
Source: Council on Public Policy
To advocate that state governments adopt laws and regulations that standardize telepharmacy practices across state lines and facilitate the use of United States-based telepharmacy services; further,

To advocate that boards of pharmacy and state agencies that regulate pharmacy practice include the following in regulations for telepharmacy services: (1) education and training of participating pharmacists; (2) education, training, certification by the Pharmacy Technician Certification Board, and licensure of participating pharmacy technicians; (3) communication and information systems requirements; (4) remote order entry, prospective order review, verification of the completed medication order before dispensing, and dispensing; (5) direct patient-care services, including medication therapy management services and patient counseling and education; (6) licensure (including reciprocity) of participating pharmacies and pharmacists; (7) service arrangements that cross state borders; (8) service arrangements within the same corporate entity or between different corporate entities; (9) service arrangements for workload relief in the point-of-care pharmacy during peak periods; (10) pharmacist access to all applicable patient information; and (11) development and monitoring of patient safety, quality, and outcomes measures; further,

To identify additional legal and professional issues in the provision of telepharmacy services to and from sites located outside the United States.

This policy supersedes ASHP policy 0716.

Regulation of Centralized Order Fulfillment (1311)

Source: Council on Public Policy

To advocate changes in federal and state laws, regulations, and policies to permit centralized medication order fulfillment within health care facilities under common ownership.

DEA Scheduling of Hydrocodone Combination Products (1314)

Source: Council on Therapeutics

To advocate that the Drug Enforcement Administration (DEA) reschedule hydrocodone combination products to Schedule II based on their potential for abuse and patient harm and to achieve consistency with scheduling of other drugs with similar abuse potential.

DEA Scheduling of Controlled Substances (1315)

Source: Council on Therapeutics

To advocate that the Drug Enforcement Administration (DEA) establish clear, measurable criteria and a transparent process for scheduling determinations; further,

To urge the DEA to use such a process to re-evaluate existing schedules for all substances regulated under the Controlled Substances Act to ensure consistency and incorporate current evidence concerning the abuse potential of these therapies; further,

To monitor the effect of DEA scheduling of products under the Controlled Substances Act and other abuse-prevention efforts (e.g., prescription drug monitoring programs) to assess the impact on patient access to these medications and on the practice burden of health care providers.

Pharmacy Technicians (1216)

Source: Council on Public Policy

To advocate that pharmacy move toward the following model with respect to the evolving pharmacy technician workforce as the optimal approach to protecting public health and safety: (1) development and adoption of uniform state laws and regulations regarding pharmacy technicians, (2) mandatory completion of an ASHP-accredited program of education and training as a prerequisite to pharmacy technician certification, (3) mandatory certification by the Pharmacy Technician Certification Board as a prerequisite to licensure by the state board of pharmacy, and (4) licensure of pharmacy technicians by state boards of pharmacy granting the technician permission to engage in the full scope of responsibilities authorized by the state; further,

To advocate, with respect to certification, as an interim measure until the optimal model is fully implemented, that individuals be required either (1) to have completed an ASHP-accredited program of education and training or (2) to have at least one year of full-time equivalent experience as pharmacy technicians before they are eligible to become certified; further,

To advocate that all pharmacy functions be performed under the general supervision of a licensed pharmacist and that licensed pharmacists and technicians be held accountable for the quality of pharmacy services provided.

(*Note:* Licensure is the process by which an agency of government grants permission to an individual to engage in a given occupation upon finding that the applicant has attained the minimal degree of competency necessary to ensure that the public health, safety, and welfare will be reasonably well protected. Certification is the process by which a nongovernmental agency or association grants recognition to an individual who has met certain predetermined qualifications specified by that agency or association.)

This policy supersedes ASHP policy 0815.

Stable Funding for HRSA Office of Pharmacy Affairs (1219)

Source: Council on Public Policy

To advocate for a sustainable level of funding, including appropriations, sufficient to support the public health mission of the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs; further,

To support initiatives of the Office of Pharmacy Affairs, including the 340B Drug Pricing Program and innovative pharmacy service models in HRSA-funded programs; further,

To encourage research on the potential impact of any proposed fees or alternative funding sources for the Office of Pharmacy Affairs.

This policy supersedes ASHP policy 0911.

Globalization of Clinical Trials (1223)

Source: Council on Therapeutics

To encourage the Food and Drug Administration (FDA) to use its existing authority to increase monitoring and inspection of foreign clinical trials to ensure the integrity and quality of those studies; further,

To advocate that the FDA expand its oversight of clinical trials conducted abroad by continuing to pursue innovative strategies, such as increased collaboration with foreign regulatory agencies and changes in domestic regulatory processes that support timely submission of foreign clinical trial information; further,

To encourage the FDA to establish a standardized electronic format and reporting standards that would be required for submission of data from foreign clinical trials; further,

To support the ethical treatment of patients in foreign clinical trials in accordance with international standards designed to protect human subjects; further,

To encourage public and private research to study the impact of the globalization of clinical trials on patient care.

Medical Marijuana (1101)

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 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.)

Agricultural Use of Hormone and Prohormone Therapies (1102)

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.

This policy was reviewed in 2015 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

Direct-to-Consumer Clinical Genetic Tests (1103)

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-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.

This policy was reviewed in 2015 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

Poison Control Center Funding (1121)

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.

This policy was reviewed in 2015 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Health Insurance Coverage for U.S. Residents (1001)

Source: Council on Public Policy

To advocate health insurance for all residents of the United States, including coverage of medications and related pharmacist patient-care services; further,

To advocate that the full range of available methods be used to (1) ensure the provision of appropriate, safe, and cost-effective health care services; (2) optimize treatment outcomes; and (3) minimize overall costs without compromising quality; further,

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

This policy was reviewed in 2014 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Risk Evaluation and Mitigation Strategies (1002)
Source: Council on Public Policy
To advocate for research on the impact of the Food and Drug Administration's Risk Evaluation and Mitigation Strategies (REMS) on patient safety, cost effectiveness, and pharmacy workflow; further,

To advocate pharmacist involvement in the development and implementation of REMS; further,

To urge computer software vendors to assist pharmacists in the identification of and compliance with REMS; further,

To advocate that any REMS that include constraint on traditional drug distribution systems be consistent with ASHP policy on restricted drug distribution.

This policy was reviewed in 2014 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

FDA Authority on Recalls (1003)
Source: Council on Public Policy
To strongly encourage the Food and Drug Administration (FDA) to develop a standard recall notification process and format to be used by all manufacturers to facilitate the timely removal of recalled drugs; further,

To advocate that such notification should (1) come from a single source, (2) clearly identify the recalled product, (3) explain why the product is being recalled, (4) provide a way to report having the recalled product, (5) give instructions on what to do with the recalled product, and (6) be provided concurrently to all entities in the supply chain; further,

To advocate that the FDA be given the authority to order mandatory recalls of medications; further,

To urge the FDA to require drug manufacturers and the computer software industry to provide bar codes and data fields for lot number, expiration date, and other necessary and appropriate information on all medication packaging, including unit dose, unit-of-use, and injectable drug packaging, in order to facilitate compliance with recalls or withdrawals and to prevent the administration of recalled products to patients; further,

To urge the FDA to encourage postmarketing reporting of adverse events and product quality issues to enhance the recall system.

This policy was reviewed in 2014 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Postmarketing Comparative Clinical and Pharmacoeconomic Studies (1004)
Source: Council on Public Policy
To advocate expansion of comparative clinical and pharmacoeconomic studies on the effectiveness, safety, and cost comparison of marketed medications in order to improve therapeutic outcomes and promote cost-effective medication use; further,

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

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

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

This policy was reviewed in 2014 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Regulation of Home Medical Equipment Medication Products and Devices (1007)
Source: Council on Public Policy
To advocate for consistent regulatory oversight of all home medical equipment, with the goals of continuity of care, patient safety, and appropriate pharmacist involvement whenever equipment is used for medication administration; further,

To monitor the impact of the Centers for Medicare & Medicaid Services quality standards on the accreditation of suppliers of medication-related durable medical equipment and supplies.

This policy was reviewed in 2014 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Preservation of Antimicrobials for Medical Treatment (1009)
Source: Council on Therapeutics
To advocate that the Food and Drug Administration (FDA) eliminate future approval of antimicrobials for nontherapeutic uses in agricultural animals that represent a safety risk by contributing to antibiotic resistance; further,

To encourage efforts to phase out and eliminate the nontherapeutic uses of antimicrobials previously approved by the FDA; further,

To support the therapeutic use of antimicrobials in animals only under the supervision of a veterinarian; further,

To encourage the FDA, Centers for Disease Control and Prevention, and other stakeholders to monitor and limit, when effective alternatives are available, the therapeutic use of antimicrobials that are essential to the treatment of critically ill human patients; further,

To advocate for the inclusion of pharmacists in antimicrobial surveillance and related public health efforts based on pharmacists' knowledge of antimicrobial drug products and antimicrobial resistance.

This policy was reviewed in 2014 by the Council on Therapeutics and by the Board of Directors was found to still be appropriate.

Use of Surrogate Endpoints for FDA Approval of Drug Uses (1011)
Source: Council on Therapeutics
To support the continued use of qualified surrogate endpoints by the Food and Drug Administration (FDA) as a mechanism to evaluate the effectiveness and safety of new drugs and new indications for existing therapies, when measurement of definitive clinical outcomes is not feasible; further,

To support efforts by the FDA and other stakeholders to qualify surrogate endpoints; further,

To advocate that the FDA consistently enforce existing requirements that drug product manufacturers complete postmarketing studies for drugs approved based on qualified surrogate endpoints in order to confirm that the expected

improvement in outcomes occurs, and to require that these studies be completed in a timely manner.

This policy was reviewed in 2014 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

Regulation of Interstate Pharmacy Practice (0909)
Source: Council on Public Policy
To advocate that state governments, including legislatures and boards of pharmacy, adopt laws and regulations that harmonize the practice of pharmacy across state lines in order to provide a consistent, transparent, safe, and accountable framework for pharmacy practice.

This policy was reviewed in 2013 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Regulation of Dietary Supplements (0811)
Source: Council on Public Policy
To advocate that Congress grant authority to the Food and Drug Administration (FDA) to (1) require that dietary supplements undergo FDA approval for evidence of safety and efficacy; (2) mandate FDA-approved dietary supplement labeling that includes disclosure of excipients; (3) mandate FDA-approved patient information materials that describe safe use in a clear, standardized format, including the potential for interaction with medications and cautions for special populations; and (4) establish and maintain an adverse-event reporting system specifically for dietary supplements, and require dietary supplement manufacturers to report suspected adverse reactions to the FDA; further,

To oppose direct-to-consumer advertising of dietary supplements unless the following criteria are met: (1) federal laws are amended to include all the requirements described above to ensure that dietary supplements are safe and effective; (2) evidence-based information regarding safety and efficacy is provided in a format that allows for informed decision-making by the consumer; (3) the advertising includes a recommendation to consult with a health care professional before initiating use; (4) any known warnings or precautions regarding dietary supplement–medication interactions or dietary supplement-disease interactions are provided as part of the advertising; and (5) the advertising is educational in nature and includes pharmacists as a source of information.

