Georgia Society of Health-System Pharmacists
Monthly Newsbriefs

Announcements

GSHP Webinar-July 21, 2016

Title: **Non-Small Cell Lung Cancer (NSCLC) Updates: Focus on Newer Therapies**

Pharmacists Objectives:

- Outline the most up to date screening guidelines for NSCLC
- Describe chemotherapy treatment options for NSCLC based on staging and patient characteristics
- Explain outcomes of newer immunotherapy options in terms of toxicity, clinical benefit, survival, etc
- Discuss the clinical data related to the newer immunotherapy options
- Differentiate patient counseling, dosing and cost for newer immunotherapy options

Pharmacy Technicians Objectives:

- List chemotherapy treatment options for NSCLC based on staging and patient characteristics
- List patient counseling and cost for newer immunotherapy options.

Speaker: Sonia Amin Thomas, PharmD

Georgia Society of Health-System Pharmacists is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. This program is approved for 1 hour (0.1 CEUs) of continuing pharmacy education credit. Proof of participation will be posted to your NABP CPE profile within 4 to 6 weeks to participants who have successfully completed the post-test. Participants must participate in the entire presentation and complete the course evaluation to receive continuing pharmacy education credit. UAN # 0228-0000-16-024-L01-P; 0228-0000-16-024-L01-T

This is a member service of GSHP. There is no charge for members to attend. Non-members will be charged $20.

Members:
To register: https://attendee.gotowebinar.com/register/2215246924895419140

Non-member to pay the $20 non-member fee: https://gshp.wildapricot.org/event-226806 then register at https://attendee.gotowebinar.com/register/2215246924895419140

Headlines

GSHP News

- Summer Meeting, July 15-17, 2016 Omni Amelia Island Plantation
- GSHP New Webpage
- Clinical Article

ASHP News

- ASHP Attends White House Meeting on Efforts to Tackle Opioid Abuse

June 2016

About GSHP

Georgia Society of Health-System Pharmacists (GSHP) is a professional society of pharmacists and related personnel practicing in organized healthcare settings.

Mission Statement
Helping our members become better practitioners.

Motto
Bringing pharmacy practice into focus.

Georgia Society of Health-System Pharmacists
3015 Shannon Lakes North
Suite 303
Tallahassee, FL 32309
(800) 913-4747

- e-mail link
- web link

About ASHP

ASHP is a 35,000-member national professional association that represents pharmacists who practice in hospitals, health maintenance organizations, long-term care facilities, home care, and other components of health care systems. ASHP is the only national organization of hospital and health-system

- WSJ Op-Ed Calls for Including Pharmacists on Patient Care Teams
- ASHP Launches Certificate Program in Sterile Compounding
- Maine Enacts Statewide Limits on Opioid Prescribing
- In Indiana, Decongestant Access Hinges Partly on Pharmacists' Judgment

Pharmacy News

- Telepharmacy Pulls Hospital Through Storm
- Williamson Medical Center Antibiotic Program Draws Applause
- Inspectors Find California Hospital's Pharmacy Posed Infection Risk
- The Top 10 C-Suite Points Bringing Pharmacy Out of the Basement
- Inventing a Machine That Spits Out Drugs in a Whole New Way
- Money-Back Guarantee: The New Trend in Drug and Device Marketing
- Education, Reminders Reduce Risky Prescriptions for Older Adults
- FDA Delays Rule on Generic Drug Labels
- How Patent Troll Legislation Can Increase Timely Access to Generic Drugs
- Three New FDA Draft Guidance Documents for Drug Compounders

GSHP News

Summer Meeting, July 15-17, 2016 Omni Amelia Island Plantation

Registration Agenda

Room Reservations-The 2016 Summer Meeting will be held at the Omni Amelia Island Plantation, Amelia Island, FL. GSHP has very attractive room rates that start at $182 single/double per night for an ocean view hotel room at the Omni Amelia Island Inn and Beach Club; $155 for a resort view room. To make your reservation, click here:

Hotel Reservations

The GSHP room rate will be honored for three days prior to group arrival and three days after group departure if available.

The Plantation has a wide variety of rooms and villas and the link above can help you with any of them.

Click here for villa information, rates, etc.

