



Oklahoma Society of Health-System Pharmacists

January - March 2007

Visit our website at www.oshp.net

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Mark your Calendar

OSHP Annual Meeting
St. Anthony Hospital
Oklahoma City, OK
April 13th, 2007

ACCP Spring Meeting
Memphis, TN
April 21st-25th, 2007
For information, go to www.accp.com

Oncology Preparatory Review
Scottsdale, AZ
May 2nd-5th, 2007

ASHP 2007 Summer Meeting
San Francisco, CA
June 24th-27th, 2007
For information, go to www.ashp.org

AACP Annual Meeting
Orlando, FL
July 14th-18th, 2007
For information, go to www.aacp.org

FROM THE PRESIDENT...

Jenean Young, Pharm.D.



It's hard for me to believe that another year has passed so quickly. I believe the older you get, the faster the years go by! For me, this past year, although fast, was an exceptional year for my term as OSHP president. This was a rewarding experience.

When I was inducted, I stated that I would like to see more involvement from students and recent graduates. As I come to the end of my term, I feel that this vision is becoming reality. I recently met with several student groups and am very impressed by the interest expressed. It appears we have a great group of student leaders in the ranks to be future leaders for OSHP.

Also, I was able to meet many other affiliate officers and leaders at the national level, and it is reassuring to see that Oklahoma shares the same issues that health systems are experiencing around the nation. One major difference I have noticed is that membership dues charged by OSHP are considerably lower when compared to those of other affiliate organizations. I do realize that when you are writing renewal checks for dues that you are not thinking about the surrounding states' charges, but I do hope that some of you will stop to think that the OSHP dues really are a bargain!

Lastly, I do hope that many of you will take advantage of the 2007 Annual Meeting on April 12th and 13th in Oklahoma City. The program has a varied agenda of CE credits with a few presentations from the national headquarters of ASHP. From my experiences this past year, I have learned exactly how much effort is required for planning both the Annual and Fall Meetings. It is such a tremendous amount of work and I would like to take the time to thank Nancy Brahm for coordinating both of these meetings. It took a lot of her time, volunteer time I might add, and it is most appreciated. If you happen to see her, please thank her for a job well done!

Thank you all for your involvement and for the encouragement that I received over the past year. I could not have represented you as president without all of your support.

Members: Don't forget to update your professional information with OSHP.

This includes changes in your address, e-mail, and membership status (e.g., from student to pharmacist). You can do this on our website at www.oshp.net.



Looking for ways to become more involved with OSHP?

OSHP committees will soon be reappointed for the 2007-2008 year. Committees include Newsletter, Nomination, Program, Membership, Scholarship and Awards, Legislative, and Finance. If you are interested in serving on a committee, please e-mail Susan Fugate at susan-fugate@ouhsc.edu.



ASHP Responds to ABC's 20/20 Report on Pharmacy Errors

On March 30th, 20/20 aired a report that raised several concerns about the role of pharmacy technicians, patients' waiver of counseling by a pharmacist, and the lack of a requirement for mandatory reporting of medication errors.

To read ASHP's positions on the issues raised by the 20/20 program, check out their website at www.ashp.org.



Can you guess who this little cutie is?

Hint . . . She's very active in OSHP and was a past president. Now she's running for treasurer. She has great phone etiquette skills, which clearly started early in her childhood. See page 3 for the answer.

LEGISLATIVE COMMITTEE UPDATE

Submitted by: Wiley "Butch" Williams, D.Ph., J.D.

OSHP Legislative Committee Chair and OPhA Legislative Committee Chair



In Oklahoma . . .

Because of the atypical 50-50 distribution between Republicans and Democrats in the Oklahoma Senate, the 2007 legislature has been very difficult to predict, and even more difficult to pass through any meaningful legislation, which leads me to report that not much is going to change for pharmacists on the local level. But that doesn't mean pharmacists should not be attentive. OPhA Executive Director Phil Woodard and Clayton Taylor have been very vigilant for OPhA as your lobbyists, and there are a couple of things happening at the legislature that you should know.

It is predicted that **HCR 1012** will garner enough votes for passage. This concurrent resolution creates a pharmacy benefits manager (PBM) task force that will be created and established until February 2008. The task force will study and make recommendations regarding the need for state regulations of the contractual relationships between PBMs and public and private entities. This is, of course, a compromise. PBMs want the legislature to stay out of their business, and local pharmacists want to level the playing field because it is perceived that major drug chains get better contracts with the PBMs. It will be interesting to see if the task force issues a meaningful report.