(*Note: Dietary supplement* as used in this policy is defined by the Dietary Supplement Health and Education Act of 1994, as amended; 21 U.S.C. 321.)

This policy was reviewed in 2012 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Medicare Prescription Drug Benefit (0813)
Source: Council on Public Policy
To strongly advocate a fully funded prescription drug program for eligible Medicare beneficiaries that maintains continuity of care and ensures the best use of medications; further,

To advocate that essential requirements in the program include (1) appropriate product reimbursement; (2) affordability for patients, including elimination of coverage gaps; (3) payment for indirect costs and practice expenses related to the provision of pharmacist services, based on a study of those costs; (4) appropriate coverage and payment for patient care services provided by pharmacists; (5) open access to the pharmacy provider of the patient's choice; (6) formularies with sufficient flexibility to allow access to medically necessary drugs; and (7) well-publicized, unbiased resources to assist beneficiaries in enrolling in the most appropriate plan for their medication needs.

(*Note: Fully funded* means the federal government will make adequate funds available to fully cover the Medicare program's share of prescription drug program costs; *eligible means* the federal government may establish criteria by which Medicare beneficiaries qualify for the prescription drug program.)

This policy was reviewed in 2012 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Federal Review of Anticompetitive Practices by Drug Product Manufacturers (0814)
Source: Council on Public Policy
To strongly oppose anticompetitive practices by manufacturers that adversely affect drug product availability and price; further,

To encourage appropriate federal review of these practices.

This policy was reviewed in 2012 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

FDA Authority to Prohibit Reuse of Brand Names (0719)
Source: Council on Public Policy
To advocate for Food and Drug Administration authority to prohibit reuse of brand names of prescription and nonprescription drugs when any active component of the product is changed or after any other changes are made in the product that may affect its safe use.

This policy was reviewed in 2011 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Minimum Effective Doses (0602)
Source: Commission on Therapeutics
To advocate that the Food and Drug Administration require manufacturers to identify minimum effective doses for medications and make this information available to health care providers.

This policy was reviewed in 2015 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

Postmarketing Safety Studies (0515)
Source: Council on Legal and Public Affairs
To advocate that Congress grant the Food and Drug Administration (FDA) authority to require the manufacturer of an approved drug product or licensed biologic product to conduct postmarketing studies on the safety of the product when the agency deems it to be in the public interest; further,

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

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

This policy was reviewed in 2014 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Mandatory Registry of Clinical Trials (0516)
Source: Council on Legal and Public Affairs
To advocate disclosure of the most complete information on the safety and efficacy of drug products; further,

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

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

To advocate that all data from registered clinical trials be posted electronically with unrestricted access, and that such posting occur (1) after Food and Drug Administration approval of the related new product but before marketing begins and (2) as soon as possible for trials completed after initial marketing.

This policy was reviewed in 2014 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Importation of Pharmaceuticals (0413)
Source: Council on Legal and Public Affairs
To advocate for the continuation and application of laws and regulations enforced by the Food and Drug Administration and state boards of pharmacy with respect to the importation of pharmaceuticals in order to (1) maintain the integrity of the pharmaceutical supply chain and avoid the introduction of counterfeit products into the United States; (2) provide for continued patient access to pharmacist review of all medications and preserve the patient-pharmacist-prescriber relationship; and (3) provide adequate patient counseling and education, particularly to patients taking multiple high-risk medications; further,

To urge the FDA and state boards of pharmacy to vigorously enforce federal and state laws in relation to importation of pharmaceuticals by individuals, distributors (including wholesalers), and pharmacies that bypass a safe and secure regulatory framework.

This policy was reviewed in 2015 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Intermediate Category of Drugs (0220)
Source: Council on Legal and Public Affairs
To support, with appropriate changes in federal statutes and regulations, the establishment of an intermediate category of drug products that do not require a prescription but are available only from pharmacists and licensed health care professionals who are authorized to prescribe medications; further,

To base such support on the following facts:

1. Some drug products that are potential candidates for switching from prescription-only to nonprescription status raise concerns about patient safety as nonprescription products; these products could be better controlled, monitored, and evaluated by making them available only from pharmacists and licensed health care professionals who are authorized to prescribe medications; and
2. Pharmacists have the education, training, and expertise to help patients make appropriate therapeutic decisions associated with the use of such drug products; further,

To support that the regulatory system for this intermediate category of drug products contain the following features:

1. Drug products appropriate for this intermediate category would be identified through the advice of pharmacists, physicians, and other licensed health professionals who are authorized to prescribe medications, on the basis of the medical conditions to be treated and potential adverse effects (as indicated in FDA-approved labeling);
2. Pharmacists would be able to provide drugs in this intermediate category directly to patients without a prescription, on the basis of appropriate assessment and professional consultation;
3. Licensed health professionals who currently have prescribing authority would continue to have the ability to prescribe medications in this intermediate category; and
4. Data from postmarketing surveillance, epidemiologic studies, and adverse-drug-reaction reporting would be collected to help determine a drug product's eventual movement to nonprescription status, return to prescription-only status, or continuation in the intermediate category.

This policy was reviewed in 2011 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Greater Access to Less Expensive Generic Drugs (0222)
Source: Council on Legal and Public Affairs
To support legislation and regulations that promote greater patient access to less expensive generic drug products.

This policy was reviewed in 2011 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

FDA's Public Health Mission (0012)
Source: Council on Legal and Public Affairs
To support the Food and Drug Administration's public health mission of ensuring the safety and effectiveness of drugs, biologics, and medical devices through risk assessment, appropriate product approval, labeling approval, manufacturing oversight, and consultation with health professionals, while deferring to state regulation and professional self-regulation on matters related to the use of drugs, biologics, and medical devices; further,

To support the allocation of sufficient federal resources to allow FDA to meet its defined public health mission; further,

To support the appointment of practicing pharmacists to FDA advisory committees as one mechanism of ensuring that decisions made by the agency incorporate the unique knowledge of the profession of pharmacy for the further benefit of the patient; further,

To support an ongoing dialogue between FDA and ASHP for the purpose of exploring ways to advocate the best

use of FDA-regulated products by consumers and health care professionals.

This policy was reviewed in 2014 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Generic Pharmaceutical Testing (9010)

Source: House of Delegates Resolution

To support and foster legislative and regulatory initiatives designed to improve and restore public and professional confidence in the drug approval and regulatory process in which all relevant data are subject to public scrutiny.

This policy was reviewed in 2015 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

ASHP Policy Positions 2009–2016 (with Rationales): Government, Law, and Regulation

1602

Drug Product Supply Chain Integrity

Source: Council on Pharmacy Management

To encourage the Food and Drug Administration (FDA) and relevant state authorities to take the steps necessary to ensure that (1) all drug products entering the supply chain are thoroughly inspected and tested to establish that they have not been adulterated or misbranded and (2) patients will not receive improperly labeled and packaged, deteriorated, outdated, counterfeit, adulterated, or unapproved drug products; further,

To encourage FDA and relevant state authorities to develop and implement regulations to (1) restrict or prohibit licensed drug distributors (drug wholesalers, repackagers, and manufacturers) from purchasing legend drugs from unlicensed entities and (2) ensure accurate documentation at any point in the distribution chain of the original source of drug products and chain of custody from the manufacturer to the pharmacy; further,

To advocate for the establishment of meaningful penalties for companies that violate current good manufacturing practices (cGMPs) intended to ensure the quality, identity, strength, and purity of their marketed drug product(s) and raw materials; further,

To advocate for improved transparency so that drug product labeling include a readily available means to retrieve the name and location of the facility that manufactured the specific lot of the product; further,

To advocate that this readily retrievable manufacturing information be available prospectively to aid purchasers in determining the quality of a drug product and its raw materials; further,

To foster increased pharmacist and public awareness of drug product supply chain integrity; further,

To urge Congress and state legislatures to provide adequate funding, or authority to impose user fees, to accomplish these objectives.

(Note: This policy supersedes ASHP policy 1503.)

Rationale

The aspect of drug product selection that is not transparent from the labeling is its quality. This information needs to be readily available so those who make the purchasing decision on behalf of hospitals and health systems can factor quality into the decision. Aspects of manufacture that affect quality include the production and compliance history of a manufacturer, the specific name and location of the manufacturing plant, and the source of raw materials. This

information has been useful in responding to a recall, but it is also important as part of the procurement process. The FDA's Strategic Plan for Preventing and Mitigating Drug Shortages recommends that purchasers of medications consider quality as a component of the purchasing decision. FDA publishes some quality information about manufacturers; however, in subcontracting and licensing situations, it is not always known who the actual manufacturer is and which specific plant location produced the product.

Hospitals and health-system pharmacy leaders have years of experience in managing the demands and challenges of ensuring that drug supply chain safety and integrity is at the highest level possible. Unfortunately, there are many forces in the marketplace that seek to divert and introduce illicit products into the supply chain.

ASHP has supported efforts to improve the integrity of the drug product supply chain, which has included advocacy on track-and-trace legislation, collaboration with the United States Pharmacopeia (USP) in its efforts on supply chain integrity, leadership in dealing with the various issues arising from drug shortages, and a voice for patients and pharmacists on needed change (regulatory and practice-based) with pharmacy's trading partners to enable pharmacists to secure legitimate drug products.

On November 27, 2013, the Drug Quality and Security Act (DQSA) was signed into law. Title II of the DQSA, the Drug Supply Chain Security Act (DSCSA) sets forth new definitions and requirements related to drug product tracing. The DSCSA outlines critical steps to build an electronic, interoperable system by November 27, 2023, which will identify and trace certain prescription drug products as they are distributed in the United States. Implementation of this new electronic, interoperable system, over a 10-year period, will enhance FDA's ability to help protect U.S. consumers by improving detection and removal of potentially dangerous products from the pharmaceutical distribution supply chain.

1621

Timely Board of Pharmacy Licensing

Source: Council on Public Policy

To advocate that the National Association of Boards of Pharmacy (NABP) collaborate with boards of pharmacy to streamline the licensure process through standardization and improve the timeliness of application approval; further,

To advocate that NABP collaborate with boards of pharmacy and third-party vendors to streamline the licensure transfer or reciprocity process; further,

To advocate that boards of pharmacy grant licensed pharmacists in good standing temporary licensure, permitting them to engage in practice, while their application for licensure transfer or reciprocity is being processed.

This policy supersedes ASHP policy 0612.

