SPRING 2014 ELECTIONS!

Please review the biographies for Chair-Elect contained in this newsletter. An email containing a hyperlink for voting will be sent by AACP.

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Kristy Brittain, PharmD, BCPS, CDE earned her Doctor of Pharmacy from Wilkes University and completed a PGY-1 Community Pharmacy Practice Residency at Campbell University and Kerr Drug, North Carolina. She joined the South Carolina College of Pharmacy (SCCP) at the Medical University of South Carolina in 2008. Currently, she is an Assistant Professor at SCCP, Clinical Pharmacy Specialist with Medical University of South Carolina Outpatient Pharmacies, and director of the SCCP PGY-1 Community Pharmacy Practice Residency program. Dr. Brittain is actively engaged in the delivery of MTM and immunizations and is a Certified Diabetes Educator with the Palmetto Pharmacist Network Diabetes Management Program. Kristy also serves as trainer for the APhA certificate training programs in immunizations, diabetes and MTM. In the classroom, Kristy dedicates herself to the self-care therapeutics course at SCCP and various electives aimed at improving the student pharmacist’s experiences in community practice.

Kristy is an active member of AACP and has served on the Pharmacy Practice Section Nominating Committee and the Self-Care Therapeutics/Nonprescription Medicines Special Interest Group (SIG) programming committee. She is also a member of APhA having served on numerous committees and the JAPhA Editorial Advisory Board. Kristy currently serves on the South Carolina Pharmacy Associations’ (SCPhA) Board of Directors since 2009 and has been involved in the creation of the Junior Board Member Program targeted at student pharmacists interested in a future in leadership. She is an active member of SCPhA, Kappa Psi, and Phi Lambda Sigma serving on numerous committees and task forces. Her most passionate position is serving as the SCCP APhA-ASP Chapter Advisor since 2008.
Dr. Karen Steinmetz Pater is an Assistant Professor at the University of Pittsburgh School of Pharmacy. She has served as the course coordinator and the primary lecturer for the required self-care course at the University of Pittsburgh since 2007, and she mentors students every semester in an elective Special Topics course that is an expansion of the required course. She has been involved in educating students on self-care and non-prescription drug therapy for the past thirteen years. Dr. Pater has clinical responsibilities at two sites – the UPMC Diabetes and Endocrinology clinic and the UPMC Matilda Theiss Family Health Center, where she is involved in disease statement of diabetes and other associated chronic conditions.

Dr. Pater has been an invited lecturer or platform presenter to the APhA Self-Care Institute and the Nonprescription Medicines Academy (NMA) in recent years, and is currently filling a term as a member of the Steering Committee of NMA (2013-2016). Her speaking engagements revolve around discussing her work in the classroom related to innovative teaching strategies in the realm of self-care including Team Based Learning and active learning through interactions with Standardized Patients. Dr. Pater has also served as a chapter reviewer for the APhA Handbook of Nonprescription Drugs over the last ten years.

Dr. Pater is involved in the local and state Pharmacist Association, and currently is completing a term as President of the Allegheny County Pharmacist Association. She has received student recognition in the recent past as Faculty Member of the Year (2011), Innovation in Teaching Award (2012), Teacher of the Year (2013), and Preceptor of the Year (2013). She is active with the student body at the University, serving as a mentor for students competing in the annual Pennsylvania Pharmacists Association NASPA/NMA Self-Care Championship.
In March 2012 the FDA sought testimony at a two-day public meeting in Maryland with respect to creating a new class of over-the-counter (OTC) drugs that would be available to consumers only with “conditions of safe use.” Because of divergent view points from different professional groups the FDA did not take action. This prompted a pharmacist leader in Washington, in collaboration with the Washington State Pharmacy Association (WSPA) and the pharmacy schools in Washington, to move forward with a model of care where a pharmacist would manage minor ailments by assessing patients and prescribing legend medications when appropriate. Twenty-five self-care collaborative practice protocols were developed and filed with the board of pharmacy by Beverly Schaefer with Katterman’s Pharmacy. These materials have been incorporated into a comprehensive training program that will be available from the WSPA in July 2013. Educational methods/activities to train student pharmacists at Washington State University and the University of Washington are currently under development.