If you need any assistance with rooms or need more information about the room types that are available, please contact Steve Glass at sglass@gshp.org

There is $10 daily resort service fee this year per room. The resort fee includes:

- Self Parking ($10 daily value)
- Unlimited high speed internet access in all accommodations ($9.95 daily value)
- On-property Transportation ($4.00 daily value)
- Unlimited use of health & fitness center ($20 daily value)
- In Room Coffee Service ($5.00 daily service)
- Meeting Concierge & 24 Public Safety Team
- Local & Toll Free Phone Access

pharmacists and has a long history of improving medication use and enhancing patient safety.

American Society of Health-System Pharmacists
7272 Wisconsin Avenue
Bethesda, MD 20814
301-657-3000

• e-mail link
• web link

Calendar

GSHP Summer Meeting
7/15/16 - 7/17/16

Omni Amelia Island Plantation, FL

National Pharmacy Preceptors Conference [ASHP]
8/11/16 - 8/13/16
Washington Hilton, Washington D.C., August 11-13, 2016
web link

GSHP New Webpage

GSHP has a new webapge. Check it out!

Then take our survey

Clinical Article

Sacubitril/valsartan (Entresto®): A Breakthrough in Heart Failure Care

Lesly-Anne Samedy, Pharm.D/Ph.D Candidate Class of 2017, Sarah V. Dang, Pharm.D. Candidate Class of 2016, Catherine Lister, Pharm.D. Candidate Class of 2016, and Maria Miller Thurston, Pharm.D., BCPS

Corresponding Author:

Maria Miller Thurston, Pharm.D., BCPS

Clinical Assistant Professor

Mercer University College of Pharmacy

3001 Mercer University Drive

Atlanta, GA 30341

T: (678) 547-6253

F: (678) 547-6384

Background

Heart failure (HF) is a debilitating chronic condition requiring lifelong management.[1] It is defined as a complex clinical syndrome caused by a structural and/or functional cardiac disorder that impairs the ability of the ventricle to fill with or eject blood. [2] Heart failure is one of the most common causes for hospital admission in the United States, accounting for

over one million primary hospitalizations each year.[3] While the number of heart failure-related deaths has declined from 2000 through 2009, it has steadily increased through 2014.[3] Optimizing treatments will not only improve the quality of life for people who have HF, but the length of life as well. A study focusing on the epidemiology of HF demonstrated that although HF is associated with significant mortality, morbidity, and healthcare expenditures, particularly among those age 65 years and older, this burden is not related to an increase in the incidence of the disease. This suggests that current therapies are not effectively reducing disease progression in all patients.[2]

Diagnosis and Clinical Practice Guidelines

The evaluation and diagnosis of HF is based on specific lab tests, presence of structural damage, as well as signs and symptomatic characteristics. The American College of Cardiology Foundation/American Heart Association (ACCF/AHA) staging system defines HF using four stages. The stages include individuals who are at high risk for developing HF (stage 1) to those with end-stage disease (stage 4). The New York Heart Association (NYHA) classification system categorizes HF into four classes based on the extent of HF symptoms.[4,5] Heart failure with a reduced left ventricular ejection fraction (LVEF) ≤ 40 percent is denoted as HFrEF, whereas HF with a preserved LVEF > 40 percent is referred to as HFpEF.[6,7] Treatment goals in individuals with HFrEF are to improve the symptoms, prevent the progression of the disease, and reduce mortality/morbidity.

Hypertension (HTN) is one of the most prevalent modifiable risk factors for the development of HF. Hypertension can increase cardiac work and it is a risk factor for the development of coronary heart disease.[8] Evidence-based guidelines used in the treatment of HTN support the use angiotensin converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB) as first line therapy due to their ability to improve vasodilation and LVEF percentage.[4,9] Add-on therapy may be included for more targeted populations; for example, in African-Americans with HF the combination use of isosorbide dinitrate and hydralazine is preferred.[9] With current treatment options and specific treatment tailoring, population morbidity and mortality are improving, but still remain high. The need for new, novel pharmacological interventions is clear.

Continue reading:

http://www.gshp.org/development_resources.aspx?a=viewPost&PostID=30596&return=viewArchive

---

ASHP News

ASHP Attends White House Meeting on Efforts to Tackle Opioid Abuse

Pharmacist Group Stresses Need to Ensure Appropriate Pain Management for Patients

5/27/2016
ASHP participated in a meeting yesterday with several senior White House officials to discuss the Obama Administration's efforts to address the opioid overdose and misuse epidemic. The session, coordinated by the Office of National Drug Control Policy, is the first in a series of meetings with healthcare provider and patient advocacy groups that are working to expand access to opioid treatment, prevention, and recovery resources.

