From MSHP President Gary Kerr:

The value of local pharmacists on the frontline of disasters has been proven over the years, both in this country and across the globe, including 9/11, the Iran and Haiti earthquakes, the Indonesia tsunami, Hurricanes Katrina and Sandy, and the Rhode Island nightclub fire.

Closer to home, on February 25, 1999 in Springfield, there was a horrific explosion and fire at the Jahn Foundry. About a dozen patients were transported to Baystate Medical Center and three suffered fatal injuries. The disaster plan was activated immediately and many pharmacy employees were deployed to the Emergency Department (ED), as there were no ED-based clinical pharmacists at that time. Since then, Baystate has activated disaster plans for a roller coaster accident at Six Flags, an oil tanker rollover and fire on I-91 and the June 1, 2011 tornado. The latter three incidents have benefited from clinical pharmacists working in the ED.

The events of April 15 remind us all as to why tabletop and live disaster drills are run on a regular basis. The teamwork skills needed in times such as these can be honed in less challenging circumstances.

In an ASHP Pharmacy News piece of April 19, 2013, several Boston-area hospitals that received victims of the senseless bombings at the Boston Marathon were highlighted in a well-written piece by Cheryl Thompson. Several front-line clinical pharmacists, as well as pharmacy leaders, were interviewed and quoted. Massachusetts General Hospital (MGH), Boston Children's Hospital and Brigham and Women's Hospital were specifically discussed, but Tufts Medical Center, Beth Israel Deaconess Medical Center, Boston Medical Center and Mt. Auburn Hospital were among others that treated the injured as well. By 7 a.m. Tuesday morning on April 16, the Boston Police stated that 176 persons had been seen; that number has since grown to over 200.

The highlighted pharmacists were directly involved in patient care or in orchestrating the pharmacy department response and deploying the resources. Nancy Balch, a 12-year ED pharmacist at MGH, described the scene there on Monday and noted that the next day had patients coming in with hearing problems and with shrapnel wounds they had not noticed. Lois Parker, another MGH clinician, was deployed from the Pediatric ICU to assist in the ED as needed.

Shannon Manzi, a veteran Children's Hospital ED pharmacist who has also worked in Haiti with earthquake victims, was paged off the marathon course from her medical tent to assist in the management of the mass casualties transported to the hospital. She led a six-pharmacist group participating on four multidisciplinary teams and described the injuries as more severe than the ones she had worked with in Haiti.

Behind the scenes, pharmacy leaders activated their own disaster plan responses. William Churchill, Chief of Service and Executive Director of Pharmacy at Brigham and Women's Hospital, worked closely with John Fanikos, Senior Director of Pharmacy, throughout the event. John deployed to the hospital's command center and served as the pharmacy unit leader. Other pharmacy managers assumed roles in the pharmacy command center. At MGH, Ray Mitrano, interim Chief Pharmacy Officer, ensured continued support for the ED pharmacists and led department responses centrally.

About MSHP
MSHP represents over 1900 pharmacists and pharmacy technicians working in organized health-systems throughout the Commonwealth.

For over fifty years, the members of MSHP have worked together in the achievement of common professional goals, including:

- Advancement of rational drug therapy in organized healthcare settings through the provision of pharmaceutical care.
- Advancement and encouragement of professional excellence by providing leadership, direction, education and communication among its members practicing in healthcare systems.
- Fostering of closer relationships between health-system pharmacy, other pharmaceutical disciplines and healthcare providers.

Massachusetts Society of Health-System Pharmacists
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- web link

About ASHP
ASHP is a 35,000-member national professional association that represents...
These fine clinicians and leaders, and so many other unnamed pharmacy staff in metro Boston hospitals, performed heroically, and “at the top of their licenses” in these horrific circumstances. They are commended for this, and for what they do every day for the patients, the health care team and for the profession. Thank you.

Headlines

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- Compounding Pharmacy Industry Has Outgrown Its Regulatory System, ASHP and FDA Say
- FDA, Green Valley Drugs Announce Voluntary Nationwide Recall of All Sterile Products
- Still Chance to Stop Carbapenem-Resistant Enterobacteriaceae, CDC Says

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- Levothyroxine sodium recalled, may be unavailable until 2014
- First U.S. State Biosimilars Bill Becomes Law
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- FDA Approves Novartis Antibacterial Treatment for Cystic Fibrosis
- Clinical Specialties Compounding Pharmacy Products: Recall - All Sterile Products Recalled Due To Lack of Sterility Assurance
- Duloxetine May Ease Neuropathy From Chemo
- Neshoba General Announces New Outpatient IV Infusion Unit
- Statin Side Effects: Brigham and Women’s Hospital Study Indicates They Usually Go Away
- Bill Would Allow Prescription, Distribution of Naloxone
- Physician-Patient Alliance for Health & Safety Invites Participation in the First National Survey of Patient-Controlled Analgesia Practices

ASHP News

FDA Wants Pharmacies to Remove Products Received From Shamrock Medical
Cheryl A. Thompson
BETHESDA, MD 12 April 2013 - Without mentioning the word recall, FDA on Thursday posted a notice advising pharmacies and other customers of Shamrock Medical Solutions Group LLC to take action to ensure drug products from that company are not administered to patients.