It is the opinion of these authors that this model of care is an important step forward as pharmacists seek recognition as health care providers. Pharmacists are successfully managing minor ailments and prescribing a limited number of legend medications suitable for safe use under protocol. The expansion of this pharmacist-delivered care can increase access to health care and free physician time for more severe illness.
The “Self-Care Family”: Creating an advanced self-care elective around the care of a 3 generational family
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The Advanced Self-Care Elective is an elective offered to third year students. It is designed to build competency in self-care knowledge across the spectrum of patient populations. The “self-care family” is a fictional family composed of patients that range from 0.75 to 70 years of age. In addition to the variation in age, each family member has one or more chronic conditions commonly found in the American population. This allows students to assess the impact of co morbidities on self-care recommendations for every class and each self-care condition discussed. The class is organized by themes, rather than simply disease states, to promote multiple disease state evaluation and discussion. For example, the “Thanksgiving” theme class was designed to discuss several GI disorders: Heartburn, dyspepsia and diarrhea. The “Family Vacation” class reintroduced these disease states but added constipation and motion sickness. The goals of the “self-care family” and themed classes were to provide common scenarios that self-care treatment is often sought, but in the setting of multiple ages and diseases states.

CAM: An Interactive approach in Pharmacy Education
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melissa.mattison@wne.edu

Complementary and alternative medicine (CAM) offerings vary widely amongst pharmacy schools. The educational need however is great as Western Medicine finally meets Eastern Medicine and many of our patients utilize traditional and nontraditional therapies. The purpose of the CAM session was to provide an interactive class experience and expose the learners to different modalities that they might otherwise not be familiar with or have experienced. A hands-on active learning session was then planned in which practitioners were brought in to deliver mini sessions of their specialty to small groups of learners (6-7) in 15 minute increments. Learners had the experience of participating in each of five sessions that included yoga, progressive muscle relaxation, Reiki, Tai Chi, and massage therapy. Active learning via participation in an intensive interactive CAM session was both an opportunity to increase students’ knowledge of CAM and an effective strategy for providing the learner with the experience to enable the recommendation of CAM to future patients.
An EBSCR (Evidence-Based Self-Care Research) Project to Improve Student Literature Evaluation and Therapeutic Application Skills

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The presentation discussed the use of an evidence-based self-care research (EBSCR) project in an Advanced Patient Self-Care Elective to enhance student literature evaluation and therapeutic application skills at the University of Waterloo School of Pharmacy. This project's goal is to enhance pharmacy students' learning focused on the critical appraisal process and ability to apply drug literature to the optimal selection of nonprescription drugs used for minor ailments. In this course students will work in groups to learn about a published critical appraisal tool and then use the tool to assess the value of nonprescription drug literature within a specific minor ailment. The final product is a web-based treatment algorithm that depicts their critically appraised findings in order to sequentially guide clinicians through the various nonprescription drug and nondrug therapeutic options for a specified medical condition.

The study of this innovative teaching approach (using EBSCR) aims to assess the effectiveness of teaching and learning using this nonprescription drug evidence-based medicine project (EBSCR) and to provide insight on how to improve the deep learning interaction between students and research literature. Qualitative data will be collected using pre and post Likert-scale student surveys. Conclusions will provide insight into deep learning outcomes delivered by this elective as a function of EBSCR as well as future guidance in further developing this innovative teaching approach.
As the market of home monitoring devices continues to grow, so does the responsibility for pharmacists to be knowledgeable of the important counseling points for these products. Pharmacists must educate patients on the proper selection, instructions for testing, interpretation of the results, and follow-up for medical care if needed. Each device is unique making it even more vital for student pharmacists to thoroughly learn these products in an active, hands-on, environment.

At the University of Rhode Island and North Dakota State University, commercially-available devices were purchased to allow professional pharmacy students hands-on exploration of each device. Examples of products included an HIV home screening kit, stool colorectal blood test, pregnancy and fertility devices, CardioChek, a home drug screening kit, Ketostix, AZO test strips, home A1C monitor, and a hepatitis C home test.

Learning activities were designed to expose student pharmacists to home testing and monitoring devices in order to increase student confidence and proficiency in discussing how to use these products and how to interpret results. Activities included “guess the retail price,” detailed patient cases, active learning vignettes via video recording, patient consultations, guided worksheets, and peer-teach-peer product presentations.