There were several bills introduced at the state level concerning over-the-counter sales of dextromethorphan (DMX). **HB 1794** is the most likely bill to make it to the Governor's desk. This bill was introduced by Rep. Don Armes (R) of Faxon and Sen. Ron Justice (R) of Chickasha. The legislation was introduced in response to a growing number of reports of school-aged children buying DMX products over the counter, abusing them, and dying from overdosing. The initial version attempted to treat DMX the same as pseudoephedrine and its related compounds. Just what pharmacy needed, another product to move behind the counter. Originally, the bill included criminal sanctions against a pharmacist for the conduct of clerks and sales personnel if they violated the provisions of the Act. Retail groceries and retail pharmacies have united in response to this bill. Currently, it is expected that HB 1794 will pass, but in a form that will impose voluntary compliance. This was a compromise worked out by OPhA and the Oklahoma Grocer's Association. Highlights of the proposed voluntary restrictions include:

- Voluntary retail age restrictions of 18 years for products containing DXM
- Retailers develop and implement Partners in Prevention retail education program
- Implement on a store by store basis, retail age restrictions
- Extend the existence of the OTC Task Force for three years
- Reconvene the task force on Abuse of OTC on or before July 1, 2009, to evaluate the effectiveness of the Partners in Prevention voluntary retail restriction program over the past two years
- Support penalties if a pharmacist dispenses, sells, or distributes a product containing unfinished dextromethorphan in the state unless it is sold to purchasers licensed by the U.S. Food and Drug Administration
- Support all education aspects of over-the-counter products that may be harmful

Nationally . . .

There has been activity on the national level as well.

H.R. 1474 is a proposal to amend Title XVIII of the Social Security Act to require the sponsor of a prescription drug plan or an entity offering an MA-PD plan to promptly pay claims submitted under part D, and to prohibit the inclusion of certain identifying information on explanatory prescription drug information and cards distributed by drug plans. In other words, this involves restricting the appearance of directing business.

LEGISLATIVE COMMITTEE UPDATE

Submitted by: Wiley "Butch" Williams, D.Ph., J.D.
(continued)

H.R. 971 is a proposal to ensure and foster continued patient safety and quality of care by making the antitrust laws apply to negotiations between groups of independent pharmacies and health plans and health insurance issuers, in the same manner as such laws apply to protected activities under the National Labor Relations Act.

OPhA and ASHP are keeping a close eye on proposed legislation from Sen. Edward Kennedy, Sen. Richard Burr, and Sen. Pat Roberts introduced as the Safe Compounding Act of 2007. The stated purpose behind the bill is to protect the public health by implementing laws and regulations that address certain problems with pharmaceutical compounding, particularly, where the compounding is really drug product manufacturing as opposed to pharmacist compounding. Health Care would be in desperate straits today if compounding pharmacies were not able to compound specialty items for oncology, bio-identical hormone replacement, and an assortment of specialty products for the elderly in LTC facilities. Drug companies, particularly Wyeth, the maker of Premarin, have been using the FDA to try to eliminate compounding pharmacies, which are their competitors. It is recommended that you keep an eye on this issue.

Lastly, I want to encourage everyone to contribute generously to the **OPhA PharmPAC**. Your donations are not tax deductible, but they will be put to good use. You can send your donation to:

OPhA PharmPAC, P.O.Box 18731, Oklahoma City, OK 73154.

OSHP District Update

Western District

Recent Meeting: February 22nd, 2007
Topic: DVT/PE Prevention
Speaker: Jay Groce, Pharm.D., CACP
Location: Ted's Café Escondido, OKC, OK

Recent Meeting: March 29th, 2007
Topic: Colon Cancer Treatment in 2007
Speaker: Patrick J. Medina, Pharm.D., BCOP
Location: Ranch Steak House, OKC, OK

Upcoming Meeting: There is no April meeting due to the 2007 Annual Meeting on April 12th-13th. We'll see you there!

Eastern District

Recent Meeting: March 15th, 2007
Topic: Enoxaparin for DVT Prophylaxis
Speaker: Suman Rathbun, M.D.
Location: Charleston's Restaurant, Tulsa, OK

Upcoming Meeting: April 19th, 2007
Topic: Bar Coding and Medi-Dot
Speaker: Marc Rafferty, DOP at Jane Phillips
Location: Coppers Restaurant, Bartlesville, OK
**Please not that this is a special meeting for April. You don't want to miss this!*

Welcome New Members:

**Roger Blackwood
Miles Compton
Michelle Condren**

**Carol Johnson
Lesley Maloney
Cassi Mettry**

**Ellen Trump
Robert Zolnierz**

Baby Picture:

That future pharmacist is Yvette Morrison, who was OSHP President from 2000-2001. She has also been OSHP Secretary and is currently Chair of the Program Committee Vendor Showcase. So thank Yvette for all of her hard work when you see her at the Annual Meeting.