Rationale

Pharmacists sometimes face challenges from delays in obtaining licensure by transfer or reciprocity when moving their practice from one jurisdiction to another. Such delay may be due

to the need for boards to review pharmacists' licensure records in all jurisdictions in which they are licensed, administer a state pharmacy law exam, complete a criminal background check, and, in some cases, schedule an interview with the board. To address these challenges, boards of pharmacy should allow pharmacists in good standing to immediately practice in a different jurisdiction when they change employment or enter a residency program. Granting pharmacists a temporary license for a period of up to six months while the board completes its review would help meet workforce demands while continuing to safeguard the public health. In some cases, pharmacists who are unable to obtain a license in a timely manner are unable to fully use the skills in which they have been trained. Without a license, the pharmacist may temporarily have to function as a technician or perform other tasks. For pharmacists participating in residency programs outside their jurisdiction of licensure, several months of their residency program can elapse before they receive licensure transfer or reciprocity. Upon completion of a year-long residency program, many residents move to another jurisdiction to practice and have to start the transfer or reciprocity process again.

Members in several states have reporting that in recent years boards of pharmacy have been slow to issue pharmacy licenses. This delay is especially problematic for pharmacy residents from another jurisdiction who rely on boards to grant them a license prior to performing in a clinical capacity. Given that the licensing period can take several months, this delay has presented a problem for pharmacy residents who have a limited timeframe to successfully complete their duties, typically one year. In some cases, state boards are urging residents to obtain a pharmacy technician license; however, this is inappropriate given the expertise and education residents have and the level of practice they're expected to engage in. Given its national scope, NABP is well-positioned to explore a broad solution to this problem rather than the current, incremental, state-by-state approach.

1622

Inclusion of Drug Product Shortages in State Price-gouging Laws

Source: Council on Public Policy

To urge state attorneys general to consider including shortages of lifesaving drug products within the definition of events that trigger application of state price-gouging laws.

Rationale

Drug product shortages can lead to price gouging and trafficking in counterfeit and diverted drug products through gray-market distributors, which can ultimately result in adverse patient outcomes and increased healthcare costs. Strategies, including specific legislation with stiff penalties for price gouging during drug product shortages, are needed to deter these activities. Thirty-one states currently have price-gouging laws that prohibit price markups on life-sustaining products (e.g., food, water, fuel), usually during a time of disaster, natural or otherwise. In the absence of laws that specifically address price gouging during drug product shortages, ASHP urges state attorneys general to consider including shortages of lifesaving medications within the definitions of disaster or other trigger mechanisms for existing price-gouging laws.

1501

PHARMACIST PARTICIPATION IN HEALTH POLICY DEVELOPMENT

Source: Council on Public Policy

To advocate that pharmacists participate with policymakers and stakeholders in the development of health-related policies at the national, state, and community levels; further,

To develop tools and resources to assist pharmacists in fully participating in health policy development at all levels.

Rationale

Health policy developed at the federal, state, and local levels increasingly impacts medication use, particularly as payment and delivery models require the interprofessional healthcare team to collaboratively deliver care to meet quality and outcomes measures. The perspective of pharmacists practicing in hospital and ambulatory care settings is essential to the development of health policy. At the federal level, policy development includes drug development, distribution, and control; coverage for medication therapy; interoperability of health information; and all aspects of patient safety. Those federal issues also exist at the state and local level, but also include the full range of scope of practice issues.

The absence of hospital and ambulatory care pharmacist input into health policy development leads to suboptimal public policy, inefficient use of resources (public and private), and the potential for suboptimal patient care at the individual patient level and with specific patient populations. Furthermore, poorly developed public policy results in pharmacists being unable to practice at the top of their licenses.

1502

PHARMACIST RECOGNITION AS A HEALTHCARE PROVIDER

Source: Council on Public Policy

To advocate for changes in federal (e.g., Social Security Act), state, and third-party payment programs to define pharmacists as healthcare providers; further,

To affirm that pharmacists, as medication-use experts, provide safe, accessible, high-quality care that is cost effective, resulting in improved patient outcomes; further,

To recognize that pharmacists, as healthcare providers, improve access to patient care and bridge existing gaps in healthcare; further,

To collaborate with key stakeholders to describe the covered direct patient-care services provided by pharmacists; further,

To advocate for sustainable compensation and standardized billing processes used by payers for pharmacist services by all available payment programs.

This policy supersedes ASHP policy 1307.

Rationale

Recognition of pharmacists as healthcare providers is emerging and being codified in state law as well as in current federal legislative proposals (e.g., H.R. 592, S. 314). In some cases this recognition also includes specified compensation through existing payment mechanisms (e.g., federal Medicare Part B or state Medicaid programs). With recognition, pharmacists should be sustainably compensated for their patient-care services by all public and private payers using standardized billing processes.

1506

PREMARKETING COMPARATIVE CLINICAL STUDIES

Source: Council on Public Policy

To advocate that the Food and Drug Administration have the authority to impose a requirement for comparative clinical trials.

This policy supersedes ASHP policy 0514.

Rationale

With the cost of drug development and approval increasing, the need for comparative clinical trials also is rising. Placebo-controlled studies are not always necessary when a product is in the same drug class as an existing drug. More generally, the FDA should be granted the authority to require comparative clinical studies when appropriate, whether or not a product in the same drug class is already approved.

1507

FUNDING, EXPERTISE, AND OVERSIGHT OF STATE BOARDS OF PHARMACY

Source: Council on Public Policy

To advocate appropriate oversight of pharmacy practice and the pharmaceutical supply chain through coordination and cooperation of state boards of pharmacy and other state and federal agencies whose mission it is to protect the public health; further,

To advocate adequate representation on state boards of pharmacy and related agencies by pharmacists who are knowledgeable about all areas of pharmacy practice (e.g., hospitals, health systems, clinics, and nontraditional settings) to ensure appropriate oversight; further,

To advocate for dedicated funds for the exclusive use by state boards of pharmacy and related agencies including funding for the training of state board of pharmacy inspectors and the implementation of adequate inspection schedules to ensure the effective oversight and regulation of pharmacy practice, the integrity of the pharmaceutical supply chain, and protection of the public; further,

To advocate that inspections be performed only by pharmacists competent about the applicable area of practice.

This policy supersedes ASHP policy 0518.

Rationale

In recent years, the regulatory scope of boards of pharmacy has grown to address new and expanded scopes of practice and healthcare while fulfilling its mission of protecting the public health. In addition, coordination with federal agencies (e.g., FDA, DEA) and related state agencies add to the complexity of a state board's mission. With this expanded scope and mission comes the need for additional resources, both financial and human. Specific knowledge acquired by pharmacists is essential to the safe regulation of the profession. Thus, inspectors need to have that knowledge and training in order to assure the health and safety of the public.

1508

SUPPORT FOR FDA EXPANDED ACCESS (COMPASSIONATE USE) PROGRAM

Source: Council on Public Policy

To advocate that the Food and Drug Administration (FDA) Expanded Access (Compassionate Use) Program be the sole mechanism for patient access to drugs for which an investigational new drug application (IND) has been filed, in order to preserve the integrity of the drug approval process and assure patient safety; further,

To advocate for broader patient access to such drugs under the FDA Expanded Access Program; further,

To advocate that IND applicants expedite review and release of drugs for patients who qualify for the program; further,

To advocate that the drug therapy be recommended by a physician and reviewed and monitored by a pharmacist to assure safe patient care; further,

To advocate for the patient's right to be informed of the potential benefits and risks via an informed consent process, and the responsibility of an institutional review board to review and approve the informed consent and the drug therapy protocol.

Rationale

Patient access to drugs for which an investigational new drug application (IND) has been filed is made available on a limited basis to individual patients under a compassionate-use program regulated by the FDA. With information about clinical trials and drugs under development readily available to patients, there is an increased demand for access to these therapies. In addition, three states have passed laws to permit patients who have exhausted approved drugs and treatment to have access to these potentially lifesaving drugs. Other states may follow suit in the future, and the FDA has begun to respond to this growing patient demand by streamlining its application process for individual patient expanded access. In order to respond to state legislative proposals, ASHP advocates preserving the integrity of drug development through strengthening the evidence-based clinical trial process and expanded patient access.

1509

APPROVAL OF BIOSIMILAR MEDICATIONS

Source: Council on Public Policy

To encourage the development of safe and effective biosimilar medications in order to make such medications more affordable and accessible; further,

To encourage research on the safety, effectiveness, and interchangeability of biosimilar medications; further,

To support legislation and regulation to allow Food and Drug Administration (FDA) approval of biosimilar medications; further,

To support legislation and regulation to allow FDA approval of biosimilar medications that are also determined by the FDA to be interchangeable and therefore may be substituted for the reference product without the intervention of the prescriber; further,

To oppose the implementation of any state laws regarding biosimilar interchangeability prior to finalization of FDA guidance; further,

To oppose any state legislation that would require a pharmacist to notify a prescriber when a biosimilar deemed to be interchangeable by the FDA is dispensed; further,

To require postmarketing surveillance for all biosimilar medications to ensure their continued safety, effectiveness, purity, quality, identity, and strength; further,

To advocate for adequate reimbursement for biosimilar medications that are deemed interchangeable; further,

To promote and develop ASHP-directed education of pharmacists about biosimilar medications and their appropriate use within hospitals and health systems; further,

To advocate and encourage pharmacist evaluation and the application of the formulary system before biosimilar medications are used in hospitals and health systems.

This policy supersedes ASHP policy 1409.

Rationale

A provision in the Patient Protection and Affordable Care Act created a new pathway for the FDA to approve biosimilar products. The FDA approved its first biosimilar application in March 2015; filgrastim-sndz should be ready for market by April 2015. Additional biosimilar applications are likely to be approved by the FDA this year.

At the state level, legislation has been proposed and enacted requiring patient and/or prescriber notification that a biosimilar medication has been interchanged. It is important to note that pharmacists cannot substitute a biosimilar medication unless the FDA has deemed

that biosimilar to be interchangeable. As of 2015, legislation in eight states (Delaware, Florida, Indiana, Massachusetts, North Dakota, Oregon, Utah, and Virginia) became law. In the 2015 state legislative session, there are fifteen states (Colorado, Georgia, Hawaii, Idaho, Illinois, Maryland, Mississippi, New Jersey, Oklahoma, Oregon, Pennsylvania, Tennessee, Texas, Virginia and Washington) that have introduced legislation on biosimilars.

In some states the prescriber/patient notification is similar to what is required for generic substitution, but in others it goes further. For example, a 2015 Georgia Senate bill would require the pharmacist to notify the prescriber within 48 hours of dispensing the medication (excluding weekends and holidays).

ASHP supports legislation and regulation that would authorize the FDA to determine the interchangeability of biosimilars, thus permitting the substitution of biosimilars for the reference product without the intervention of the prescriber. Further, ASHP opposes the implementation of any state laws regarding biosimilar interchangeability prior to finalization of FDA guidance and opposes any state legislation that would require a pharmacist to notify a prescriber when a biosimilar deemed to be interchangeable by the FDA is dispensed. The Council felt that the FDA's determination of interchangeability is all that is needed in order to substitute the biosimilar with the reference product.