As the public interest in home and ambulatory care testing increases, pharmacists are becoming increasingly involved in the administration and interpretation of such tests. In particular, the OraQuick® In-Home HIV test, approved by the FDA in July 2012, was the focus of a recent Centers for Disease Control (CDC) pilot involving pharmacists administering the test for patients in the community pharmacy setting. The CDC hoped this pharmacy-based testing would become as routine as blood pressure checks or immunizations and ultimately improve the access to HIV testing in the inner-city and rural areas most affected by the virus.
Key points for the OraQuick® In-Home HIV test include:

• Test should be performed at least 3 months after potential exposure to allow sufficient antibody response

• Do not eat, drink, brush teeth or use any oral care products less than 30 minutes before performing test

• Use the absorbent pad to swab the outer surface of the gums, both top and bottom, thoroughly from one side of the mouth to the other

• Place the pad in the vial of test solution

• Results will occur in 20-40 minutes. Do not read the results after 40 minutes, as this may cause a false positive

• Two purple lines = positive for HIV-1 antibodies

• One purple control line = negative for HIV-1 antibodies

• If the test is positive, it must be confirmed by a second test performed by a healthcare provider. Patients must seek medical care and avoid activities potentially exposing others to the virus

In summary, it is important for professional pharmacy students to gain comprehensive education on home testing and monitoring devices and to explore these products in an active, hands-on, environment in preparation for their role as tomorrow’s pharmacists.

Information for this article garnered from the following reference(s):


New OTC Product: Nasacort Allergy 24HR

Eileen Langstraat, Pharm.D. Candidate and Sarah Parnapy Jawaid, Pharm.D. Bernard J. Dunn School of Pharmacy, Shenandoah University, Winchester, VA

Allergic rhinitis is the most common form of rhinitis and is estimated to affect 30 to 60 million people in the United States every year, including 10-30% of adults and up to 40% of children. It is an immune-mediated disease characterized by the presence of one or more of the following symptoms: nasal congestion, pruritis, rhinorrhea, and sneezing. Other symptoms commonly associated with this type of rhinitis include “allergic shiners,” an “allergic crease” on the nose secondary to the “allergic salute,” and mouth breathing also known as the “allergic gape.” Symptoms of allergic rhinitis occur in response to exposure to indoor or outdoor allergens such as animal dander, dust mites, insects, molds, or pollens. Including both direct and indirect costs it is estimated that allergic rhinitis cost anywhere from $2 to $5 billion in the United States annually.

Allergic rhinitis is not curable, treatment goals focus on reducing symptoms and improving quality of life. In general there is a three-step approach to treating allergic rhinitis – allergen avoidance, pharmacotherapy, and immunotherapy. Each of these steps should be maximized before moving on to the next step. Avoidance of allergen triggers is the primary non-pharmacologic method of preventing rhinitis symptoms, but is not usually able to completely alleviate symptoms. Because of this, pharmacotherapy with a single agent is often combined with allergen avoidance. If this does not provide sufficient symptom relief then combination therapy using drugs with different mechanisms of action can be used. In more severe cases immunotherapy should be considered.
Several different medication classes are available for the treatment of allergic rhinitis. Medication options include: oral and intranasal antihistamines, oral and topical decongestants, over-the-counter (OTC) cough and cold medications, oral and intranasal corticosteroids, intranasal cromolyn, intranasal anticholinergics, leukotriene receptor antagonists, omalizumab, and saline. Of these options, intranasal corticosteroids are the most effective medication class for treatment of allergic rhinitis. Several comparison studies have shown intranasal corticosteroids to have superior efficacy compared to combination therapy with an antihistamine plus leukotriene receptor antagonist. Intranasal corticosteroids relieve symptoms mainly via their anti-inflammatory activity and adverse effects associated with this medication class are minimized because administration is localized to the intranasal area. These agents are considered to be first-line treatment as monotherapy, and can also be used in combination with another medication type. On average, the onset of action is 30 minutes, with peak effects occurring in several hours to days and maximal effect seen after two to four weeks of medication use. Until recently, all intranasal corticosteroids were available by prescription only. Nasacort (triamcinolone acetonide) is the first OTC intranasal corticosteroid available.