Read More

---

web link | return to headlines

WSJ Op-Ed Calls for Including Pharmacists on Patient Care Teams

5/23/2016
A recent Wall Street Journal op-ed assessing ways to reduce medical errors in the U.S. strongly recommends including pharmacists on care teams. "How to Make Hospitals Less Deadly" by James B. Lieber notes that pharmacists' extensive knowledge of medications offers an important barrier to common medical errors. "Doctors have only glancing knowledge of how an ever-multiplying number of drugs interact with diet, age, disease, body type and each other," he writes, pointing to a study that showed placing pharmacists in patient areas decreased errors by 45% and cut errors leading to death or severe harm by 94%.

Read More

---

web link | return to headlines

ASHP Launches Certificate Program in Sterile Compounding

Online Continuing Education Provides Practice-based Training in Fundamentals of Aseptic Processing

5/23/2016
ASHP recently released the latest offering from its Professional Certificate line, the Sterile Product Preparation Training and Certificate Program. The online continuing education program provides pharmacists and pharmacy technicians with the knowledge and essential skills necessary for safe and effective sterile product preparation.

Read more

web link | return to headlines

Maine Enacts Statewide Limits on Opioid Prescribing

[June 15, 2016, AJHP News]

Kate Traynor

BETHESDA, MD 20 May 2016 - Healthcare providers in Maine have about six months to rethink their approach to pain treatment before a new state law limiting opioid dosages and the duration of therapy takes effect.

The law, which goes into effect on January 1, 2017, restricts opioid prescriptions to a dosage of no more than 100 morphine milligram equivalents (MME) per day of any opioid or combination of opioid-containing medications.

Read more

web link | return to headlines

In Indiana, Decongestant Access Hinges Partly on Pharmacists' Judgment

[June 15, 2016, AJHP News]

Cheryl A. Thompson

BETHESDA, MD 20 May 2016 - With partial credit to the Indiana Pharmacists Alliance, a new law in the Hoosier state leverages pharmacists' judgment to accomplish two goals: (1) to keep pseudoephedrine available without a prescription to residents with a clinical need for the decongestant and (2) to disrupt the supply chain for methamphetamine production.

Read more

web link | return to headlines

Pharmacy News

Telepharmacy Pulls Hospital Through Storm
Drug Topics (04/10/16) Vecchione, Anthony

When Winter Storm Jonas hit North Carolina in January, some personnel, including pharmacists, were prevented from getting to work. However, other pharmacists who worked in their home offices far from the storm were able to verify orders remotely as a result of technology from PipelineRx. Working in conjunction with hospital IT personnel, PipelineRx's certified pharmacists gained access to patients' electronic health records (EHR) remotely through a secure channel such as virtual private network (VPN). The ability to have a pharmacist verify orders remotely decreases the pharmacy's burden or can eliminate the need for having a pharmacist on call, says Lindsay Burke, PharmD, director of pharmacy at North Carolina Specialty Hospital. At present, the hospital employs the services of PipelineRx over weekends, on holidays, and during weather emergencies. Brian Roberts, CEO of PipelineRx, says PipelineRx employs about 120 experienced hospital pharmacists (PharmDs) who work from home offices nationwide. "We have customers between 200 and 1,000 beds — large medical centers where they give us a wing or a portion of their hospital," says Roberts. Some hospitals that need 1.5 fulltime equivalents (FTEs) at night might outsource half the FTEs to PipelineRx, where they work side-by-side with the nighttime pharmacist. PipelineRx's client base also includes surgery centers, long-term-care centers, and rehab hospitals. Recently, the company started selling or leasing its technology back to large hospital chains.

return to headlines

Williamson Medical Center Antibiotic Program Draws Applause
Tennessean (05/17/16) Fletcher, Holly

An initiative by Williamson Medical Center of Franklin, TN, to curb unnecessary antibiotic use has been lauded in a recent report from Pew Charitable Trusts' antibiotic resistance project. The report examines how different facilities are trying to design programs to make sure antibiotics are prescribed appropriately. CDC reports that antibiotic-resistant strains of bacteria are concerning to public health officials because more than 2 million patients are infected annually with resistant organisms. Antibiotic stewardship programs, such as the one developed by Williamson Medical Center, helps clinicians decide when is appropriate to use antibiotics, said David Hyun, MD, senior officer of Pew Charitable Trusts' antibiotic resistance project. Officials at Williamson Medical Center began talking about a stewardship program in 2009 when a "forward thinking" physician wanted to tackle how the hospital was prescribing antibiotics, said Montgomery Williams, an internal medicine and antibiotic stewardship pharmacist at Williamson Medical Center. The hospital has a microbiology department and lab on site that tests cultures. A team of pharmacists makes recommendations for modified treatments, and the hospital has a system to track how often the recommendations are accepted by physicians. Williams attributes much of the success of the program —pharmacist recommendations were accepted more than 87% of the time in 2014—to the physicians' willingness to work with the pharmacists.