1512

DEVELOPMENT OF ABUSE-RESISTANT NARCOTICS

Source: Council on Therapeutics

To advocate that the Food and Drug Administration investigate the efficacy of abuse-resistant formulations in preventing prescription drug abuse.

Rationale

The abuse potential of prescription narcotic medications has a large impact on public health. In October 2013, Zohydro, a long-acting formulation of hydrocodone without abuse-resistant features, was approved by the FDA against the recommendation of an FDA advisory committee. Some states and localities then initiated efforts to ban such agents. A coalition that includes 29 state attorneys general has formed to reverse the approval. In March 2014, the governor of Massachusetts attempted to ban the sale of Zohydro in the state, but a court ruled the ban unconstitutional. Six state attorneys general have drafted a letter to the Secretary of Health and Human Services questioning the FDA decision to approve Zohydro.

Despite the groundswell of support for abuse-resistant opioid formulations, there is not strong evidence that such formulations deter abuse. One study of 232,874 patients across 437 facilities found an increase in abuse prevalence of all opioids after introduction of an abuse-resistant formulation. That study showed little success in deterring abuse, finding instead that patients had switched to alternative drugs. There may also be unintended consequences of preferring abuse-resistant formulations to regular formulations, such as increased costs borne by patients who legitimately need the medications.

Addressing the growing rate of opioid abuse will require a multifaceted strategy; no one tactic will solve the problem. While ASHP supports measures such as abuse-resistant formulations and rescheduling to prevent abuse of opioids, more research is necessary to determine which tactics are the most effective at deterring abuse.

1513

QUALITY PATIENT MEDICATION INFORMATION

Source: Council on Therapeutics

To support efforts by the Food and Drug Administration (FDA) and other stakeholders to improve the quality, consistency, and simplicity of written patient medication information (PMI); further,

To encourage 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 PMI; further,

To advocate that research be conducted to validate these models in actual-use studies in pertinent patient populations; further,

To advocate that FDA explore alternative models of PMI content development and maintenance that will ensure the highest level of accuracy, consistency, and currency; further,

To advocate that the FDA engage a single third-party author to provide editorial control of a highly structured, publicly accessible central repository of PMI in a format that is suitable for ready export; further,

To advocate for laws and regulations that would require all dispensers of medications to comply with FDA-established standards for unalterable content, format, and distribution of PMI.

This policy supersedes ASHP policy 1012.

Rationale

ASHP supports the intent of efforts to improve the quality, consistency, and simplicity of patient medication information (PMI), which the FDA defines as a single standard document for communicating essential information about prescription drugs. However, because these efforts were largely based on consensus of expert opinion, rather than quantitative and well-documented evidence, and because subsequent studies were conducted using expert-based focus groups and other study designs that do not reflect typical patients and under flawed methodology, ASHP encourages the development of evidence-based models for PMI that are designed to support desired outcomes (e.g., better medication use, improved patient safety). In addition, research to validate the effectiveness of any new PMI models under real-use conditions by actual patients, including establishment of a universal literacy level for PMI, should be encouraged. Evidence to establish the essential PMI content needed for the safe and effective use of medications by patients remains to be determined.

Although drug information publishers have made significant progress in improving the quality of PMI, this content is often truncated or provided in illegible formats to accommodate size restrictions or marketing information on patient drug information leaflets that are stapled to prescription packaging.

Because of the FDA's long history of failure to ensure the consistency, currency, and

accuracy of the professional labeling on which PMI would be based; potential for inclusion of biased or promotional information; and the resulting patient confusion and possible harm, ASHP strongly opposes FDA's current proposal for manufacturer-authored PMI that would not be subject to FDA review. Approximately 85% of professional labeling has not been reviewed or updated since 1992 to reflect FDA's current standard for the Physician Labeling Rule (PLR) format. In addition, numerous inconsistencies and inaccuracies in such labeling continue. Given these limitations, the majority of information on which PMI would be based under FDA's proposal would not be likely to "enhance the safe and effective use of prescription drug products and in turn reduce the number of adverse reactions resulting from medication errors due to misunderstood or incorrectly applied drug information," which is the main goal of the FDA requirements.

ASHP further advocates that state legislatures and regulatory agencies require that all dispensers distribute PMI according to FDA-established standards and be held accountable if PMI content or format is modified in a manner that results in nonconformance to the standards.

Creation and maintenance of PMI by a single third-party author (subject to FDA-contracted standards and quality assurance metrics) would provide clear, concise, unbiased, evidence-based PMI that is both timely and consistent for the same drug and for relevant information within the same drug class. Such coordination of the medication information database would allow for consistency in style and content, as well as more frequently updated content.

1405

AUTOMATIC STOP ORDERS

Source: Council on Pharmacy Practice

To advocate that the Centers for Medicare & Medicaid Services (1) remove the requirement in the Hospital Conditions of Participation that all medication orders automatically stop after an arbitrarily assigned period to include other options to protect patients from indefinite, open-ended medication orders, and (2) revise the remainder of the medication management regulations and interpretive guidelines to be consistent with this practice; further,

To affirm that the requirement for automatic stop orders for all medications is a potential source of medication errors and patient harm; further,

To encourage pharmacists to participate in interprofessional efforts to establish standardized methods to assure appropriate duration of therapy.

This policy supersedes ASHP policy 0904.

Rationale

Automatic stop orders on medications are intended to safeguard patients against unnecessary or prolonged drug therapy, yet they also have been shown to cause medication errors when critical therapy is inadvertently and arbitrarily discontinued. The Centers for Medicare & Medicaid Services Hospital Conditions of Participation (CMS COP) continue to require automatic

stop orders for all medications, not accounting for shorter lengths of stay and other means of reviewing drug therapy for appropriateness. The CMS COP should be revised to reflect better, more effective approaches to re-evaluating the appropriateness of medications.

1406
FEDERAL AND STATE REGULATION OF COMPOUNDING
Source: Council on Public Policy

To advocate that the applicable compendial standards of the United States Pharmacopeia be included in state and federal laws and regulations that govern compounding by any health professional; further,

To advocate for mandatory state registration of compounding facilities (e.g., pharmacies, physician offices, clinics, ambulatory surgery centers) that provide products for specific patient prescriptions or in anticipation of specific patient prescriptions or medication orders; further,

To advocate for mandatory Food and Drug Administration registration and current good manufacturing practices requirements for outsourcing facilities that compound and sell products without patient-specific prescriptions across state lines; further,

To advocate for improved patient safety and care through education of regulatory inspectors, increased frequency and improved effectiveness of compliance inspections, and enhancing interagency communications; further,

To advocate that state and federal agencies develop standardized definitions and nomenclature relating to sterile and nonsterile compounding, including but not limited to definitions of compounding, manufacturing, repackaging, and relabeling.

This policy supersedes ASHP policy 1308.

Rationale
The practice of compounding has evolved along with the profession of pharmacy. With the advancement of pharmaceutical manufacturing, the preparation of individualized medications based on a prescription or medication order has also evolved. In particular, sterile preparation and related best practices (e.g., ASHP guidelines) and standards of practice (relevant USP chapters) have also evolved. However, cases of contamination, adulteration, and misbranding have persisted, culminating in the meningitis tragedy caused by contaminated sterile preparations compounded by the New England Compounding Center (NECC). That contamination resulted in 64 deaths and over 700 patient cases, as reported by the Centers for Disease Control and Prevention.

The NECC case highlighted the need for accountability and clear regulatory jurisdiction between state boards of pharmacy and the federal Food and Drug Administration. Since 1997, there has been discussion and debate over the proper oversight of compounding. The NECC case demonstrated the real and potential national public health threat posed by the lack of

oversight of the practice of compounding. This threat is particularly acute when high-risk sterile products are prepared in large quantities and sold across state lines without adherence to either relevant USP chapters or Food and Drug Administration (FDA) current good manufacturing practices (cGMPs). Over the past 16 years, a series of court decisions in various federal circuits has resulted in a patchwork application of Section 503A of the Federal Food Drug and Cosmetic Act. In addition, a new type of supplier of sterile compounded preparations has emerged to fill a critical need for high-risk sterile preparations for hospitals and health systems. Those health systems are often unable to make the capital and/or human resource investments to prepare these high-risk preparations and seek to use outside suppliers to meet their patients' needs. In 2013, Congress passed H.R. 3204, the Drug Quality and Security Act (DQSA) and President Obama signed it into law (P.L. 113-54) on November 27, 2013. Prior to the passage of the DQSA, these outside suppliers operated as licensed pharmacies and in some cases also registered as drug establishments with the FDA. However, the authority for FDA to inspect and enforce either cGMPs or USP standards was unclear. DQSA is designed to provide that clarity as well as delineate the accountability between the FDA and state boards.

ASHP advocates federal oversight of certain entities that compound and engage in interstate commerce to address the wider public health threat when these preparations can potentially be distributed nationwide. ASHP continues to call for state regulation of compounding by health professionals (including pharmacists, physicians, and nurses) that would require meeting the applicable USP standards. ASHP believes that federally registered compounding facilities should be required to meet applicable cGMPs and that state-registered facilities engaged in "traditional compounding" (i.e., compounding for specific patient prescriptions or in anticipation of specific patient prescriptions or medication orders) be required to meet applicable USP standards. ASHP also advocates for inspection by the relevant regulatory body, training of inspectors, and enhanced communication among federal and state regulatory authorities. Finally, ASHP calls for standard definitions and nomenclature for certain terms that may have different definitions within federal law and regulation and between federal and state law and regulation (FDA, Drug Enforcement Administration [DEA], pharmacy practice act and regulation).

1407

340B DRUG PRICING PROGRAM SUSTAINABILITY

Source: Council on Public Policy

To affirm the intent of the federal drug pricing program (the "340B program") to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services; further,

To advocate legislation or regulation that would optimize access to the 340B program in accordance with the intent of the program; further,

To advocate for clarification and simplification of the 340B program and any future federal discount drug pricing programs with respect to program definitions, eligibility, and compliance measures to ensure the integrity of the program; further,

To encourage pharmacy leaders to provide appropriate stewardship of the 340B program by documenting the expanded services and access created by the program; further,

To educate pharmacy leaders and health-system administrators about the internal partnerships and accountabilities and the patient-care benefits of program participation; further,

To educate health-system administrators, risk managers, and pharmacists about the resources (e.g., information technology) required to support 340B program compliance and documentation; further,

To encourage communication and education concerning expanded services and access provided by 340B participants to patients in fulfillment of its mission.

This policy supersedes ASHP policy 0506.