The Food and Drug Administration approved Nasacort Allergy 24HR (triamcinolone acetonide) for OTC sales on October 11, 2013. Manufactured by Sanofi, it is indicated to treat symptoms of allergic rhinitis in adults and children two years of age and older. The OTC product is available in two different sized metered dose nasal spray bottles containing either 60 or 120 sprays; each will be 55mcg per spray and dosages are the same as those for the prescription product. Nasacort Allergy 24HR is available in stores now and the manufacturer is planning on discontinuing the prescription product Nasacort AQ completely.
Patients need to be educated on the proper use of Nasacort Allergy 24HR. Prior to administration, priming is required with the first dose or if not used in 2 weeks or more; clean the spray bottle and discarded after their total number of doses (either 60 or 120 doses, depending on product size) have been exhausted, even if the bottle does not feel empty.\textsuperscript{9,12} Dosing is dependent upon age of the patient\textsuperscript{12}:

<table>
<thead>
<tr>
<th>Patient Age</th>
<th>Dosing</th>
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</table>
| Children ≥ 12 years old & Adults | • Spray 2 times into each nostril once daily, gently sniffing  \   
|                              | • Reduce to 1 spray in each nostril per day once allergy symptoms improve | |
| Children 6 – 11 years old*    | • Spray once into each nostril once daily, gently sniffing  \   
|                              | • If allergy symptoms do not improve, increase to 2 sprays once daily then reduce to 1 spray in each nostril per day once allergy symptoms improve | |
| Children 2 – 6 years old*     | • Spray once into each nostril once daily, gently sniffing | |
| Children < 2 years old        | • Do not use in this population | |

*An adult should supervise use. Due to concerns regarding reduced growth rate in children, use for more than 2 months out of the year should be only in consult with child’s healthcare provider.

Although Nasacort is well tolerated overall, the most common adverse effects include nasal discomfort, epistaxis, and sneezing.\textsuperscript{12} Other more serious side effects with this medication include increased risk of infection, vision changes, glaucoma, cataracts, and growth inhibition in children.\textsuperscript{9,12} Some controversy surrounded the approval within this drug class. Though inhaled corticosteroids have been linked to potential slowing of growth rate in children, this is dependent upon dose and length of exposure. Warnings regarding this concern are included twice within the Drug Facts labeling, prompted by those on the FDA Nonprescription Drug Advisory Committee and outside medical experts. In addition, any child < 12 years old that will need the medication for more than 2 months should be referred to the supervision of their healthcare provider.\textsuperscript{13,14} Nasacort Allergy 24HR is contraindicated for patients with hypersensitivity to triamcinolone or any other formulation component.\textsuperscript{12}
Although Nasacort is well tolerated overall, the most common adverse effects include nasal discomfort, epistaxis, and sneezing.\textsuperscript{12} Other more serious side effects with this medication include increased risk of infection, vision changes, glaucoma, cataracts, and growth inhibition in children.\textsuperscript{9,12} Some controversy surrounded the approval within this drug class. Though inhaled corticosteroids have been linked to potential slowing of growth rate in children, this is dependent upon dose and length of exposure. Warnings regarding this concern are included twice within the Drug Facts labeling, prompted by those on the FDA Nonprescription Drug Advisory Committee and outside medical experts. In addition, any child < 12 years old that will need the medication for more than 2 months should be referred to the supervision of their healthcare provider.\textsuperscript{13,14} Nasacort Allergy 24HR is contraindicated for patients with hypersensitivity to triamcinolone or any other formulation component.\textsuperscript{12}

With the move from prescription to OTC, pharmacists must be prepared to determine if this medication is appropriate for patients on an individual basis. Patients need to be education regarding symptoms of allergic rhinitis, including severity and frequency of these symptoms. Pharmacists are also instrumental in helping a patient select the best product for them, once the need for treatment has been established. Nasacort is the only OTC medication in the class proven to be most effective for treatment of allergic rhinitis. However cost, comorbidities, and patient formulation preference also need to be taken into account when deciding which OTC medication is best for your patient. Once a patient has been deemed an appropriate candidate for Nasacort Allergy 24HR, pharmacists should provide the proper patient education on its use.

The switch from prescription to OTC increases patient accessibility. With it comes a likely jump in sales, as both patients and providers prefer OTC treatment first line.\textsuperscript{15,16} Historically, increased access to a medication due to a Rx-to-OTC switch results in decreased healthcare costs due to a reduction in doctors visits for the condition which can now be self-treated.\textsuperscript{15,16}

References:


15 Spangler DC. FDA nonprescription drugs advisory committee meeting re: Nasacort AQ sNDA. Powerpoint presented at CHPA Advisory Committee Meeting: 31 July 2013.

