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A STUDENT-OPERATED NEWSLETTER BY THE ST. JOHN'S UNIVERSITY COLLEGE OF PHARMACY AND HEALTH SCIENCES' RHO CHI BETA DELTA CHAPTER

Inside This Issue

An Interview with Dr. Barile: Professor, Reseacher, and Editor

By: Katharine Cimmino, Editor-in-Chief & Bharat Kirthivasan, Co-Copy Editor

Frank A. Barile, Ph.D. is a Professor of Clinical and Applied Toxicology at St. John's University College of Pharmacy and Health Sciences. He is also a St. John's University alumnus, having received a B.S. in Pharmacy, an M.S. in Toxicology, and a Ph.D. in Pharmacology. At St. John's University, Dr. Barile teaches several undergraduate courses including Drugs and Disease Neurology, Drugs and Disease Cancer Chemotherapy, Pharmacotoxicology, Clinical Immunology, Anatomy and Physiology and graduate advanced topics in Clinical Toxicology and Cell Culture Methods. In addition to being a professor, Dr. Barile is also a published author and participant on many editorial boards. Most notably, he is the Editor-in-Chief of Toxicology in Vitro. Toxicology in Vitro publishes original research on the use of in vitro systems to understand the toxicology of chemicals. Dr. Barile joined St. John's University back in 2000 for the research experiences as well as to teach pharmacy and toxicology students. He commented that the nice thing about working at St. John's University is the opportunities that a private university has to offer. He said, "One can still do research even if you don't acquire a ton of grant money. Actually here at St. John's you are rewarded for research and rewarded for publishing material."

Read the Full Interview on Page 20

Single Line Stories

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The editors & staff of the Rho Chi Post

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to the family and friends of

Dr. Amrit L. Kapoor

Professor
Department of Pharmaceutical Sciences
College of Pharmacy and Health Sciences

In lieu of flowers, contributions can be made to the
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College of Pharmacy and Health Sciences
St. Albert Hall – Room 164A

NEWS

Novel Virus, Standard Vigilance

By: Davidta Brown, Staff Editor

When the seasons transition from winter into spring, healthcare providers brace for a shift into a time of increased sneezes, requests for cough medication, and vaccinations, otherwise known as flu season. The rounds of illness that pass each year are usually more of an annoyance than a cause for serious concern, and typically only pose a threat to the very young, the elderly, and those of compromised immune systems. However, during some years, the strain of influenza virus is more dangerous and requires more than the usual surveillance. For example, the influenza A, subtype H7N9 virus that appeared in China this past spring proved to be virulent enough to warrant international concern and investigation, and provided an opportunity for the public health defenders of the world to put protocol and procedure to the test.

The first introduction to a new flu virus came in March of this year, with the hospital admission of three individuals – two from the city of Shanghai, and one from the Anhui province – in eastern China.[1,2] Throat-swab samples were collected from the patients and were put through the reverse-transcription polymerase chain reaction where they were then tested with probes for the H1 to H16 and N1 to N9 influenza subtypes.[3] These tests proved that the flu variety that had caused severe sickness, and eventually death for the three patients, was an avian H7N9 virus. While H7 viruses are common in birds, they had never before been observed among the human population in Asia.[1] The N9 classification was even more unusual, as human infection with this subtype had previously never been documented. As more and more cases appeared across eastern China, and with the median time between symptom onset and death at most twenty days, it soon became clear that this new influenza outbreak warranted decisive action; Chinese authorities therefore took the first step by closing markets that sold live birds.[2, 4]

After the identification of the new type of viral threat, the next course of action was sequencing the genetic material of H7N9. The viral sequences obtained from the original three cases first needed to be tested for similarity. This was achieved as the sequences were shown to be 97.7% to 100% identical.[2] Next, phylogenetic analysis needed to be performed in order to trace the avian origins of H7N9. It was found that the gene coding for hemogluttin in this viral strain was most similar to H7N9 subtype KO14, found in a duck in Zhejiang in 2011. Furthermore, six internal genes in the new virus were closest to influenza A (H9N2), found in a brambling (a small bird) in Beijing.[3] The observed variation in genetic origins made it clear that H7N9 was the result of reassortment between several bird flu viruses.

Further genetic analysis indicated traits in the new virus that proved to be of great significance in understanding its transmission and virulence. The absence of certain key insertion and deletion mutations in the genetic sequence for hemgglutinin revealed that H7N9 is actually a "low-pathogenic" virus for many bird species, including chickens.[2] This means that the pathogen could be spread across avian populations without detection because of its nearly asymptomatic nature in birds, while still posing serious risk to people who come into contact with the infected poultry. Also of clinical importance was a mutation identified in the PB2 proteins of some of the viral samples collected from human cases reported later; single amino-acid substitutions at positions 627 or 701 suggested enhanced viral replication at temperatures similar to those found in the upper airways of humans and other mammals.[1,2] Curiously, these mutations were not observed in H7N9 samples collected from birds, suggesting that they were selected

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for in the human host.[2] With the obvious significance of these genetic discoveries, the full genome sequences of influenza A (H7N9) were deposited into the Global Initiative on Sharing Avian Influenza Data database on March 29th of this year.[3]