return to headlines

Inspectors Find California Hospital's Pharmacy Posed Infection Risk
Kaiser Health News (05/19/16) Terhune, Chad

State records show that 7,300 patients at Paradise Valley Hospital in National City, CA, may have been exposed to infection from contaminated medications last year. Inspectors found "dust, stains, and foreign material" in a supposedly sterile environment where thousands of I.V. drugs were prepared between January and August. The report also stated that the hospital's head of infection control both neglected the compounding lab in question and falsified documents to cover up her failure. She was fired in August. The hospital was fined $17,500 in December, and a spokesman said it is appealing the fine, noting that outside lab tests found no contamination of the pharmacy or medications. According to a spokeswoman for Prime Healthcare Services, which owns Paradise Valley, it was not necessary to notify patients who received the compounded medications during the 8-month period because "further analysis found no evidence of contamination during this time period."

return to headlines

The Top 10 C-Suite Points Bringing Pharmacy Out of the Basement
Hospitals & Health Networks (05/16) Sloane, Todd

As the health industry shifts to value-based care, C-suite executives are turning to pharmacists to anchor multidisciplinary care teams aimed at managing patients with chronic conditions. There are many situations that executives will face in which pharmacists can help, including adverse drug events, tougher compounding medication regulations, opioid abuse, pharmacy leadership issues, and antibiotic stewardship. Pharmacists may be the necessary contacts for these pain points, providing both knowledge and insight pertaining to the specifics of drugs and their effects as well as information regarding patient safety. Other issues facing the C-suite include health system integration, the 340B Drug Pricing Program, hospital readmissions, accreditation, and rising drug costs. Pharmacists can assist in all of these areas because pharmacy plays a critical role in patient care and health system operations. In addition, pharmacists can help formulate plans to usher in a new era of national policy that lowers drug costs and makes health safer and more affordable for patients.

return to headlines

Inventing a Machine That Spits Out Drugs in a Whole New Way
NPR Online (05/23/16) Bebinger, Martha

A prototype machine developed at the Massachusetts Institute of Technology (MIT) produces 1,000 capsules in 24 hours, a process that can take months for some batches at a big pharmaceutical manufacturing plant. The device—which is about the size of a kitchen refrigerator—raises the possibility that hospitals and pharmacies could make their own tablets as needed, potentially lowering the high costs of medications by creating competition between manufacturers. The drug industry has two key concerns about the widespread use of the device: intellectual property rights and safety. Drug manufacturers own exclusive rights to produce the drugs they develop for a period of time, and worries about safety include continuous monitoring of machines to ensure safety and quality. MIT developers are currently focused on making a smaller more portable unit, producing more and more complex drugs, and seeking FDA approval for the device.

return to headlines

Money-Back Guarantee: The New Trend in Drug and Device Marketing
STAT News (05/31/16) Numerof, Rita E.

To overcome price resistance for costly drugs and medical devices, manufacturers increasingly are offering hospitals, insurers, and other buyers money-back guarantees. Cigna, for example, has promised to lower the price paid for two new cholesterol drugs if actual patient outcomes are not on par with clinical trial results. Meanwhile, Stryker agreed to pony up as much as $5 million in legal costs if its tracking technology misses a sponge accidentally left in a surgical patient. This shared-risk model positions drug and device makers to champion the true value and performance of their products, writes Rita E. Numerof, PhD, president of Numerof & Associates. "Embracing true reform of the payment model is one way [the pharmaceutical industry] can begin winning back goodwill," adds Numerof, whose company guides health care-related businesses to strategies for winning in dynamic markets. "This is market-based health care at work, which is a good thing for us all."

return to headlines

Education, Reminders Reduce Risky Prescriptions for Older Adults
Medscape (05/21/16) Harrison, Laird