The agency said these products "may be mislabeled."

Shamrock Medical describes itself as an FDA-registered drug repackager that is licensed in more than 20 states.

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Compounding Pharmacy Industry Has Outgrown Its Regulatory System, ASHP and FDA Say
[May 1, 2013, AJHP News]
Cheryl A. Thompson
BETHESDA, MD 11 April 2013—In the half year since a compounding pharmacy in Massachusetts announced a recall of all its products "due to the potential risk of contamination," two other pharmacies declared recalls "due to lack of sterility assurance."
And at least two additional compounding pharmacies have recalled their maybe-not-so-sterile products after FDA personnel inspected the facilities.

The human toll is real.

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**FDA, Green Valley Drugs Announce Voluntary Nationwide Recall of All Sterile Products**

4/11/2013 The Food and Drug Administration (FDA) has announced that Green Valley Drugs has issued a voluntary recall of all sterile products compounded, repackaged, and distributed at its facility in Henderson, NV.

According to the FDA website, the recall is being issued by the company after observations of clean room personnel and certain aseptic techniques.

In light of the recall, ASHP members should take the following steps:

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**Still Chance to Stop Carbapenem-Resistant Enterobacteriaceae, CDC Says**

4/9/2013 The American Society of Health-System Pharmacists (ASHP) dedicated its Bethesda headquarters today as the Joseph A. Oddis Building. In a ceremony held on the plaza in front of the building entrance, at 7272 Wisconsin Avenue, nearly 200 people gathered to hear remarks and honor the man known as the father of ASHP. The dedication recognized the contributions of Joseph A. Oddis, Sc.D., a former chief executive officer (1960 – 1997) of the professional society that represents pharmacists who practice in hospitals, health systems, and clinics.

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**Pharmacy News**

Levothyroxine sodium recalled, may be unavailable until 2014

*Endocrine Today (04/01/13)*

Pfizer has expanded its recall of Levoxyl (levothyroxine sodium), which may result in the drug being unavailable until 2014. The recall was initially reported during the last week of March when Pfizer subsidiary King Pharmaceuticals sent a letter to healthcare providers and pharmacists letting them know that shipping had been halted for all strengths of Levoxyl on Feb. 13, and that the backorder situation was being discussed with the FDA. Complaints from pharmacists and patients of an "uncharacteristic odor" following the opening of some bottles and a discussion with the FDA, led to the decision to voluntarily recall all strengths of the drug on the retail level. The odor was linked to the oxygen-absorbing canister located in the 100-count and 1,000-count bottles, and "is not likely to cause any adverse health consequences," Pfizer noted. Pharmacists and other healthcare providers are asked to take the shortage into account in their practice patterns and make plans for managing those patients currently taking the drug.

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**First U.S. State Biosimilars Bill Becomes Law**

*PharmaTimes (03/25/13) Taylor, Lynne*

Virginia is the first U.S. state to pass legislation governing the substitution of biosimilar drugs for prescribed biologics, and the generics industry has assailed the new statute for overriding FDA guidance. The law "permits pharmacists to dispense a biosimilar that has been licensed by the U.S. [FDA] as interchangeable with a prescribed biological product unless the prescriber indicates such substitution is not authorized or the patient insists on
dispensing of the prescribed biological product." It also "requires any pharmacist who dispenses an interchangeable biosimilar to inform the patient prior to dispensing the biosimilar and record the brand name or the product name and name of the manufacturer of the biosimilar on the record of dispensing and the prescription label."

Patient Genetics the Basis for Mount Sinai Prescription Support Tool
Fierce HealthIT (04/08/13) Bowman, Dan

Mount Sinai Medical Center in New York has created a system that promises to help physicians write prescriptions that are more tailored to the needs of their patients. The system, which is being tested through Mount Sinai's Clinical Implementation of Personalized Medicine through Electronic health Records and Genomics (CLIPMERGE) program, requires patients to submit saliva samples so that their genetic information can be entered in a database. This information is then used to help predict how certain drugs will affect each patient. Healthcare providers will automatically receive alerts from the system in the event that a patient is prescribed a drug which has a higher risk of side effects.