Rationale

Statutory and other policy changes to the federal drug pricing ("340B") program in recent years have spurred an increase in the number of hospitals and other eligible entities that participate. Between 2011 and 2013, the number of 340B-eligible and participating hospitals more than doubled. Policymakers and other stakeholders have raised questions about the integrity of the program as well as its original intent. In addition, compliance with the current program continues to be challenging. Specifically, clarification to existing policy guidance or via newly proposed regulation is needed with respect to various issues. These include the definition of a patient, use of contract pharmacies, eligibility by various hospitals, and use of group purchasing organizations to purchase drugs for inpatient and outpatient use. Moreover, expansion of Medicaid eligibility in 2014 (through provisions in the Affordable Care Act) will allow additional hospitals to participate in the program and continue the scrutiny and questions from policymakers and stakeholders. These factors demonstrate the need for pharmacy leaders to engage in a strategic response to this compliance environment.

The original intent of the 340B program was to "to enable these entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." (H.R. Rept. 102-384, pt. 2, at 12 [1992]). ASHP believes that the program should expand in alignment with its intent, which may or may not include use in the inpatient setting. ASHP emphasizes the need for clarification and simplification (to the extent possible) of the program in order to enable compliance and maintain program integrity. In response to policymaker and stakeholder concerns, ASHP recognizes the important intent and role of the 340B program and stresses the need for its continued sustainability.

1408

STATE PRESCRIPTION DRUG MONITORING PROGRAMS

Source: Council on Public Policy

To advocate for mandatory, uniform prescription drug monitoring programs that collect real-time, relevant, and standard information from all dispensing outpatient entities about controlled substances and monitored 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 full interstate integration to allow for access by prescribers, pharmacists, and other qualified designees across state lines; further,

To advocate for federal and state funding to establish and administer these programs; further,

To promote research, education, and implementation of best practices in prescription drug monitoring programs.

This policy supersedes ASHP policy 1122.

Rationale

ASHP recognizes the important contributions to public health made by state prescription drug monitoring programs (PDMPs). To be effective, these programs need to be mandatory; must collect standardized, relevant, and real-time information for analysis and comparison among states; and need to be universal. Some PDMPs do not update information in real time. When updating lags reporting by days (or even weeks), program effectiveness is compromised. Moreover, relevant information is sometimes not required, and not all dispensing sites are required to participate, which impacts the ability of practitioners to make relevant clinical decisions. PDMPs need to be fully integrated across state lines so information from other jurisdictions is available to practitioners and prescribers to assist them in balancing the goals of discouraging prescription drug abuse while providing appropriate therapeutic management. It is also important to ensure the integration and interoperability of these programs with the evolving use of electronic health records and information exchanges so that prescription monitoring programs can be an educational tool for prescribers and practitioners. Finally, adequate state and federal funding is essential to sustain the viability of these programs and to encourage research, education, and implementation of best practices in PDMPs. Such research and education would serve to raise awareness about how to best address the growing public health issue of prescription drug abuse and misuse.

1410

ACCESS TO ORAL CONTRACEPTIVES THROUGH AN INTERMEDIATE CATEGORY OF DRUG PRODUCTS

Source: Council on Therapeutics

To advocate that oral contraceptives be provided only under conditions that ensure safe use, including the availability of counseling to ensure appropriate self-screening and product selection; further,

To support expanded access to these products through a proposed intermediate category of drug products, as described by ASHP policy, that would be available from all pharmacists and licensed health care professionals (including pharmacists) who are authorized to prescribe medications; further,

To advocate that the proposed reclassification of these products be accompanied by coverage changes by third-party payers to ensure that patient access is not compromised and that pharmacists are reimbursed for the clinical services provided.

Rationale

There have been repeated calls to make oral contraceptive products more widely available, with the intent of expanding access to women's reproductive health therapies and reducing unintended pregnancies. These proposals have merit, but ASHP believes that there are important differences in safety and effectiveness profiles for drug products within this class that necessitate the availability of a pharmacist or other health care professional to provide patient guidance. ASHP supports the availability of these products via an intermediate category of drug products, as described in ASHP policy 0220, Intermediate Category of Drugs, and the *ASHP Statement on Criteria for an Intermediate Category of Drug Products*, which would facilitate appropriate use of these therapies after patient assessment and professional consultation by a pharmacist or other licensed health care professional who is authorized to prescribe medications. Patient screening and product selection would be improved through pharmacist-provided counseling that assists patients in identifying absolute and relative contraindications (e.g., hypertension, heart or kidney disease) and assessing other patient-specific factors (e.g., adherence practices). This process would guide the determination of whether a progestin-only or combination oral contraceptive product would be more safe and effective for an individual patient. ASHP does not believe that the current model for behind-the-counter access to some drug products (e.g., pseudoephedrine, emergency contraception) is appropriate for oral contraceptives because it would place the pharmacist in a gatekeeping role, not the clinical one that is necessary to ensure safe and effective use of these therapies.

Given the intent to expand access to these therapies, ASHP advocates that the proposed reclassification should not result in increased costs to women. Modifications to national, regional, and local drug coverage decisions may be needed to ensure that payer policies do not unintentionally restrict or prevent access. In addition, ASHP believes that the reclassification would result in increased workload and potential liability associated with pharmacist provision of this care, which includes patient screening, product selection, counseling, therapeutic monitoring, and documentation of the care provided in the pharmacy and medical record.

Therefore, ASHP advocates that pharmacists should be compensated for these and other patient-care services as described in ASHP policy 1307, Pharmacist Recognition as a Health Care Provider.

1411
EXPEDITED PATHWAYS FOR FDA DRUG APPROVAL
Source: Council on Therapeutics

To support the use of expedited pathways for Food and Drug Administration (FDA) approval of new drugs that expand access to innovative therapies while protecting patient safety; further,

To advocate for the development of unique labeling requirements that would be used on an interim basis to identify products approved by these pathways in order to increase awareness of data limitations and guide clinician use of these drugs until additional evidence becomes available; further,

To advocate that the FDA be diligent in enforcing postmarketing commitments for drug products approved via expedited pathways, including utilizing its existing authority to enforce penalties when these requirements are not met; further,

To encourage research to evaluate the impact of expedited pathways on drug product development and patient care, including drug development timelines and costs, overall health care costs, patient access to care, and the effectiveness and safety of these therapies.

Rationale
Expedited approval programs provided by the FDA have resulted in substantial public health benefits as illustrated by the use of surrogate endpoints to approve therapies for HIV and AIDS in the 1990s. The FDA provides four mechanisms to expedite the development and review process for drugs: fast track designation, breakthrough therapy designation, accelerated approval, and priority review designation. The structure and requirements for each of these mechanisms differs as described in a 2013 draft guidance for industry. However, to qualify for any of these programs a drug must (1) address an unmet medical need, (2) provide benefit over available drug treatments, and (3) be used in the treatment of a serious or life-threatening condition. Further, the FDA guidance states that these programs are "intended to help ensure that therapies for serious conditions are approved and available to patients as soon as it can be concluded that the therapies' benefits justify their risks." Processes used to ensure a favorable risk–benefit profile include, but are not limited to, requirements for postmarketing studies to evaluate safety and effectiveness of the drug as used in real-world scenarios. However, the accelerated approval program is the only program that includes postmarketing studies as a requirement of the program. The FDA has discretion to require additional studies on a case-by-case basis for drug products approved via the other expedited mechanisms. Despite these safeguards, some features of these programs (e.g., smaller clinical trials, alternate trial designs, or limited-duration trials) can result in increased patient risk because less is known about a drug's side effect profile and efficacy due to limited patient exposure. In addition, as with all

drugs, safety assessments benefit from use of the drug in post-approval patient populations, which better reflect real-world use as compared to the controlled environment of a clinical trial.

Because these drugs represent medical advances, their post-approval use can be extensive. Further, off-label use of these drug products, like all therapies, is common. However, prescribers and other clinicians are frequently unaware that an expedited pathway was utilized and that evidence limitations exist. This scenario raises significant concerns about whether there is sufficient clinician awareness to ensure appropriate use of drugs approved via these pathways. Therefore, ASHP proposes unique labeling requirements that would increase awareness through use of a logo or other mechanism that would be used on an interim basis to inform clinicians about data limitations and provide guidance on appropriate use. This labeling would describe appropriate patient populations and monitoring parameters. Similar labeling requirements have been proposed for a new pathway being considered for the development of antibiotics used to treat life-threatening infections. ASHP supports the approach, but recommends that the increased labeling requirements be discontinued once the drug product manufacturer and FDA agree that sufficient data is available to support safe and effective use, or after the drug manufacturer completes any required postmarketing study commitments.

Given data limitations associated with approval of these therapies, ASHP advocates that the FDA be extremely diligent in ensuring that postmarketing commitments are met. Further, the FDA should use its existing authority as described under 21 CFR 314 subpart H and 21 CFR 601 subpart E if timelines or expectations for these commitments are not satisfactory. This authority allows the FDA to take legal action through penalties that include requiring labeling changes or rescinding marketing approval.

Finally, ASHP believes that there is a need for research to determine whether these expedited pathways are achieving the desired benefits, which include decreasing the time and costs associated with drug product development, lowering overall health care costs, and increasing patient access to safe and effective drug therapies.

1412

FDA OVERSIGHT OF LABORATORY-DEVELOPED TESTS

Source: Council on Therapeutics

To advocate that the Food and Drug Administration be granted increased authority to regulate laboratory-developed tests as medical devices, including tests used for pharmacogenetic testing; further,

To support development of a risk-based framework for regulatory oversight of laboratory-developed tests that promotes innovation while providing a mechanism to ensure that test results are reliable, reproducible, and clinically relevant; further,

To encourage expanded availability of commercially marketed pharmacogenetic tests that would be available for use by laboratory and health care professionals to guide drug therapy.

Rationale

The use of *in vitro* pharmacogenetic tests has become increasingly common as efforts continue to achieve the promise of personalized medicine. However, the current system of regulatory oversight of these and other laboratory tests used to guide drug therapy is complex and inconsistent. Some laboratory tests (e.g., companion diagnostics devices) receive premarket review and approval by the Food and Drug Administration (FDA) when the test is either developed in tandem with drug development or following the drug's approval. Other tests, commonly called laboratory-developed tests (LDTs), are proprietary tests that are developed and validated for use at specific laboratory facilities. These tests do not undergo premarket review and approval by the FDA. LDTs currently fall under a mixed system of oversight by the FDA and Centers for Medicare & Medicaid Services (CMS), which regulates these tests based on facilities' compliance to the Clinical Laboratory Improvement Amendments (CLIA). CLIA compliance serves as the primary mechanism for oversight, as the FDA has traditionally practiced discretionary authority, meaning that only a few of the most complex tests are scrutinized by that agency. While an LDT is monitored for validity and reliability at the laboratory where it is conducted, results may not be reproducible if the test is conducted at a different laboratory site. This variability complicates the interpretation and application of this information in patient care. Therefore, ASHP advocates for the FDA to have increased authority to regulate these LDTs as medical devices to ensure that results are reliable, reproducible, and clinically relevant to patient care.

