Washington Metropolitan Society of Health-System Pharmacists Newsletter

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President's Message

Dear WMSHP Members,

It has been another wonderful summer month, and I wanted to provide some updates on some of the key activities we have been actively working on:

WMSHP Fall Meeting

We are excited to announce our Fall 2017 event entitled "Breaking Ground II: Enhancing Clinical Knowledge in Pharmacotherapeutics"! This event will feature a wide range of topics which include: Informatics, Cardiology, Critical Care, Alternative Medicine, Compounding, and Policy. This event will take place on **Saturday, September 23rd starting at 7:00 am at the University of Maryland at Shady Grove** – save the date!

WMSHP Summer Picnic

We are excited to announce our Summer Picnic event themed "Summer Picnic Pool Party"! Keep in mind this a "themed" event, so please be creative and bring your best goggles, flotation devices, and pool attire. This event is free to all members, non-members, family and friends. Park amenities include: train ride, playground, and hiking/biking trails. WMSHP will provide burgers, hot dogs, and soft drinks – please bring a signature side dish or dessert. This event will take place on **Saturday, August 12th at Cabin John Regional Park Shelter "J" (7400 Tuckerman Lane, Rockville MD 20852) –** save the date!

WMSHP Website Design

We are excited to announce updates to our website design and layout! This new and innovative design will permit rolling "real-time" ribbons in order to provide for Financial and Industry advertisements. This new design will provide a new and innovative way to generate additional monthly revenue streams from all interested parties. Our first advertisement buy-in will go into effect early next month – **check the website early next month for updates!**

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President's Message

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WMSHP Scholarships

The WMSHP Student Leadership Scholarship recognizes students with an interest in pharmacy practice in health-systems who have demonstrated leadership ability. The scholarship recognizes and celebrates the contributions of students who represent the very best attributes and accomplishments of WMSHP student members. WMSHP has **increased the number and amount of scholarships awarded annually from one to three ($750, $500, and $250).** Check out our website for additional details early next month!

Warm regards and best wishes,
Justin Sebakijje, PharmD, BCPS
President, WMSHP

Clinical Capsule

Tips for Submitting Case Reports to FDA MedWatch
By Sorana G. Pisano, Pharm.D.
Pharmacy Practice Resident (PGY-1)
Sibley Memorial Hospital-Johns Hopkins Medicine

Pharmacists play a major role in pharmacovigilance and are directly involved in reporting adverse drug reactions. The definition of pharmacovigilance is to detect, assess, understand and prevent adverse effects or any other drug-related problem.[2] Safety monitoring of medications continuing past the approval phase is a crucial part of clinical practice. Information collected from pre-clinical studies and phase 1-3 trials during drug testing are not adequate to determine rare, but serious adverse reactions due to the sample sizes of the studies, especially in smaller trials like those in oncology, and animal models used may not predict safety in humans.[1] For these reasons, pharmacists are ideally positioned from their training as medication experts and interactions with patients and other healthcare providers to monitor and report adverse reactions.

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Upcoming Events

An expert review on BENDEKA™ (bendamustine HCl) injection
(NON-CE Event)

Location:
Ruth's Chris Steak House
7315 Wisconsin Ave
Bethesda, MD 20814

Thursday, July 6, 2017
6:00 – 8:00 PM

RSVP: charles.Stewart@tevapharm.com

WMSHP Summer Picnic

Location:
Cabin John Regional Park
Shelter "J"
7400 Tuckerman Ln
Rockville MD 20852

Saturday, August 12, 2017
11:00 AM – 4:00 PM

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The Food and Drug Administration MedWatch program is for health professionals and the public to voluntarily report serious reactions and problems with medical products, including both drugs and medical devices.[3] Case reports can be submitted online or through a paper form both found at https://www.fda.gov/Safety/MedWatch/HowToReport/default.htm. There are four primary components of a valid case report: patient identifier, reporter identifier, event/problem, and suspected product. Here are tips on how to submit a good case report:[4]

1. **Patient Identifier:** include specific patient characteristics, like demographic information (e.g. age, race, sex), co-morbid conditions
2. **Reporter identifier**: include complete contact information when submitting, at least phone number and email so the FDA may reach out for additional information
3. **Event/Problem:** include a description of the adverse events, time to onset of signs or symptoms, clinical course of the event, patient outcomes (e.g. hospitalization or death), and pertinent laboratory data
4. **Product**: include suspected and concomitant product therapy details (dose, lot number, schedule, dates, duration), over-the-counter medications, dietary supplements, recently discontinued medications, and information about response to dechallenge and rechallenge of the suspected product, if applicable

When writing case reports, it is recommended to be through and detailed. The quality of the report is critical for appropriate evaluation of the relationship between the product and adverse events.[4] Pharmacists can use these tips to both efficiently and effectively record and submit case reports to MedWatch.

References:

1. World Health Organization. Safety monitoring of medicinal products: reporting system for the general public. Geneva: World Health Organization; 2012.
2. World Health Organization Collaborating Centre for International Drug Monitoring. Safety Monitoring of Medicinal Products: Guidelines for Setting Up and Running a Pharmacovigilance Centre. Sweden: *the* Uppsala Monitoring Centre (*the* UMC), WHO Collaborating Centre for International Drug Monitoring, 2000. http://apps.who.int/medicinedocs/en/d/Jh2934e/. Accessed May 15, 2017.
3. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. U.S. Food and Drug Administration website. https://www.fda.gov/Safety/MedWatch/default.htm. Updated May 9, 2017. Accessed May 15, 2017.
4. U.S. Food and Drug Administration. Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment, 2005. https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm126834.pdf. Accessed May 15, 2017.

Photo Gallery

Breaking Ground: Enhancing Clinical Knowledge in Pharmacotherapeutics
Sunday, May 21, 2017

Harish Jarrett, MD
Pulmonary Hypertension

Bryan LeBude, MD
Lipid Lowering with PCSK9 Inhibition

Breaking Ground 2017
Holy Cross Hospital