Overactive bladder (OAB) results from the involuntary contraction of the bladder muscle which results in accidental leaks and the frequent feeling of the urge to go to the bathroom.\(^1\) OAB should be initially treated with behavioral and lifestyle modifications. Behavioral modifications include Kegel exercises (tightening and relaxing certain pelvic muscles), bladder training (schedule bathroom visits regardless of the urge to go) and bladder control strategies (gradually increasing the time between urination). Additional lifestyle modifications can also be recommended and include reducing caffeine and alcohol intake, fluid management and limiting the intake of carbonated beverages, artificial sweeteners and irritants (tomatoes, citrus, spicy foods, etc.). If behavioral and lifestyle modifications alone are not enough to manage OAB, it is appropriate to consider drug therapy.\(^2\)

Oxytrol for Women\(^®\) is a transdermal system or patch containing oxybutynin, and is the OTC branded and marketed equivalent of prescription Oxytrol patch. Oxybutynin is a muscarinic antagonist indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency and frequency. Oxybutynin acts as a competitive antagonist of acetylcholine at postganglionic muscarinic receptors, resulting in relaxation of bladder smooth muscle, and a decrease in urinary urgency and frequency of both incontinence episodes and voluntary urination.\(^3\) In patients with conditions characterized by involuntary detrusor contractions, oxybutynin increases maximum urinary bladder capacity and increases the volume to first detrusor contraction.
The safety and efficacy of oxybutynin patch versus placebo in adults with urge and mixed urinary incontinence was investigated using combined results from double-blind stages of 2 phase 3 clinical trials. Efficacy analysis included 241 patients receiving oxybutynin patch and 244 receiving placebo. Most participants were Caucasian women (92%), with approximately 60% having received prior anticholinergic therapy. Primary outcome was determined by changes from baseline to end of treatment in frequency of incontinence episodes, frequency of urination, and void volume. Oxybutynin patch was significantly more effective than placebo in reducing median daily incontinence episodes (−3.0 vs placebo −2.0; P=.00004) and daily urinary frequency (−2.0 vs −1.0; P=.0023), and in increasing void volume (25 mL vs 5.5 mL; P<.00001).

Transdermal administration of oxybutynin may be preferred over the oral dosage forms as it bypasses the first-pass gastrointestinal and hepatic metabolism, reducing the formation of the active N-desethyl metabolite and thus reducing anticholinergic side effects such as dry mouth and constipation. For example, dry mouth is 7% with the transdermal dosage compared to 40% with the extended-release and 65-70% with the immediate-release oral dosage forms. In clinical trials, overall rates of anticholinergic adverse events (AEs) were 12.8% for oxybutynin patch and 11.0% for placebo (P=0.5421). The most common systemic anticholinergic side effects were dry mouth (7.0% for oxybutynin-TDS vs 5.3% for placebo) and constipation (2.1% vs 2.0%).

Application site erythema occurred in 7.0% of participants who received oxybutynin-TDS (3.7% discontinuation rate); pruritus occurred in 16.1% (3.3% discontinuation rate). Concomitant use of oxybutynin patch with other anticholinergic drugs or with other agents that produce dry mouth, constipation, somnolence, and/or other anticholinergic-like effects may increase the frequency and/or severity of such effects.
Oxybutynin is contraindicated in patients with or who are at risk for urinary retention, gastric retention, or uncontrolled narrow-angle glaucoma and in patients who have demonstrated hypersensitivity to oxybutynin. Oxybutynin should be used with caution in patients who have hepatic or renal impairment, clinically significant bladder outflow obstruction or with gastrointestinal obstructive disorders because of the risk of urinary or gastric retention, gastroesophageal reflux and/or those who are concurrently taking drugs (such as bisphosphonates) that can cause or exacerbate esophagitis and in patients who have ulcerative colitis, intestinal atony, or myasthenia gravis because oxybutynin may decrease gastrointestinal motility. Angioedema requiring hospitalization and emergency medical treatment has occurred with the first or subsequent doses of oral oxybutynin. In the event of angioedema, oxybutynin-containing products should be discontinued and appropriate therapy promptly provided.  

