

Marketing

Promotion of Off-Label Uses (1620)

Source: Council on Public Policy

To advocate for authority for the Food and Drug Administration (FDA) to regulate the promotion and dissemination of information about off-label uses of medications and medication-containing devices by manufacturers and their representatives; further,

To advocate that such off-label promotion and marketing be limited to the FDA-regulated dissemination of unbiased, truthful, and scientifically accurate information based on peer-reviewed literature not included in the New Drug Approval process.

This policy supersedes ASHP policy 1120.

Ban on Direct-to-Consumer Advertising for Prescription Drugs and Medication-Containing Devices (1624)

Source: Council on Public Policy

To advocate that Congress ban direct-to-consumer advertising for prescription drugs and medication-containing devices.

This policy supersedes ASHP policy 1119.

Identification of Prescription Drug Coverage and Eligibility for Patient Assistance Programs (1521)

Source: Council on Pharmacy Management

To advocate that pharmacists or pharmacy technicians ensure that the use of patient assistance programs is optimized and documented to promote continuity of care and patient access to needed medications; further,

To advocate that patient assistance programs should incorporate the pharmacist–patient relationship, including evaluation by a pharmacist as part of comprehensive medication management; further,

To support the principle that medications provided through manufacturer patient assistance programs should be stored, packaged, labeled, dispensed, and recorded using systems that ensure the same level of safety as prescription-based programs that incorporate a pharmacist–patient relationship.

This policy supersedes ASHP policy 0603.

Manufacturer-Sponsored Patient Assistance Programs (1420)

Source: Council on Pharmacy Management

To encourage pharmaceutical manufacturers to extend their patient assistance programs (PAPs) to serve the needs of both uninsured and underinsured patients; further,

To advocate that pharmaceutical manufacturers and PAP administrators enhance access to and availability of such programs by standardizing application criteria, processes, and forms, and by automating PAP application processes through computerized programs, including Web-based models; further,

To advocate expansion of PAPs to include high-cost drugs used in inpatient settings; further,

To encourage pharmacists and pharmaceutical manufacturers to work cooperatively to ensure that essential elements of pharmacist patient care are included in these programs.

This policy supersedes ASHP policies 0404 and 9703.

Pharmaceutical Distribution Systems (1016)

Source: Council on Pharmacy Management

To support wholesaler/distribution business models that meet the requirements of hospitals and health systems with respect to timely delivery of products, minimizing short-term outages and long-term product shortages, managing and responding to product recalls, fostering product-handling and transaction efficiency, preserving the integrity of products as they move through the supply chain, and maintaining affordable service costs.

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

Restricted Drug Distribution (0714)

Source: Council on Public Policy

To affirm support for the current system of drug distribution in which prescribers and pharmacists exercise their professional responsibilities on behalf of patients; further,

To acknowledge that there may be limited circumstances in which constraints on the traditional drug distribution system may be appropriate if the following principles are met: (1) the requirements do not interfere with the continuity of care for the patient; (2) the requirements preserve the pharmacist–patient relationship; (3) the requirements are based on scientific evidence fully disclosed and evaluated by prescribers, pharmacists, and others; (4) there is scientific consensus that the requirements are necessary and represent the least restrictive means to achieve safe and effective patient care; (5) the costs of the product and any associated product or services are identified for purposes of reimbursement, mechanisms are provided to compensate providers for special services, and duplicative costs are avoided; (6) all requirements are stated in functional, objective terms so that any provider who meets the criteria may participate in the care of patients; and (7) the requirements do not interfere with the professional practice of pharmacists, prescribers, and others; further,

To advocate that the Food and Drug Administration (FDA) be granted the authority to consult with practicing pharmacists and others when the establishment of a restricted distribution system is contemplated for a drug product; further,

To advocate that FDA be granted the authority to require that manufacturers disclose all of the considerations that led to the establishment of a restricted distribution system for a specific product; further,

To advocate that FDA be granted the authority to require that manufacturers include in each restricted distribution system a mechanism that will ensure medication reconciliation and continuity of care as patients transition from one level or site of care to another; further,

To advocate that FDA be granted the authority to require manufacturers to conduct a follow-up assessment of the impact of a restricted drug distribution system.

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.

Drug Samples (9702)

Source: Council on Legal and Public Affairs

To oppose drug sampling or similar drug marketing programs that (1) do not provide the elements of pharmaceutical care, (2) result in poor drug control, allowing patients to receive improperly labeled and packaged, deteriorated, outdated, and unrecorded drugs, (3) provide access to

prescription drugs by unauthorized, untrained personnel, (4) may encourage inappropriate prescribing habits, or (5) may increase the cost of treatment for all patients.

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.