Development of a risk-based framework represents the ideal model to provide sufficient oversight while creating conditions that support continued innovation in this field. Further, the development of nationally validated and marketed tests that are available for use by laboratory and health care professionals is desirable. ASHP believes that this scenario would provide the most assurance to pharmacists and other health care professionals that the results of these tests are reliable, reproducible, and clinically relevant to patient care.

1310

REGULATION OF TELEPHARMACY SERVICES

Source: Council on Public Policy

To advocate that state governments adopt laws and regulations that standardize telepharmacy practices across state lines and facilitate the use of United States-based telepharmacy services; further,

To advocate that boards of pharmacy and state agencies that regulate pharmacy practice include the following in regulations for telepharmacy services: (1) education and training of participating pharmacists; (2) education, training, certification by the Pharmacy Technician Certification Board, and licensure of participating pharmacy technicians; (3) communication and information systems requirements; (4) remote order entry, prospective order review, verification of the completed medication order before dispensing, and dispensing; (5) direct patient-care services, including medication therapy management services and patient counseling and education; (6) licensure (including reciprocity) of participating pharmacies and pharmacists; (7) service arrangements that cross state borders; (8) service arrangements within the same corporate entity or between different corporate entities; (9)

service arrangements for workload relief in the point-of-care pharmacy during peak periods; (10) pharmacist access to all applicable patient information; and (11) development and monitoring of patient safety, quality, and outcomes measures; further,

To identify additional legal and professional issues in the provision of telepharmacy services to and from sites located outside the United States.

This policy supersedes ASHP policy 0716.

Rationale

In light of continuing advances in technology, there an increasingly urgent need for state board of pharmacy regulation of the provision of pharmacist care services from off-site locations through electronic technology (telepharmacy). It is important to acknowledge the regulatory purview of state boards of pharmacy regarding the use of telepharmacy and recognize that the intent of such regulations should be to balance protection of the public health with the increased patient access to the patient care services of pharmacists provided by telepharmacy. Although such regulations should allow for various arrangements across state borders and within or between health systems, they all need to address a number of common concerns.

ASHP policy 0716 was revised to address the provision of medication therapy management and other direct patient-care services in any regulation of telepharmacy services and to advocate that patient safety, quality, and outcomes measures be developed and monitored. The policy was also revised to include advocacy to state governments to harmonize the practice of pharmacy across state lines and to update requirements for technician functions in the provision of telepharmacy services be performed by technicians that are certified by the Pharmacy Technician Certification Board (PTCB) and licensed by the state board of pharmacy. The revised policy also calls on ASHP to continue efforts to identify additional legal and professional issues in the provision of international telepharmacy services.

1311

REGULATION OF CENTRALIZED ORDER FULFILLMENT

Source: Council on Public Policy

To advocate changes in federal and state laws, regulations, and policies to permit centralized medication order fulfillment within health care facilities under common ownership.

Rationale

The Council discussed the increased use of centralized order fulfillment within health systems as well as fulfillment by contracted entities. Health systems use centralized facilities to provide a range of medications in order to improve efficiency, decrease redundancy, optimize preparation expertise, and decrease overhead and inventory costs. Importantly, health systems use centralized facilities to provide medications that are in short supply or are difficult to compound safely.

The Drug Enforcement Administration prohibits central repackaging and distribution of controlled substances to other facilities that are part of the same health system. Moreover, health systems with facilities in multiple states find additional requirements in each state by

boards of pharmacy and other state regulators when providing medications across state borders from a centralized facility.

The Council and Board recognized the importance of maintaining practice standards and related safeguards to assure patient safety. In fact, health systems use centralized facilities in order to have the most-qualified personnel prepare these medications in the safest facility. The Council and Board identified the need to seek regulatory changes at the state and federal level in order to optimally use centralized facilities that are under the common ownership and therefore quality control of the health system.

1314

DEA SCHEDULING OF HYDROCODONE COMBINATION PRODUCTS

Source: Council on Therapeutics

To advocate that the Drug Enforcement Administration (DEA) reschedule hydrocodone combination products to Schedule II based on their potential for abuse and patient harm and to achieve consistency with scheduling of other drugs with similar abuse potential.

Rationale

The Council, Board, and House of Delegates discussed proposals to reschedule Vicodin (hydrocodone and acetaminophen) and other hydrocodone combination products to Schedule II under the Controlled Substance Act. These therapies are currently under Schedule III. A meeting of FDA's Drug Safety and Risk Management Advisory Committee was scheduled for October 29 and 30, 2012, to address the public health benefits and risks of these therapies, including the potential for abuse. The Council was asked to advise ASHP on these topics to support the Society's participation in that discussion. The Council considered this issue at its September meeting and during a follow-up teleconference that was convened on December 21, 2012, to evaluate information released by the FDA after the Council developed the proposed policy in September. The new information, which was released as a pre-meeting report, included data on prescribing trends, abuse potential, and patient harms. This summary reflects both discussions, as noted throughout. [Note: The initial FDA advisory committee meeting was postponed due to inclement weather and rescheduled for January 24 and 25, 2013. At the conclusion of that meeting, the advisory committee voted 19 to 10 in favor of rescheduling hydrocodone combination products to Schedule II].

The Council's September assessment initiated with a review of the DEA's criteria for drugs in Schedule II and Schedule III, and reports from the Centers for Disease Control and Prevention (CDC) and other entities concerning the extent of abuse and patient harm from these and other opioid analgesics. As defined by the DEA, Schedule II controlled substances are those that "have a high potential for abuse which may lead to severe psychological or physical dependence." Hydrocodone as a single-ingredient product, if commercially available, would be included in Schedule II. However, at lower dosages and with the addition of acetaminophen, these combination products are assigned to Schedule III. In contrast, oxycodone is designated as Schedule II regardless of dosage or whether the drug is provided as single ingredient or as a combination product with acetaminophen. Schedule III controlled substances are those that "have a potential for abuse less than substances in Schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence." Recent data from

the CDC show that every year since 2003 more deaths have occurred from overdoses of opioid pain relievers, including hydrocodone combination products, than from overdoses of cocaine and heroin combined. In addition to this morbidity and mortality data, the Council reviewed clinical guidelines on pain management, opioid prescribing trends, and research on the relative addictive potentials of opioid products. The Council found no evidence that the lower dose of hydrocodone contained in these combination products, or the addition of acetaminophen, lowered the abuse potential of hydrocodone. The Board and House supported this assessment.

During the December conference call, the Council discussed data contained in the FDA pre-meeting report on prescribing trends (e.g., prescriber type, indication, duration of therapy), abuse potential, and patient harms. The Council found this data informative, but questioned whether it reflected the true extent of abuse of these therapies given the high prevalence of pill sharing and diversion of legal prescriptions. The Board and House agreed. The Council noted that adverse drug events and other patient harms may be underreported when these products are misused or obtained illegally. The Council also stated that the FDA data provided no insight as to whether these prescriptions were appropriate (i.e., issued according to evidence-based guidelines for appropriate indications and durations of use). Given these variables, the Council stated that the data are difficult to interpret and apply to a rescheduling decision, and the Board and House agreed. Central to the Council's deliberation were criteria used by DEA to determine whether to control or reschedule a drug, which include (a) the drug's actual or relative potential for abuse; (b) scientific evidence of its pharmacological effect, if known; (c) the state of current scientific knowledge regarding the abuse of the drug or other substance; (d) its history or current pattern of abuse; (e) the scope, duration, significance of abuse; (f) what, if any, risk there is to public health; (g) its psychic or physiological dependence liability; and (e) whether the substance is a precursor of a substance already controlled under the law. Based on an assessment using these criteria, the Council, Board, and House believed that hydrocodone combination products were similar to other controlled substances found in Schedule II and should therefore be assigned to Schedule II. Of note, the Council stated that these criteria were never intended to take into account potential administrative and other burdens on pharmacists and other clinicians (e.g., stricter recordkeeping and security processes).

The Council also addressed concerns that rescheduling hydrocodone combination products may not decrease abuse. While it is difficult to predict the impact rescheduling would have on abuse, a majority of Council members believed that abuse would decrease, stating that the current extent of abuse is supported by easy access to, and excessive supply of, these therapies. The Board and House agreed with this assessment. The Council also considered a recommendation from the FDA to delay a decision on rescheduling until more data are available concerning the impact of alternative strategies, such as prescription drug monitoring programs, risk evaluation and minimization strategies (REMS), prescriber and patient education, and enforcement actions. The Council stated that these strategies can be effective, but noted that these approaches are largely reactive, not proactive. The Council believed that many of these strategies have been in place for years, yet there has been limited scientific evaluation of their effectiveness despite the costs and burdens they impose. In addition, clinician willingness to follow clinical guidelines and other measures to ensure appropriate medication use of all therapies has historically been low. Overall, the Council questioned whether more or better information would be gained by further delaying a decision on

rescheduling these therapies. In light of these findings, the Council, Board, and House believed that continued inaction was inappropriate given the public health concern.

In considering this policy, the Council, Board, and House weighed the potential public health benefit of rescheduling these therapies against concerns about restricting patients' access to treatment and increasing administrative and other burdens on pharmacists and other clinicians. The proposed change to a more restrictive schedule would require stricter recordkeeping and security processes, which could in turn make providers reluctant to prescribe these therapies for patients who need pain management. The Council, Board, and House believed that these were very significant and valid concerns. However, in balancing these concerns, they concluded that increased control of drugs with high abuse potential is in the best interests of patients and public health. In addition, the Council questioned whether the inability to prescribe refills (which would be a primary impact of rescheduling) would have as broad an impact on patient access as initially feared. The Council highlighted data from the FDA pre-meeting report demonstrating that a majority of prescriptions for these products were issued for treatment of acute pain. The FDA's evaluation of the 131 million prescriptions issued in 2011 found that these products were most commonly prescribed for diseases of the musculoskeletal system and connective tissues; diseases of the respiratory system (for hydrocodone combination products that are used as antitussives); and fractures, sprains, contusions, and injuries. The average duration of therapy was 14 days. The Council stated that this information indicates that the burden on patients and providers should be less than feared because prescriptions for acute pain treatment would have no refills (or limited refills). The Council also noted several factors that would address concerns about access and burden, including the ability to predate prescriptions, proposed changes to e-prescribing standards that would permit electronic prescribing for these therapies, and the ability to fax prescriptions in many instances. However, the Council did acknowledge that existing state practice acts could prevent some mid-level practitioners from prescribing these drugs should a schedule change be implemented. The Council, Board, and House encouraged DEA and others to monitor the impact of this scheduling change on patient access and practice, as well as to monitor the impact of other strategies that have been implemented to minimize the abuse and diversion of these therapies.

As part of their discussion, the Council also expressed concern about the current process used by the DEA to determine abuse potential for all controlled substances. A separate policy recommendation was developed to address this topic.