When deciding if Oxytrol for Women® should be used, first evaluate if the patient has tried behavioral and lifestyle modifications. If the patient has not tried to manage symptoms with behavioral and lifestyle modifications, recommend those modalities prior to considering drug therapy. If behavioral and lifestyle modifications fail or inadequately control symptoms, Oxytrol for Women® could be considered for women who have at least two of the following symptoms for three months: urinating eight or more times per day, urgent need to urinate, and/or inability to control the urge to go. When recommending Oxytrol for Women®, the patient should be educated to apply one patch (3.9mg/day) to dry, intact skin on the abdomen, hip, or buttock every 3 to 4 days (or twice weekly). A new application site should be selected with each new system to avoid re-application to the same site within 7 days. Patient should also be counseled on possible anti-cholinergic side effects, local application site reactions and to monitor for fever and heat stroke due to decreased sweating in a hot environment. Although unlikely, should symptoms consistent with angioedema occur, patients should discontinue immediately and seek medical attention. Patients should also be educated that long-term use of Oxytrol for Women® is not recommended and a to see a provider if their symptoms last more than two weeks, as there may be an underlying condition causing urinary frequency and urgency that requires a formal evaluation.
Oxytrol for Women® adds access to a proven treatment option associated with improved daily life for women who properly self-manage their over-active bladder. At about $4 a patch, it has the potential to be a cost-saving alternative compared to prescription Oxytrol patch. The transdermal formulation of oxybutynin has a safe drug-drug and drug-food interaction profile, is better tolerated when compared to the oral prescription dosage forms and can be safely used as a self-treatment option for the recommended time of two weeks.

References:


Pseudoephedrine Update
Patricia Fabel, PharmD, BCPS, South Carolina College of Pharmacy
Catherine Cone, PharmD, BCPS, College of Pharmacy, University of New Mexico

Introduction/Background
In 1885 a Japanese chemist, Nagayoshi Nagai, discovered “pseudoephedrine”. Originally derived from plants belonging to the family of Ephedraceae Ephedra, pseudoephedrine is now synthetically derived. The Ephedra family of plants continues to be marketed and sold in the other countries as a “natural” product often referred to as Ma Huang. Ephedra is used as a decongestant, for weight loss, and for its athletic performance enhancing effects. It was banned by the US Federal government in 2004. The name ephedra was felt to be too similar to ephedrine, and thus when marketed in the United States (US), the name was changed to pseudoephedrine to prevent confusion.

Pseudoephedrine is utilized in the US to treat nasal congestion and Eustachian tube dysfunction. It became more widely used after phenylpropanolamine and most ephedrine products were taken off the market. At this time, pseudoephedrine and phenylephrine are essentially the only available decongestants on the market for purchase either behind the counter (in the case of pseudoephedrine) or over the counter (in the case of phenylephrine). Although phenylephrine was approved by the FDA in 1978 as safe and effective\(^1\), its effectiveness has recently been questioned.\(^2\) It is thought that phenylephrine was marketed by drug manufacturing companies, not because of its effectiveness but to avoid the inconvenience and perhaps loss of revenue that the behind the counter status of pseudoephedrine would cause.\(^2\)

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
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<tbody>
<tr>
<td>1976</td>
<td>Phenylpropanolamine, pseudoephedrine, phenylephrine safe and effective by FDA</td>
</tr>
<tr>
<td>2000</td>
<td>Phenylpropanolamine pulled secondary to hemorrhagic strokes</td>
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<tr>
<td>2004</td>
<td>Ephedra banned in the US</td>
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<tr>
<td>2005</td>
<td>Combat Methamphetatmine Act passed</td>
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<tr>
<td>2006</td>
<td>Pseudoephedrine given behind the counter status</td>
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<tr>
<td>2007</td>
<td>Phenylephrine 10mg marketed over the counter</td>
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Table 1: Timeline – Oral Decongestants in the United States
Mechanism of Action

Pseudoephedrine is a sympathomimetic amine and a diastereomer of ephedrine structurally similar to methamphetamine. Pseudoephedrine’s mechanism of action is on the adrenergic receptor. Through an indirect mechanism, it causes release of norepinephrine from the presynaptic neurons, thus displacing noradrenaline, which is then released into the synaptic cleft. Noradrenaline then activates the postsynaptic adrenergic receptors eventually causing vasoconstriction of the blood vessels. This vasoconstriction lessens mucous production.