A program that provides systematic education and reminders in an emergency department (ED) can greatly reduce the risk of inappropriate medications being given to older patients. Researchers, who presented their work at the American Geriatrics Society 2016 Annual Scientific Meetings, discussed the EQUiPPED (Enhancing Quality of Prescribing Practices for Older Veterans Discharged From the Emergency Department) program. The program is made up of a team of geriatricians, gerontologists, geriatric pharmacy specialists, and others—all working to reduce the proportion of risky prescriptions prescribed to older veterans to less than 5%. To do this, the team educated the providers and scheduled one-on-one meetings to talk about medications that could be risky. Then they collected the data and modified prescription order sets to work safer and more effectively for older patients. At four separate sites, the proportion of potentially inappropriate medical prescriptions dropped after applying the EQUiPPED program. The EQUiPPED program is now being used in eight Veterans Affairs medical centers, and the team is helping other EDs and non-VA hospitals to implement the program.

return to headlines

FDA Delays Rule on Generic Drug Labels
New York Times (05/20/16) Thomas, Katie

The Food and Drug Administration (FDA) will wait until next year to decide whether generic drug companies can be sued for failing to update warning labels to reflect new risks. While both brand-name and generic makers are obliged to make the change, the Supreme Court in 2011 ruled that patients harmed by generic versions of a drug could not take legal action because the manufacturers had no control over the language in the warning labels. The FDA proposed 2 years later to hold generic companies to the same standard as brand-name manufacturers but has yet to take action on this front. While the delay in decision making comes as a frustration to consumers advocates and representatives for trial lawyers, generic drug makers, pharmacists, hospitals, physicians, and other interests applaud the agency's unrushed approach. "FDA clearly appreciates the strong concerns articulated by a majority of health care experts, particularly those closest to patient prescribing," said Generic Pharmaceutical Association CEO Chip Davis.

return to headlines

How Patent Troll Legislation Can Increase Timely Access to Generic Drugs

JAMA Internal Medicine (05/16/16) Treasure, Carolyn L.; Kesselheim, Aaron S.

Congress has rolled out legislation to rein in "patent trolls," which acquire patents for the sole purpose of suing companies that develop products infringing on those rights. Although the measure likely will have the biggest impact on the technology sector, there are also implications for the generic drug industry, write Carolyn L. Treasure and Aaron S. Kesselheim of Brigham and Women's Hospital and Harvard Medical School. Off-brand medications are routinely delayed from entering the market for years through secondary patents, sought during clinical testing and based on small changes in product formulation or other minute differences. These 20-year secondary patents, which overlap the 20-year primary patent and thus afford drugmakers prolonged market exclusivity for a medication, could become easier for generic drug companies to beat in court if the Protecting American Talent and Entrepreneurship (PATENT) Act becomes law. By introducing the inter partes review process, a much less costly and more streamlined proceeding than litigation, the PATENT Act would make it possible for generic drugmakers to challenge frivolous patent lawsuits without spending millions of dollars. The biopharmaceutical and biotechnology industries naturally are opposed to the law and have lobbied for a blanket exemption to the inter partes process, without much success so far.

return to headlines

Three New FDA Draft Guidance Documents for Drug Compounders

Regulatory Affairs Professionals Society (04/15/2016) Brennan, Zachary

FDA on April 15 released three draft guidance documents for drug compounders, describing the agency's interpretation of the prescription requirement in section 503A of the Food Drugs & Cosmetics Act, how the agency intends to apply such a requirement to compounding for hospitals or health system pharmacies, and the definition of the term "facility," in reference to section 503B of the FD&C Act. Each draft guidance document is available for public comment for 90 days. Lee Rosebush, a partner with the law firm BakerHostetler, says the guidance "is going to hurt traditional compounding pharmacies, as it is clear they are not going to be able to do office use compounding." FDA has also expanded the role of a 503B facility, particularly into the hospital market, he says. The draft guidance on prescription requirements notes: "Hospitals, clinics, and health care practitioners can obtain non-patient-specific compounded drug products from outsourcing facilities registered under section 503B. Outsourcing facilities, which are subject to CGMP requirements, FDA inspections according to a risk-based schedule, specific adverse event reporting requirements, and other conditions that provide greater assurance of the quality of their compounded drug products, may, but need not, obtain prescriptions for identified individual patients prior to distribution of compounded drug products." Rosebush says there will be a major impact on hospital pharmacies as "a pharmacy in a hospital cannot compound medication and send to another hospital in the same system unless the hospital pharmacy is registered as a 503B facility with the FDA."

return to headlines