1315

DEA SCHEDULING OF CONTROLLED SUBSTANCES

Source: Council on Therapeutics

To advocate that the Drug Enforcement Administration (DEA) establish clear, measurable criteria and a transparent process for scheduling determinations; further,

To urge the DEA to use such a process to re-evaluate existing schedules for all substances regulated under the Controlled Substances Act to ensure consistency and incorporate current evidence concerning the abuse potential of these therapies; further,

To monitor the effect of DEA scheduling of products under the Controlled Substances Act and other abuse-prevention efforts (e.g., prescription drug monitoring programs) to assess the

impact on patient access to these medications and on the practice burden of health care providers.

Rationale

The Council discussed the DEA's current classification structure used to determine the schedule of controlled substances as part of their discussion of proposals to reschedule hydrocodone combination products. The Council believed that the current stratification of abuse potential into low, moderate, and high categories lacks clarity and contributes to perception of inconsistency in assigning schedules. The Board concurred. The Council also noted that the existing schedules do not appear to take into account evolving evidence about the abuse potential of these drugs. Therefore, the Council and Board recommended that ASHP advocate that the DEA establish clear, measurable criteria, to the extent possible for this complex area, and a transparent process for scheduling determinations. Further, the DEA was encouraged to use those criteria to re-evaluate current schedule assignments for all controlled substances based on the most recent evidence.

1216

PHARMACY TECHNICIANS

Source: Council on Public Policy

To advocate that pharmacy move toward the following model with respect to the evolving pharmacy technician workforce as the optimal approach to protecting public health and safety: (1) development and adoption of uniform state laws and regulations regarding pharmacy technicians, (2) mandatory completion of an ASHP-accredited program of education and training as a prerequisite to pharmacy technician certification, (3) mandatory certification by the Pharmacy Technician Certification Board as a prerequisite to licensure by the state board of pharmacy, and (4) licensure of pharmacy technicians by state boards of pharmacy granting the technician permission to engage in the full scope of responsibilities authorized by the state; further,

To advocate, with respect to certification, as an interim measure until the optimal model is fully implemented, that individuals be required either (1) to have completed an ASHP-accredited program of education and training or (2) to have at least one year of full-time equivalent experience as pharmacy technicians before they are eligible to become certified; further,

To advocate that all pharmacy functions be performed under the general supervision of a licensed pharmacist and that licensed pharmacists and technicians be held accountable for the quality of pharmacy services provided.

(*Note:* Licensure is the process by which an agency of government grants permission to an individual to engage in a given occupation upon finding that the applicant has attained the minimal degree of competency necessary to ensure that the public health, safety, and welfare will be reasonably well protected. Certification is the process by which a nongovernmental agency or association grants recognition to an individual who has met certain predetermined qualifications specified by that agency or association.)

This policy supersedes ASHP policy 0815.

Rationale

ASHP policy 0815 was revised to advocate for licensure of pharmacy technicians in response to Recommendation D8 by the Pharmacy Practice Model Initiative (PPMI) Summit and subsequent discussion by the ASHP Board of Directors. Optimal use of pharmacy technicians will enable pharmacists to devote more time to drug therapy management. Uniformity among state laws is essential to achieve the preferred vision for practice. Moreover, requiring licensure rather than registration will enable state boards to require competency, impose disciplinary sanctions, and hold technicians accountable for their actions.

The process proposed for pharmacy technicians to achieve licensure follows the same steps outlined in policy 0815: education and training, followed by examination and certification, as prerequisites to licensure. The movement to technician licensure was essential to assure the public that the medication-use system includes individuals competent to assist pharmacists to provide and manage their medication regimens. Licensure will provide state boards with the tools necessary to provide that assurance to the public.

1219

STABLE FUNDING FOR HRSA OFFICE OF PHARMACY AFFAIRS

Source: Council on Public Policy

To advocate for a sustainable level of funding, including appropriations, sufficient to support the public health mission of the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs; further,

To support initiatives of the Office of Pharmacy Affairs, including the 340B Drug Pricing Program and innovative pharmacy service models in HRSA-funded programs; further,

To encourage research on the potential impact of any proposed fees or alternative funding sources for the Office of Pharmacy Affairs.

This policy supersedes ASHP policy 0911.

Rationale

The Office of Pharmacy Affairs (OPA) currently relies on general funding from its parent agency, HRSA, and not a line-item annual appropriation to administer the 340B Drug Discount Program. The OPA and HRSA have sought funding to establish a cost recovery (user fee) program to administer the program. The initial fee would be 0.1 percent of the total 340B drug purchases paid by participating covered entities. HRSA and OPA contend that the cost recovery fee will create a sustainable funding source to meet the demands of the existing and projected growth of the 340B program, the changing marketplace, and new statutory program requirements. There is a need for stable and sustainable funding for the OPA. A variety of funding sources should be considered, perhaps involving entities that do not participate in the 340B program. Any user fee program should include an annual review of the percentage used to determine the annual fee charged to participating entities. In addition, OPA should not be solely dependent on

user fees for its program administration; some level of congressional appropriations would serve as an important to safeguard against such a dependency.

1223
GLOBALIZATION OF CLINICAL TRIALS
Source: Council on Therapeutics

To encourage the Food and Drug Administration (FDA) to use its existing authority to increase monitoring and inspection of foreign clinical trials to ensure the integrity and quality of those studies; further,

To advocate that the FDA expand its oversight of clinical trials conducted abroad by continuing to pursue innovative strategies, such as increased collaboration with foreign regulatory agencies and changes in domestic regulatory processes that support timely submission of foreign clinical trial information; further,

To encourage the FDA to establish a standardized electronic format and reporting standards that would be required for submission of data from foreign clinical trials; further,

To support the ethical treatment of patients in foreign clinical trials in accordance with international standards designed to protect human subjects; further,

To encourage public and private research to study the impact of the globalization of clinical trials on patient care.

Rationale
More than 80% of marketing applications for drugs approved in fiscal year 2008 were supported by data from foreign clinical trials, and more than 50% were based on data from trials that were conducted entirely outside of the United States. This trend toward the globalization of clinical trials is expected to continue because of potential benefits to drug manufacturers (e.g., decreased costs, availability of treatment-naive patients). ASHP is concerned that limited experience with clinical trials in some countries could affect data integrity and questioned whether results from foreign clinical trials could always be generalized to patients in the United States because of differences in genetics and cultural factors (e.g., diet, use of supplements). Existing FDA authority allows for oversight of foreign clinical trials, including a requirement for mandatory reporting. However, according to the 2010 Office of Inspector General (OIG) report, *Challenges to FDA's Ability to Monitor and Inspect Foreign Clinical Trials*, only 0.7 percent of foreign trial investigators were inspected in FY 2008 (compared to 1.9% of investigators in the United States). The FDA should increase oversight of foreign clinical trials given the potential for inconsistencies in protocol implementation and concerns about the availability and integrity of data noted in the OIG report. Development of innovative approaches to expand oversight given limited FDA resources is also encouraged. ASHP supports a recent FDA agreement with the European Medicines Agency to share information from inspections conducted by that agency and encourages the FDA to establish this type of agreement with other countries, including those whose experience with clinical

trials is limited. The FDA should also explore regulatory changes that would support more timely submission of foreign clinical trial information. This recommendation is based on concern that some aspects of current regulations may encourage drug manufacturers to favor foreign clinical trials. For example, submission of an investigational new drug (IND) application triggers FDA oversight, including required submission of clinical trial protocols. Timely submission of an IND is necessary for studies conducted within the United States because it provides an exemption from interstate commerce laws, which is needed to conduct clinical trials. However, interstate commerce laws do not apply abroad. Therefore, there is no requirement or incentive for manufacturers to submit study protocols for foreign trials if they are conducted prior to the IND submission. However, results from those trials are sometimes used to support marketing applications for drug approval. While the FDA can review protocol and data from these studies retrospectively, data omissions and other factors limit the effectiveness of this approach. Earlier submission of this information would enhance the effectiveness of FDA's oversight. Standardization and electronic submission of data from foreign clinical trials should also be encouraged, given the OIG finding that data from these trials was sometimes not available to FDA reviewers. Ethical concerns associated with foreign clinical trials, including documented lapses in informed consent, support the need for improved adherence to ethical standards for conducting clinical research, such as those described in the International Conference on Harmonisation Tripartite Guideline for Good Clinical Practice and other international guidelines. Finally, the FDA and private entities are encouraged to study the potential patient care impact of the globalization of clinical trials to determine whether there is an impact even when studies are conducted appropriately.

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 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 and House concurred with this assessment. The councils, Board, and House believed additional and well-designed research was necessary to further define the medical use of marijuana, including determination of its therapeutically active components; 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, Board, and House recommended standardizing these factors, to the extent possible, to ensure the quality and reliability of research results. The councils, Board, and House 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. The Council on Public Policy, the Board, and the House 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 activites could jeopardize the pharmacy or facility's registration with the DEA. Finally, the councils, Board, and House 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.

The House and Board further agreed to oppose state legislation authorizing use of medical marijuana until there is evidence to supports its safety and efficacy and a standardized product subject to the same regulations as a prescription drug product, and to oppose the smoking of marijuana where smoking is prohibited.

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.

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 and House concurred. The House suggested and the Board agreed that pro-hormone therapies should be re-evaluated as well. The Council and Board also encouraged additional research to examine the public health impact of agricultural uses of hormone therapies.

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-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.

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-to-consumer clinical 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 and House 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, Board, and House 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, Board, and House 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 and House agreed. Education of consumers and clinicians about use of these tests was supported by the Council, Board, and House.

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.

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 and House concurred. The Council, Board, and House 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 all-hazards 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, and the Board and House agreed. The Council further noted that the IOM report concluded that poison control centers should be better integrated and coordinated, and the Board and House agreed that such integration and coordination should be supported where appropriate.

1001
HEALTH INSURANCE COVERAGE FOR U.S. RESIDENTS
Source: Council on Public Policy

To advocate health insurance for all residents of the United States, including coverage of medications and related pharmacist patient-care services; further,

To advocate that the full range of available methods be used to (1) ensure the provision of appropriate, safe, and cost-effective health care services; (2) optimize treatment outcomes; and (3) minimize overall costs without compromising quality; further,

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

This policy supersedes ASHP policy 0512.

Rationale

This policy expresses ASHP's stance on health insurance coverage for the uninsured in the United States. The policy emanated from ASHP policies dealing with affordability and accessibility of pharmaceuticals. ASHP believes that it is important to address the larger issue of health insurance coverage for the uninsured, particularly due to the impact of the cost of medications on the nation's overall health care budget as well as pharmacy budgets in hospitals and health systems.