ASHP Policy Positions 2009–2016 (with Rationales)

Pharmaceutical Industry: Marketing

1620

Promotion of Off-Label Uses

Source: Council on Public Policy

To advocate for authority for the Food and Drug Administration (FDA) to regulate the promotion and dissemination of information about off-label uses of medications and medication-containing devices by manufacturers and their representatives; further,

To advocate that such off-label promotion and marketing be limited to the FDA-regulated dissemination of unbiased, truthful, and scientifically accurate information based on peer-reviewed literature not included in the New Drug Approval process.

This policy supersedes ASHP policy 1120.

Rationale

Congress is considering significant changes in the way drugs are developed, approved, and marketed in the United States. A provision in the House-passed 21st Century Cures bill (H.R. 6) would allow pharmaceutical manufacturers to promote off-label uses of their products to clinicians. This change has raised concerns about the accuracy and sources of such information. Sources of such information, if unreliable, could put patient safety at risk. Despite these concerns about promotion of off-label uses by manufacturers, ASHP has suggested an amendment that would require Food and Drug Administration (FDA) oversight of such promotion and require promotional materials to be unbiased, truthful, scientifically accurate, and based upon peer-reviewed literature not included in the approved labeling of the drug. Materials would therefore require approval by the proper authority (FDA), meet certain requirements, and be truthful and scientifically accurate.

1624

Ban on Direct-to-Consumer Advertising for Prescription Drugs and Medication-Containing Devices

Source: Council on Public Policy

To advocate that Congress ban direct-to-consumer advertising for prescription drugs and medication-containing devices.

This policy supersedes ASHP policy 1119.

Rationale

Direct-to-consumer advertising (DTCA) of prescription drugs and drug-containing implantable medical devices has [both positive and negative potential effects](#). The positive potential effects include broader public awareness and use of therapies, increased patient engagement in their healthcare, and better return on investment in drug and medical device research. These

potential benefits need to be weighed against the potential negative effects, however, which include higher drug and device costs, inappropriate prescribing of more costly new drugs or devices without any justifying improvement in patient outcomes, and increased adverse effects. In 2015, the American Medical Association (AMA) adopted a [policy](#) calling for a ban on DTCA of prescription drugs and implantable medical devices due to its impacts on drug prices and physician prescribing practices.

Public health researchers have characterized the U.S. experience with direct-to-consumer advertising (DTCA) of prescription drugs since 1997 as “a large and expensive uncontrolled experiment in population health, which to date shows decidedly mixed effects.”¹ Those researchers and others^{2,3,4,5} have identified major impacts of DTCA on public health, including an increase in inappropriate prescribing and adverse effects, medicalization of symptoms previously not defined as illness, and increased costs due to inappropriate prescribing.

The impact of DTCA on the prescriber-patient relationship is hard to quantify. In some surveys, physicians have indicated that they fulfilled questionable DTCA-prompted patient requests for prescriptions.¹ A Food and Drug Administration (FDA) survey the found that “many physicians felt some pressure to prescribe something” when patients mentioned a drug they learned about through DTCA.² Studies of claims data support the conclusion that DTCA led to inappropriate prescribing of COX-2 inhibitors and proton pump inhibitors, and experimental evidence suggests that DTCA could induce clinically questionable prescribing of antidepressants for adjustment disorder.¹ Although the connection cannot be proved, it has been suggested that the increasing reliance of physician payments on patient satisfaction surveys could present an economic risk to prescribers who deny patient requests. Studies show that DTCA increases prescribing volume and patient demand, and shifts prescribing.³ DTCA’s effects include overuse of prescription drugs,⁴ a shift to less appropriate prescribing,³ and switches to less cost-effective treatment.³ In addition, differential effects by patient price sensitivity have been implicated in sustained sales despite a price increase.³ Researchers have concluded that the overall effects of DTCA on physician–patient communication are unclear,¹ and that the effects of DTCA on improving the quality of care are mixed¹ or lacking in evidence.³

The educational value of DTCA has also been questioned. Consumers of DTCA recall more benefit than risk information.¹ Critics of the educational value of DTCA also note that DCTA could exacerbate health disparities due to differing levels of health literacy and lack of incentive to advertise to low-income populations.¹ Researchers have questioned whether purported improvements in adherence, based mainly on negative trials, stand up to scrutiny.³

¹ Frosch DL, Grande D, Tarn DM, et al. A decade of controversy: Balancing policy with evidence in the regulation of prescription drug advertising. *Am J Publ Health* 2010; 100: 24-32. Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2791253/> (accessed 2016 Jun 22).

² <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143562.htm>

³ Mintzes B. Advertising of prescription-only medicines to the public: Does evidence of benefit counterbalance harm? *Annu Rev Publ Health* 2012; 33: 259-77. DOI: 10.1146/annurev-publhealth-031811-124540.

⁴ Donohue JM, Cevasco M, Rosenthal MB. *N Engl J Med*. 2007; 357:673-81. DOI: 10.1056/NEJMsa070502 Available at www.nejm.org/doi/full/10.1056/NEJMsa070502 (accessed 2016 Jun 22).

⁵ Dhaval D, Henry S. Impact of direct-to-consumer advertising on pharmaceutical prices and demand. *Southern Econ J*. 2012; 79: 97–126.