Efficacy and Effectiveness

The FDA through the 1976 monograph declared pseudoephedrine, phenylephrine, and phenylpropanolamine to be safe and effective. These medications were grandfathered into the current system as they had been available prior to changes in how efficacy and effectiveness were evaluated in the United States. Few studies exist on pseudoephedrine by itself, but those that do, show that it is efficacious. In comparison, phenylephrine in a randomized placebo controlled cross over study was equivalent to placebo in the relief of congestion. A metanalysis in 2007, concluded there was insufficient evidence for the effectiveness of phenylephrine. Furthermore, in a head-to-head comparison of pseudoephedrine and phenylephrine, only pseudoephedrine had significant effect on nasal congestion.

Safety

Safety is a concern for pseudoephedrine use. While it is considered safe by the FDA when used at appropriate doses in adults, the FDA now recommends that it not be marketed or used for any OTC products in children under the age of 2. Drug manufacturers responded and re-packaged all their products stating that they should not be used for any children under the age of 4. It should be noted that it is considered safe for breastfeeding by the American Academy of Pediatrics. Safety concerns for pseudoephedrine mostly relate to drug-disease state interactions including: hypertension, diabetes, coronary artery disease (coronary heart disease or ischemic heart disease), prostatic hypertrophy, and elevated intraocular pressure. Adverse effects that can be experienced include cardiovascular effects like raising blood pressure, tachycardia, palpitations or arrhythmias and central nervous system stimulation effects like insomnia, tremors, hallucinations, fears, or nervousness. In the head-to-head comparison with phenylephrine, pseudoephedrine and phenylephrine were felt to be safe and well tolerated.
Illicit and other uses
Besides the approved uses of pseudoephedrine, it has been used for more nefarious reasons including: performance enhancement in athletes, mixed with cocaine to create a “buzz” high, and used to make methamphetamine. Athletes who compete are always looking for an “edge” in competition. Pseudoephedrine has evidence that it improves performance in athletes. Hence the reason it is banned by the Olympics and in many other high level competitions. Pseudoephedrine has also been studied for weight loss, but it was shown to be ineffective, requiring doses 6-10 times the maximum recommended adult doses to increase thermogenics in humans. However, phenylpropanolamine was incorporated into many products in the 1990’s to improve weight loss. About a decade later in 2000, after studies showing phenylpropanolamine increased the risk of stroke especially in young women, it was pulled off the market. Thus, phenylpropanolamine was eliminated for weight loss and as a decongestant.

Federal and State Legislation
Over the years, pseudoephedrine has become an easy source for people to make methamphetamine (meth) illegally. In an effort to decrease the number of clandestine meth laboratory seizures, the United States federal government passed the Combat Methamphetamine Epidemic Act (CMEA) in 2005. The CMEA restricted the sales of PSE by placing limits on the amount of PSE someone can purchase as well as requiring photo identification. The number of meth lab incidents in the United States when from almost 25,000 in 2004 to less than 7,000 in 2007. Although not required by the CMEA, 19 states have implemented a state-wide electronic tracking system that stops the sale of pseudoephedrine if the person purchasing it has already met the legal limit. Seventeen states use the National Precursor Log Exchange (NPLEx) system; which keeps track of pseudoephedrine sales in all of the participating states.

Despite these efforts, the number of meth lab incidents have started to increase again – in 2010 there were over 15,000 incidents in the United States; majority (over 9,000) being in the Southeastern United States. It is believed that this increase is due to two reasons: a new Nazi/Birch method of making meth (also known as the One Pot or Shake & Bake method), and actions that allow individuals to avoid pseudoephedrine sale restrictions. Ways in which individuals avoid sale restrictions include paying another person to purchase pseudoephedrine for the individual making meth and smurfing. Smurfing is when a group of people each purchase the legally allowed maximum and combine their purchases to make large quantities of meth.
Federal and State Legislation, cont.

Since the sales restrictions mandated by CMEA and a national electronic tracking system have not completely reduced the number of meth lab incidents, several states have tried to further restrict the sale of pseudoephedrine. Oregon, Mississippi, and several local governments in Missouri require patients obtain a prescription for pseudoephedrine; Oregon and Mississippi require pseudoephedrine prescriptions to be entered into their state prescription drug monitoring program. Between 2010 and 2012, eighteen states introduced bills requiring a prescription for pseudoephedrine products. In 2013 alone, 8 states introduced legislation requiring a prescription for pseudoephedrine products; some went further and classified pseudoephedrine as a controlled substance. Table 2 lists states that submitted bills in 2013 regarding pseudoephedrine.