1002

RISK EVALUATION AND MITIGATION STRATEGIES

Source: Council on Public Policy

To advocate for research on the impact of the Food and Drug Administration's Risk Evaluation and Mitigation Strategies (REMS) on patient safety, cost effectiveness, and pharmacy workflow; further,

To advocate pharmacist involvement in the development and implementation of REMS; further,

To urge computer software vendors to assist pharmacists in the identification of and compliance with REMS; further,

To advocate that any REMS that include constraint on traditional drug distribution systems be consistent with ASHP policy on restricted drug distribution.

Rationale

Risk Evaluation and Mitigation Strategies (REMS) are part of new authority granted to the Food and Drug Administration (FDA) to ensure that a drug's benefits outweigh its risks. An increasing number of drug products require REMS in order to be marketed, and some REMS require Medication Guides as well as other "elements to assure safe use." These elements beyond a Medication Guide have included prescriber and pharmacist training, patient registry, and additional patient monitoring. ASHP believes that more research should be conducted by either the FDA or drug manufacturers to determine the effectiveness of and need for REMS. Health-system pharmacists have encountered problems with REMS that were developed without input from health-system pharmacy. Pharmacist input in the development of REMS is essential to avoid unnecessary barriers to patients and burdensome interruptions to pharmacy workflow that could impact patient care and safety.

Drug information and knowledge vendors providing information technology and decision support systems will need to include gateways to specific information about REMS so that pharmacists and other health professionals have access to information about all REMS-required products and the specific requirements for a particular REMS that includes elements to assure safe use.

Finally, REMS that include constraints on traditional drug distribution systems should be consistent with existing ASHP policy on restricted drug distribution.

1003
FDA AUTHORITY ON RECALLS
Source: Council on Public Policy

To strongly encourage the Food and Drug Administration (FDA) to develop a standard recall notification process and format to be used by all manufacturers to facilitate the timely removal of recalled drugs; further,

To advocate that such notification should (1) come from a single source, (2) clearly identify the recalled product, (3) explain why the product is being recalled, (4) provide a way to report having the recalled product, (5) give instructions on what to do with the recalled product, and (6) be provided concurrently to all entities in the supply chain; further,

To advocate that the FDA be given the authority to order mandatory recalls of medications; further,

To urge the FDA to require drug manufacturers and the computer software industry to provide bar codes and data fields for lot number, expiration date, and other necessary and appropriate information on all medication packaging, including unit dose, unit-of-use, and injectable drug packaging, in order to facilitate compliance with recalls or withdrawals and to prevent the administration of recalled products to patients; further,

To urge the FDA to encourage postmarketing reporting of adverse events and product quality issues to enhance the recall system.

Rationale
A recall is a manufacturer or distributor's voluntary removal or correction of a marketed product. The Food and Drug Administration (FDA) may request a recall in "urgent situations." For each recall, the manufacturer or distributor develops a recall strategy based upon guidance from the FDA; there is no standard format for recall notices, and communication timelines, format, content, and distribution vary.

Managing product recalls within hospitals and health systems is a complex process. Past recall events have highlighted the complexity of the process and demonstrate the need for improvements to ensure that recalled product can be removed effectively and efficiently to protect patients from inadvertent administration. During the 2008 recall of heparin, for example, 94 hospitals were found to have recalled product remaining on their shelves. Further evaluation of how the recall was implemented revealed flaws in the system. Some pharmacy departments reported that they never received the recall notice; in other cases, recalled product was shipped to the pharmacy after the hospital had completed its review of supplies and quarantined all recalled product.

The FDA must have the authority to clearly communicate with stakeholders about recalls of marketed products. Inconsistent, unclear, and confusing information has been

communicated during past recalls. A standardized recall notification process and format would enable practitioners and others in the drug distribution chain to readily identify and respond to a recall. Such a notification process should contain the following elements: a single source to designate a point of contact and control communication, clear identification of the recalled product to assist in removing the product from stock, an explanation of why the product is being recalled in order to understand the nature of the recall and communicate with patients and other stakeholders, a feedback mechanism (a reporting loop) so manufacturers and the FDA know where recalled product is located, instructions on how to return or dispose of the recalled product, and concurrent notification of all entities in the supply chain.

ASHP advocates that the FDA be given the authority to order a mandatory recall of a product to avoid the miscommunication that has occurred in past voluntary recalls. In addition, ASHP has long encouraged the FDA to require that lot number, expiration date, and other necessary information be provided electronically (e.g., by bar code or radio frequency identification) as part of the manufacturer's information on all unit dose, unit-of-use, and injectable drug packaging.

Finally, postmarketing reporting of adverse events and product quality issues must be encouraged. Voluntary reporting will provide information for FDA to analyze to determine with the manufacturer the correct course of action.

1004

POSTMARKETING COMPARATIVE CLINICAL AND PHARMACOECONOMIC STUDIES

Source: Council on Public Policy

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

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

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

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

This policy supersedes ASHP policy 0513.

Rationale

Pharmacists, other members of the health care team, patients, and private and public payers need objective, authoritative, reliable evidence in order to make the best treatment decisions. Since the passage of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, the Agency for Healthcare Research and Quality (AHRQ) has been tasked with studying the outcomes, comparative clinical effectiveness, and appropriateness of health care items and services. For such research to contribute to the practice of evidence-based patient care, good clinical decision-making, and rational drug use, AHRQ must evaluate devices, invasive procedures, and prescription and nonprescription medications, including both labeled and

unlabeled uses of prescription drugs. Since prescription drugs represent a significant and growing portion of health care costs, the need for such research is increasingly important. Although impartial private sector entities can supplement the research efforts of government agencies such as AHRQ, only the federal government has the ability to support such independent research, provide oversight to safeguard the integrity of the research process, and disseminate the findings.

1007

REGULATION OF HOME MEDICAL EQUIPMENT MEDICATION PRODUCTS AND DEVICES

Source: Council on Public Policy

To advocate for consistent regulatory oversight of all home medical equipment, with the goals of continuity of care, patient safety, and appropriate pharmacist involvement whenever equipment is used for medication administration; further,

To monitor the impact of the Centers for Medicare & Medicaid Services quality standards on the accreditation of suppliers of medication-related durable medical equipment and supplies.

Rationale

Federal and state regulation of home medical equipment (HME) and durable medical equipment (DME) suppliers creates a gap in pharmacist review and input in medication-related aspects of the services these suppliers provide to patients, particularly when a patient is discharged from the hospital to the home. The Centers for Medicare & Medicaid Services (CMS) provides conditions of participation for home health services, and states may regulate HME and DME suppliers, home health agencies, and suppliers of medical gases. Furthermore, CMS has proposed surety bond requirements for pharmacies that are also DME suppliers. The Council recommended and the Board and House agreed that ASHP should advocate for consistent regulatory oversight of these medication-related aspects so that this medication-use process ensures patient safety, improves continuity of care, and guarantees appropriate pharmacist involvement.

1009

PRESERVATION OF ANTIMICROBIALS FOR MEDICAL TREATMENT

Source: Council on Therapeutics

To advocate that the Food and Drug Administration (FDA) eliminate future approval of antimicrobials for nontherapeutic uses in agricultural animals that represent a safety risk by contributing to antibiotic resistance; further,

To encourage efforts to phase out and eliminate the nontherapeutic uses of antimicrobials previously approved by the FDA; further,

To support the therapeutic use of antimicrobials in animals only under the supervision of a veterinarian; further,

To encourage the FDA, Centers for Disease Control and Prevention, and other stakeholders to monitor and limit, when effective alternatives are available, the therapeutic use of antimicrobials that are essential to the treatment of critically ill human patients; further,

To advocate for the inclusion of pharmacists in antimicrobial surveillance and related public health efforts based on pharmacists' knowledge of antimicrobial drug products and antimicrobial resistance.

Rationale

ASHP supports the public health approach to antimicrobial use in agricultural animals outlined in the July 2009 Food and Drug Administration (FDA) testimony to Congress. The goal of this approach is to minimize the development of antimicrobial resistance, preserving the effectiveness of antimicrobial therapies that are critical in human medicine. According to the FDA, an enhanced action plan would seek to phase out the use of antimicrobials for nontherapeutic purposes (e.g., animal growth promotion, food efficiency) by eliminating future approvals for new nontherapeutic indications. ASHP also supports the FDA's request for increased statutory authority that would facilitate removal of previously approved nontherapeutic uses of antimicrobials. This two-pronged approach is critical to preserving the effectiveness of existing antimicrobials as well as those in development. ASHP opposes nontherapeutic uses but supports animal use of antimicrobials for therapeutic purposes (e.g., treatment of disease or prevention of disease in animals within a population that has documented disease) when this use occurs under the supervision of a veterinarian. In addition, ASHP advocates that FDA approval and subsequent use of antimicrobials should take into consideration the public health impact of the drugs' use. Pharmacists' knowledge of antimicrobial drugs and antimicrobial resistance will be critical to these efforts, including the identification of antibiotic classes for which animal treatment use should be minimized in order to retain the effectiveness of these drugs for the treatment of critically ill human patients.

1011

USE OF SURROGATE ENDPOINTS FOR FDA APPROVAL OF DRUG USES

Source: Council on Therapeutics

To support the continued use of qualified surrogate endpoints by the Food and Drug Administration (FDA) as a mechanism to evaluate the effectiveness and safety of new drugs and new indications for existing therapies, when measurement of definitive clinical outcomes is not feasible; further,

To support efforts by the FDA and other stakeholders to qualify surrogate endpoints; further,

To advocate that the FDA consistently enforce existing requirements that drug product manufacturers complete postmarketing studies for drugs approved based on qualified surrogate endpoints in order to confirm that the expected improvement in outcomes occurs, and to require that these studies be completed in a timely manner.

Rationale

ASHP supports the use of surrogate endpoints, when appropriate, for approval of new drugs or new indications for existing therapies because the use of surrogate endpoints can shorten the time to availability for life-saving therapies, including those used to treat human immunodeficiency virus (HIV) infection and acquired immunodeficiency syndrome (AIDS). To support this goal, ASHP encourages the FDA and other stakeholders to collaborate to qualify surrogate measures that could be used in clinical studies, because such qualification would standardize and improve the applicability of surrogate endpoints. In addition, ASHP encourages the FDA to utilize its current authority to require postmarketing studies for drugs approved using surrogate endpoints to ensure that these drugs demonstrate the effectiveness and safety anticipated when the drugs were approved.

0909

REGULATION OF INTERSTATE PHARMACY PRACTICE

Source: Council on Public Policy

To advocate that state governments, including legislatures and boards of pharmacy, adopt laws and regulations that harmonize the practice of pharmacy across state lines in order to provide a consistent, transparent, safe, and accountable framework for pharmacy practice.

Rationale

With the emergence of new technology, state borders are becoming more artificial and coordination between states is increasingly needed. To achieve the highest level of patient safety possible, state regulatory bodies need to work closely together to provide a consistent and transparent regulatory framework for pharmacy practice. Dialogue between the National Association of Boards of Pharmacy and individual state boards can help harmonize the practice of pharmacy across state lines by producing model language that can be adopted by individual states.