ASHP recognizes that banning a constitutionally protected right to free speech, even commercial speech, must be reinforced by evidence that indicates the banned speech negatively impacts society. In the case of DCTA, those negative impacts, including intrusion on the patient-prescriber relationship and increased healthcare costs, are evident and overwhelming. Given the outsized role prescription drug products have as a cost driver to the healthcare system, the detrimental effects of DCTA, and the limited potential benefits, ASHP has concluded that a ban on DTCA of prescription drugs and drug-containing implantable medical devices is warranted.

1521

IDENTIFICATION OF PRESCRIPTION DRUG COVERAGE AND ELIGIBILITY FOR PATIENT ASSISTANCE PROGRAMS

Source: Council on Pharmacy Management

To advocate that pharmacists or pharmacy technicians ensure that the use of patient assistance programs is optimized and documented to promote continuity of care and patient access to needed medications; further,

To advocate that patient assistance programs should incorporate the pharmacist-patient relationship, including evaluation by a pharmacist as part of comprehensive medication management; further,

To support the principle that medications provided through manufacturer patient assistance programs should be stored, packaged, labeled, dispensed, and recorded using systems that ensure the same level of safety as prescription-based programs that incorporate a pharmacist-patient relationship.

This policy supersedes ASHP policy 0603.

Rationale

Ensuring patients' medication histories are accurate and continuity of medication therapies is a critical role for pharmacists to monitor and document as patients transition through the healthcare system. Additionally, pharmacists have an important role in ensuring patients have means to access their medications, both upon hospital admission and discharge. With the numerous channels patients use to obtain their medications, it has become increasingly difficult to verify this information and in some cases obtain the medications needed to care for a patient.

Patient assistance programs (PAPs) present a unique challenge for healthcare providers. Documentation of the utilization of a PAP by a patient is important information for providers accessing the patient electronic health record, and improving that documentation should be a priority for healthcare providers. Additionally, pharmacists need to provide leadership in facilitating the utilization of PAPs to ensure continuity of care, the patient's ability to access needed medications when appropriate, and a comprehensive pharmacist-patient relationship.

1420

MANUFACTURER-SPONSORED PATIENT-ASSISTANCE PROGRAMS

Source: Council on Pharmacy Management

To encourage pharmaceutical manufacturers to extend their patient assistance programs (PAPs) to serve the needs of both uninsured and underinsured patients; further,

To advocate that pharmaceutical manufacturers and PAP administrators enhance access to and availability of such programs by standardizing application criteria, processes, and forms, and by automating PAP application processes through computerized programs, including Web-based models; further,

To advocate expansion of PAPs to include high-cost drugs used in inpatient settings; further,

To encourage pharmacists and pharmaceutical manufacturers to work cooperatively to ensure that essential elements of pharmacist patient care are included in these programs.

This policy supersedes ASHP policies 0404 and 9703.

Rationale

ASHP recognizes the value of the patient assistance programs (PAPs) in improving continuity of care while controlling costs and advocates expanded use of these programs for uninsured and underinsured patients in ambulatory and inpatient care settings. Some organizations have demonstrated success in achieving the benefits of these programs through dedicated resources and a mastery of the many programs available. Simplification of these programs (similar eligibility criteria, a common data format) would reduce the resources required to participate and improve access and utilization. ASHP notes that while the number of PAPs in ambulatory care settings has increased, there has been little growth in programs for inpatients. Hospitals must then absorb the costs of patient care, which results in fewer resources in the overall health care system. ASHP believes that expansion of PAPs for high-cost drugs used for indigent inpatients would significantly offset some of the costs to hospitals and ultimately improve care. To ensure that these programs achieve their objectives, ASHP advocates that development of these programs ensure that they contain the elements of pharmacist patient care.

1016

PHARMACEUTICAL DISTRIBUTION SYSTEMS

Source: Council on Pharmacy Management

To support wholesaler/distribution business models that meet the requirements of hospitals and health systems with respect to timely delivery of products, minimizing short-term outages and long-term product shortages, managing and responding to product recalls, fostering product-handling and transaction efficiency, preserving the integrity of products as they move through the supply chain, and maintaining affordable service costs.

This policy supersedes ASHP policy 0605.

Rationale

Wholesaler distributors have traditionally contracted with hospitals and health systems for basic drug product distribution and other services. Many wholesalers have made a large portion of their revenue through speculative buying and other business practices that are no longer desirable because of requirements for pedigrees, the risk of buying counterfeit or adulterated products, demands by manufacturers to limit product transactions, and the need to manage drug recalls. These changes, plus the vast diversification of many wholesaler distributors, have resulted in new business models that will affect how hospitals acquire and manage pharmaceuticals. These changing models for distribution may result in higher costs for hospitals and health systems, as current wholesaler distribution systems have become very efficient. ASHP supports wholesaler/distribution business models that meet the requirements of hospitals and health systems.