Do you have a baby picture to submit? Then contact the Newsletter Committee.



Attention Potential Authors:

If you or a colleague is interested in submitting an article for publication in the OSHP Newsletter, please contact the OSHP Newsletter Committee or a Board Member.

Newsletter Committee Co-Chairs are Darin Smith and Nancy Williams:

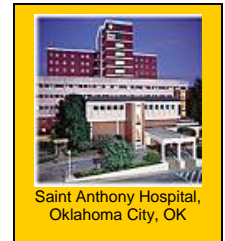
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Chapter News

❖ OSHP ANNUAL MEETING

The OSHP Annual Meeting 2007 will be held at St. Anthony Hospital in Oklahoma City on April 13th, 2007. The program will offer six ACPE-accredited continuing education hours. A variety of topics are being presented, which include the ASHP 2015 Initiative, smoking cessation, venous thromboembolism, toxicology, medication regimens for patients with weight challenges, and atherthrombosis. New to this meeting, is a session on Clinical Pearls, which has been very popular at the ASHP Midyear Clinical Meetings.



The meeting will be kicked off by a Pre-Meeting Symposium Dinner held on Thursday, April 12th, at Crabtown in Oklahoma City. The Pre-Meeting Symposium, titled "Atherthrombosis/Make the Connection: ACS, PDA, and Stroke", will offer an additional 1 hour of ACPE credit.

For complete meeting and registration information, visit www.oshp.net. You don't want to miss this meeting!

Scenes From OSHP Chapter Meetings and Activities



Western District Meeting on 2/22/07 with speaker Dr. Jay Groce. (Green boxes)



SWOSU-OSHP pharmacy student chapter group picture (above); students speaking to 2nd graders about poison prevention (left) and working on St. Patrick's Day door decorations for hospice patients (below). (Gold boxes)



Western District Meeting on 3/29/07 with speaker Dr. Patrick Medina. (Blue boxes)



OU pharmacy students at the sOSHP meeting on 4/2/07. (Red box)





The intention of clinical pearls is to highlight information regarding various therapeutic topics pertinent to health-system pharmacy practice. If you or your institution has information, protocols, etc. and are willing to share, please contact the OSHP Newsletter Committee.

Regulatory Actions on Quinine Sulfate

Submitted by: *Julia Chiappe, Pharm.D., Drug Information Specialist
Integris Baptist Medical Center; Oklahoma City, OK*

QUESTION:

What is the status on the use of quinine sulfate for nocturnal leg cramps?

ANSWER:

On December 11, 2006, the Food and Drug Administration (FDA) mandated that all unapproved drug products containing quinine be discontinued within 60 days.¹ Only Mutual Pharmaceutical's Quaalain® obtained FDA approval (August 2005) for the treatment of uncomplicated *Plasmodium falciparum* malaria and is allowed to remain on the market. The package insert specifically mentions that quinine sulfate is not approved for the treatment or prevention of nocturnal leg cramps.² Because malaria is life-threatening, the FDA has stated that the risks associated with quinine use are justified for that condition but not to treat leg cramps. Since 1969, the FDA has received 665 reports of adverse events with serious outcomes associated with quinine use, including 93 deaths.¹ The hospital cost for the approved formulation of quinine sulfate is \$3.40 per 324 mg capsules compared to the \$0.14 to \$0.37 price range for the unapproved formulations soon to be unavailable.

Mutual Pharmaceuticals originally was a manufacturer of an unapproved quinine sulfate formulation. The company correctly predicted the FDA's regulatory actions once an approved version became available. A precedent was set in July 2002 when actions against unapproved guaifenesin extended release tablets were announced after Mucinex® received FDA approval. Unapproved products containing carbinoxamine were also acted upon in June 2006.^{2,3}

The FDA has estimated that approximately 2,000 marketed, unapproved drugs exist. Most fall into one of the following categories: drugs that were available in some form prior to the 1938 Food Drug and Cosmetic Act requiring new drugs be proven safe or that drugs be identical, related or similar to a pre-1938 drug (i.e., drugs claiming grandfather status); drugs that did not undergo independent approval due to claims that these were identical or similar to drugs who underwent safety approval between 1938 and 1962; or drugs introduced into the market between 1938 and 1962 based on the manufacturers own conclusion that the products were generally recognized as safe (GRAS).^{3,4,5}