<table>
<thead>
<tr>
<th>Prescription-required Legislation</th>
<th>Controlled Substance Legislation</th>
</tr>
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<tbody>
<tr>
<td>Hawaii</td>
<td>South Carolina</td>
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Table 2: States Introducing Pseudoephedrine Legislation in 2013

Therapeutic Alternatives

With the increasing number of states attempting to require a prescription for pseudoephedrine products, pharmacists should become familiar with the other over-the-counter options for treating nasal congestion.

Nasal Steroids

Triamcinolone (Nasacort) is a nasal steroid and is now available over-the-counter. It is approved for the treatment of nasal allergy symptoms, which includes nasal congestion. There is evidence to suggest nasal steroids significantly reduce nasal symptoms when used every day or as needed. One randomized controlled trial demonstrated triamcinolone nasal spray prevented nasal symptoms in patients allergic to ragweed when given at least 1 week prior to high pollen levels.
**Phenylephrine**

There is very little data available comparing phenylephrine to pseudoephedrine. Since manufacturers make products with both ingredients they have not released any comparative studies. In one placebo controlled study, oral phenylephrine did not significantly improve mean nasal congestion score compared to placebo. A meta-analysis did not find sufficient evidence to recommend phenylephrine as a decongestant. Out of 11 studies evaluating phenylephrine 10 mg, only 4 showed any efficacy at relieving nasal congestion. This may be due to the bioavailability of phenylephrine. Only 38% of the orally administered PE dose reaches systemic circulation due to first-pass metabolism, this is compared to 90% of a PSE dose.

**Topical Decongestants**

Topical decongestants, like oxymetazoline (Afrin) and phenylephrine (Neo-Syneprine), are available over-the-counter. They cause local vasoconstriction and are less likely to have a systemic effect on the blood pressure. A major concern with nasally administered decongestants is rhinitis medicamentosa, or rebound congestion. When patients continue to use topical decongestants, they experience severe nasal congestion when they attempt to discontinue use. To avoid this, patients should limit use of topical decongestants to 3 to 5 days.

**Conclusion**

Phenylpropanolamine, pseudoephedrine, and phenylephrine were all considered safe and effective oral, over-the-counter treatments for nasal congestion by the FDA in 1976. However, since then phenylpropanolamine has been removed from the market due to an increased risk of stroke. Over the years, pseudoephedrine has become an easy source for people to make meth illegally. In an effort to decrease the number of meth incidents, the US federal government passed the CMEA in 2005 which restricted the sales of pseudoephedrine by placing limits on the amount of pseudoephedrine someone can purchase as well as requiring photo identification. Since 2006, several states have introduced legislation that further restricts the sale of pseudoephedrine by either requiring a prescription or classifying it as a controlled substance. Phenylephrine has limited evidence to support its use as an oral nasal decongestant. Nasal steroids are appropriate for nasal congestion due to allergic rhinitis, and topical decongestants can be used for short term relief of nasal congestion. With the potential for further restrictions on pseudoephedrine sales, health care providers should be aware of other options to treat nasal congestion over-the-counter.
References


Save the Dates

**AACP Annual Meeting and Seminars**
Gaylord Texan Resort and Convention Center, Grapevine, Texas
July 26 – July 30, 2014

**SCT/NM SIG Business Meeting**
Tuesday, July 29th
6:45 a.m. - 7:45 a.m.

**SCT/NM SIG Programming**
Combating the Dr. Oz Effect: Teaching Critical Thinking in Self-Care
Tuesday, July 29th
8:00 a.m. - 9:30 a.m.

Patients get their drug information from a variety of sources. Pharmacists need to be prepared to quickly evaluate patient requests and choose appropriate therapies. This session will provide an overview of critical thinking and describe how it can be applied to self-care and nonprescription therapeutics. Audience members will apply the skills to case scenarios.

**Speakers:** Adam M. Persky, University of North Carolina at Chapel Hill; Bella Mehta, The Ohio State University; Cydney E. McQueen, UMKC School of Pharmacy

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