FDA Approves Novartis Antibacterial Treatment for Cystic Fibrosis
Drug Store News (03/25/13) DeArment, Alaric

The FDA has approved a treatment for managing a type of bacterial infection in patients with cystic fibrosis. Novartis announced the approval of tobramycin inhalation powder (Obi Podhaler) for managing cystic fibrosis patients with Pseudomonas aeruginosa, or Pa bacteria, in the lungs. The product is the only FDA-approved dry-powder inhaled antibacterial for Pa in the United States. The safety and effectiveness of tobramycin inhalation powder was evaluated in a clinical study that assigned 95 pediatric and adult patients to receive the drug or a placebo. Results showed that patients treated with tobramycin achieved a 12.5 percent increase in forced expiratory volume in one second (FEV1) compared to 0.09 percent in patients treated with placebo. Common adverse events reported in the study included cough, including a cough that produces phlegm or mucus; hemoptysis; lung disorder; shortness of breath; fever; mouth and throat pain; dysphonia; and headache.

Clinical Specialties Compounding Pharmacy Products: Recall - All Sterile Products Recalled Due To Lack of Sterility Assurance
Medwatch (03/21/2013)

Clinical Specialties is voluntarily recalling all lots of sterile products repackaged and distributed by the pharmacy due to lack of sterility assurance. This action follows the pharmacy's initial recall of bevacizumab (Avastin) after five patients were diagnosed with endophthalmitis infections associated with intravitreal injection of the product. The updated recall now also includes all sterile products distributed nationwide by Clinical Specialties between October 19, 2012 and March 19, 2013.

Duloxetine May Ease Neuropathy From Chemo
MedPage Today (04/02/13) Petrochko, Cole

A phase III trial recently published in the Journal of the American Medical Association has found that the depression and anxiety drug duloxetine is effective at treating peripheral neuropathy caused by chemotherapy. The study found that peripheral neuropathy patients who took duloxetine for five weeks experienced significantly larger decreases in pain as measured by the Brief Pain Inventory Short Form than did those in the placebo group. In addition, the study found that 59 percent of duloxetine patients experienced some degree of pain reduction, compared with 38 percent of patients given a placebo. However, patients who were given duloxetine and then given a placebo had a higher drop out rate than patients who took the placebo before taking duloxetine.
Neshoba General Announces New Outpatient IV Infusion Unit
*Neshoba Democrat (MS) (03/20/2013)*

Neshoba County General Hospital and Nursing Home has announced the opening of the Outpatient IV Infusion Unit. The infusion unit will feature registered nurses and trained pharmacists with specialized training in IV infusion therapies. The nurses are trained to provide a wide range of infusion therapy services for IV antibiotics and chronic disease.

Statin Side Effects: Brigham and Women's Hospital Study Indicates They Usually Go Away
*Boston Globe (04/01/13) Kotz, Deborah*

Researchers at Brigham and Women's Hospital have published a study about the adverse events associated with statins. The study examined the medical records of nearly 108,000 patients treated with statins over an eight-year period, and found that approximately 17 percent stopped taking the drugs because of various adverse events. However, more than half of these patients were eventually able to start taking statins once again and achieve good results, indicating that some adverse events associated with statins go away in time. Researchers said that patients who experience adverse events while on statins should consider switching to a different drug or taking a lower dose.

Bill Would Allow Prescription, Distribution of Naloxone
*Cincinnati.com (OH) (04/02/13) DeMio, Terry*

Kentucky Gov. Steve Beshear is expected to sign into law a bill that would make it easier to distribute a drug used to counteract overdoses in opiate users. Under the bill, which will likely be signed into law in July, doctors and pharmacists will be able to distribute nasal naloxene so that a third party can administer the drug to people overdosing on street drugs like heroin or opiate prescription medications. The bill an attempt to address the problem of opiate overdoses in Kentucky. It remains to be seen how a sufficient amount of nasal naloxene will be distributed to pharmacies so that it can be given to those who need it.

Physician-Patient Alliance for Health & Safety Invites Participation in the First National Survey of Patient-Controlled Analgesia Practices
*Albany Times Union (NY) (03/20/13)*

The Physician-Patient Alliance for Health & Safety (PPAHS) is soliciting participation in what is believed to be the first countrywide survey on patient-controlled analgesia practices. "Data from the survey should provide valuable information that will help determine current practices and indicate practices that may be adopted to improve patient safety and health outcomes," said PPAHS executive director Michael Wong. Physicians, nurses, respiratory therapists, pharmacists, and other healthcare providers are encouraged to participate in the research, which is being conducted in cooperation with the nonprofit A Promise to Amanda Foundation. The survey can be accessed at http://www.surveymonkey.com/s/PCAhospitalsurvey.