The Drug Efficacy Study Implementation (DESI) review, a retrospective evaluation of the effectiveness of drug products approved only as safe between 1938 and 1962, was required by the 1962 amendment to the Food, Drug, and Cosmetic Act. The DESI review unfortunately added the following additional categories of marketed, unapproved drugs: drugs proven to be effective under the DESI process whose manufacturer did not submit applications to receive approval for continued marketing as well as drugs identical, related, or similar to the DESI drugs that did not submit applications for continued marketing.^{3,4,5}

Actions on marketed, unapproved drugs increased in priority after the death of 40 premature infants in 1983 was associated with E-Ferol®, a high potency vitamin E injection. This formulation was found to have never undergone review because it underwent market introduction prior to the 1938 Food Drug and Cosmetic Act and was therefore not subject to the DESI review. In response, the FDA created a program for addressing marketed, unapproved drugs that had not undergone safety or efficacy evaluations. A drug that was subject to this Prescription Drug Wrap-Up program was classified as an illegally marketed product unless the manufacturer could establish that the drug was covered by either the Grandfather Clause of 1938 or the Grandfather Clause of 1962. The FDA has stated that there are likely very few drugs on the market that are entitled to grandfather status because the drugs likely differ from the original versions in strength, dosage form, route of administration, indications, or intended patient population.⁵

In June 2006 the FDA issued the "Marketed Unapproved Drugs - Compliance Policy Guide". This document summarizes how the FDA plans to prioritize enforcement actions on marketed, unapproved drugs and what manufacturers of these drugs should do to comply. Drugs with potential safety risks, drugs lacking evidence of effectiveness, and drugs that constitute health fraud will be prioritized first.⁵

References

1. FDA News (December 11, 2006). FDA advances effort against marketed unapproved drugs. Press release. <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01521.html> . Retrieved December 28, 2006.
2. Package insert. Quinine sulfate (Quaalain). Philadelphia, PA: Mutual Pharmaceuticals Co, August 2005. <http://www.fda.gov/cder/foi/label/2005/021799lbl.pdf> . Retrieved December 28, 2006.
3. Rubin R. Hundreds of unapproved drugs sold by prescription. USA Today 2006 Sept 19; http://www.usatoday.com/news/health/2006-09-17-unapproved-drugs-cover_x.htm . Retrieved December 13, 2006.
4. FDA News (June 8, 2006). FDA acts to improve drug safety and quality. Press release. <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01384.html> . Retrieved December 28, 2006.
5. FDA Guidance Document: Marketed Unapproved Drugs - Compliance Policy Guide (June 8, 2006). <http://www.fda.gov/cder/guidance/6911fnl.pdf> . Retrieved December 28, 2006.





Anticoagulation Clinic Pharmacists

Submitted by: Susan Fugate, Pharm.D., CACP, BCPS



Check it Out!

This is a new section in our newsletter that highlights different areas of pharmacy practice. If you are doing something interesting that may benefit others, then please contact the OSHP Newsletter Committee so we can profile you. Don't keep it to yourself . . . brag about your area of practice!

Record Numbers of Students Head for Residencies

Approximately 1900 pharmacy students applied for the more than 1600 available postgraduate year one residencies. More than 1300 applicants were matched with a residency program, a 31% increase from last year.

Wow!!

Anticoagulation clinics have been around for a few decades, and the number of clinics has grown over the years. Anticoagulation clinics were one of the first models for disease state management for pharmacists. There is a large body of clinical evidence, in addition to the consensus statement of the American College of Chest Physicians, supporting the statement that coordinated anticoagulation management reduces thrombosis and bleeding events compared with routine medical care.

In the outpatient clinic setting, anticoagulation management is primarily focused on warfarin therapy. An initial anticoagulation consultation usually consists of an interview to collect pertinent medical history and an education session on the patient's anticoagulant medication(s). A follow-up anticoagulation visit usually consists of an interview to assess for complications with therapy (i.e., bleeding, recurrent thromboembolism) and any pertinent changes that would impact warfarin dosing (i.e., dietary intake, medication changes, nonadherence, alcohol and tobacco use). All visits include laboratory assessment, anticoagulant dosing, and follow-up recommendations. Most anticoagulation clinics use point-of-care devices to assess the INR, thus providing quick feedback to the patient on his/her response to therapy and allowing immediate adjustments of regimens, when necessary.

Many anticoagulation clinics have expanded their services to encompass higher complexity situations that arise in anticoagulation management. For warfarin-treated patients, protocols can be developed to manage overanticoagulation with vitamin K, to bridge with unfractionated heparin/low molecular weight heparin (LMWH) during warfarin interruptions for surgery and procedures, to use hemostatic mouthwashes following dental extractions and other oral surgeries, and for patient self-testing (of the INR). Protocols and programs may also be established to manage LMWH or fondaparinux in the outpatient treatment of acute deep vein thrombosis.

A variety of provider models are used for anticoagulation clinics across the country. Pharmacists, physician assistants, nurse practitioners, and nurses commonly serve as anticoagulation providers in the clinic setting. The CACP (Certified Anticoagulation Care Provider) is a national certification process for anticoagulation providers that require documentation of clinical interventions and passing of a standardized exam. Most anticoagulation clinics will appoint a medical director as well. For pharmacists, it is essential to have a collaborative practice agreement with a physician to allow the pharmacist to make adjustments in the anticoagulation regimens and to order/conduct laboratory testing.

A great resource to find out more information on anticoagulation therapy, the CACP certification, and locations of anticoagulation clinics in the U.S. is the Anticoagulation Forum (www.acforum.org). In addition, feel free to contact me at 405-951-2377 or susan-fugate@ouhsc.edu for more information regarding anticoagulation therapy and clinics.



OUCOP Student Chapter Report

Advisor: Michele Splinter

The OU College of Pharmacy student chapter of OSHP continues to hold bimonthly meetings throughout the year at the college. In February, our student chapter treasurer, Django Belote, gave a very informative presentation on the pharmacist's role in cardiac arrest management. Dr. Janine Young, current OSHP President, gave an encouraging talk in March about the various opportunities for student involvement with OSHP. Our April speaker, Dr. Fugate, President-Elect of OSHP, discussed the benefits of OSHP membership and further encouraged student involvement with OSHP through the committees. Students also continue to attend the Eastern and Western District Meetings on a regular basis.

We are honored to have the upcoming speakers, Dr. Jonathan Ference, a Clinical Assistant Professor at the OU College of Pharmacy, and Dr. Teresa Cooper, a Clinical Oncology/Bone Marrow Transplant Pharmacist at St. Francis in Tulsa. Annual student officer elections will be held for our chapter in late April. While we are excited about welcoming our new student officers and look forward to their ideas and input, we are also very grateful for our current officers and all of their hard work these past two semesters.

OFFICERS	SPRING 2006- SPRING 2007
President	Jennifer Gass
President-Elect	Mark Bateman
Vice President	Amanda Bishop (OKC), Katherine O'Neal (Tulsa)
Secretary	Lisa Mayer
Treasurer	Django Belote
Historian	Misty Broyles (OKC), Jesse Schmidt (Tulsa)



SWOSU Student Chapter Report

Advisors: Erin Callen, Mark Gales, Virgil Van Dusen, Nancy Williams

The SWOSU College of Pharmacy OSHP student chapter has had a productive semester thus far. Membership has climbed since the spring semester from 23 to 35 students. We have hosted three speakers to date. In February, Dr. Patrick Medina, an OU College of Pharmacy faculty member, came to speak about his specialty in oncology medicine. In March, Dr. Randall Sharp, a clinical faculty member of SWOSU College of Pharmacy, came to speak about his specialty in cardiology medicine and his activities at Heart Solutions of Oklahoma. Our April speaker, Dr. Erin Callen, also a clinical faculty member of SWOSU College of Pharmacy, spoke about pharmacy residencies and how they can be beneficial in a clinical pharmacy career.

Our chapter also participated in several community service projects. We spent an afternoon at the Trinity Hospice in Weatherford making St. Patrick's Day door decorations for the hospice patients. It was both a fun and rewarding experience for everyone who participated. Additionally, in early April, we visited the local elementary school to speak to the second-graders about poison prevention and drug safety. What a great experience!

As the semester is quickly coming to an end and new student officers are elected, we'd like to take an opportunity to thank the current officers for all of their hard work this past semester.

OFFICERS	SPRING 2007
President	Cassi Mettry
President-Elect	Jessica Bowen
Secretary	Jaime Miller
Treasurer	Donovan Fuller
Fundraising Chairs	Beverly Medcalf and Melissa Gloden



WATCH FOR UPCOMING ISSUES OF THE OSHP NEWSLETTER

April-June 2007, July-September 2007