While most confirmed cases of influenza A (H7N9) could be traced to contact with live birds such as those found in open markets, one patient had no known experience of such contact in the two weeks prior to the onset of symptoms.[1] Consequently, transmission of the virus through the air has not been ruled out, nor has the possibility of another mammalian reservoir, pigs being the most likely candidates.[1] Additionally, the lack of known contact between the confirmed cases, as well as a phylogenetic distinction between one of the original three H7N9 patients and the other two, indicate the likelihood that the virus has had at least two introductions into human populations.[2, 3]

Confirmed cases of the H7N9 virus were studied for their clinical implications, such as symptoms and typical treatments, the information likely of most interest to both healthcare providers and the general public. A case of H7N9 was considered "confirmed" upon diagnosis of pneumonia with H7N9 viral RNA, or upon isolation of the virus itself from a patient's respiratory specimens.[3] Among all of the cases identified, the most common symptoms were most typically "flu-like", namely high fever and cough.[3] However, the complications of infection were usually more serious, consisting of septic shock, respiratory failure, or bacterial and fungal infections.[2] Acute respiratory distress syndrome was also a common result.[3] It should be noted that the majority of confirmed cases were in patients with underlying chronic conditions, and that those hospitalized with pneumonia and with a history of systemic, high-dose steroid use appeared susceptible to increased viral replication and the emergence of antiviral resistance.[2]

The median time span between the onset of influenza symptoms and hospitalization among all of the cases observed to date is four-and-a-half days, and as mentioned before, the time between symptom onset and death ranges from seven to twenty days.[2] Clearly, prompt diagnosis and treatment are of the utmost importance in dealing with H7N9. A substitution mutation in the M2 protein of the virus indicated resistance to adamantane antiviral drugs, but the influenza strain did display sensitivity to neuraminidase inhibitors, leading experts to suggest that oral oseltamivir or inhaled zanamivir be used as soon as possible in confirmed or suspected cases.[1, 5]

At present, there have been a total of 132 human cases of H7N9 infection, and 37 reported deaths.[5] The potential for an even more widespread epidemic prompted the World Health Organization to suggest the use of the viral sample isolated from the patient in Anhui in the preparation of vaccines, in case of a future pandemic.[5] In addition, the WHO is still on watch for events considered "high significance", such as new cases of H7N9, or evidence of human-to-human transmission.[2] While the number of detected cases fell sharply after April of this year, perhaps due to containment measures and the change of seasons, public health officials continue to keep a watchful eye on the pathogen that could potentially become an international crisis when cold weather returns.[4]

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NEWS

FDA's New Warning: Acetaminophen Associated with Serious Skin Reactions

By: Andy Zhang, PharmD Candidate c/o 2015

On August 1st, 2013, the U.S. Food and Drug Administration (FDA) released a new warning of serious acetaminophen associated skin reactions, including Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN) and acute generalized exanthematous pustulosis (AGEP).[1] Acetaminophen is one of the most widely used over-the-counter (OTC) medication, and can be found as an individual drug or in combination with other drugs used to treat pain and fever. The FDA now requires warnings on all the labels of prescription medications containing acetaminophen and is working with manufacturers to have the warnings added to the labels of OTC medications as well.[2]

SJS, TEN and AGEP are rare skin disorders that occur in less than ten out of one million cases annually.[3,7] Both SJS and TEN are characterized by the acute onset of painful blistering eruptions that form over a person's body, usually within seven to fourteen days of exposure, that then undergo necrosis and slough off.[3]

The rapid peeling of the epidermis results in significant fluid loss, drop in blood pressure, electrolyte imbalance, and secondary skin infection. The condition is classified as SJS when skin sloughing is less than 10% of the body surface, and TEN when skin sloughing is greater than 30%. Anything that lies in between 10% and 30% is considered a SJS/TEN overlap.[4] Because of the rapid deterioration of the two disorders, mortality rates are high—SJS and TEN have 10% and 30% mortality rates, respectively.[4] These disorders are immune complex hypersensitivity reactions to offending agents, most notably drugs, and require immediate medical attention.[3] Patients with SJS/TEN present with fever, headache and respiratory symptoms.

Although AGEP is also associated with exposure to drugs, it is characterized by acute formation of pustules over erythematous skin, unlike the other two disorders.[5] Patients often present with fever and blood leukocytosis, which can be self-limiting after the discontinuation of the offending agent.[6] Mortality rate of AGEP is around 5%.[6]

Evidence supporting the relationship between acetaminophen and serious skin reactions comes from a small number of cases, in which patients who have already experienced adverse skin reactions are re-challenged with acetaminophen without any other medications and experience adverse serious skin reactions.[2] Other supportive data were found in the FDA Adverse Event Reporting System (FAERS) database and literature.[2] A search through the FAERS database revealed 91 cases of SJS/TEN and 16 cases of AGEP from 1969 to 2012, in which acetaminophen was the only drug administered before the reaction. The majority of the doses taken were within the recommended dosing ranges. Of all the cases 67 ended in hospitalizations and 12 in deaths.[2]

Pharmacists need to be aware of the warning put out by the FDA and be able to talk to their patients about taking acetaminophen, the risk of developing skin reactions, and how to respond to a reaction if it does occur. Even if they had no problems with the medication in the past, patients should still be counseled on the adverse skin reactions that can occur with acetaminophen.[2] Patients should also be notified that if they develop a skin rash or reaction after using a product containing acetaminophen, they should stop using the product and immediately seek medical attention. A dermatologist can evaluate whether or not the skin reaction is related to acetaminophen.[2] Patients who have had serious skin reactions to acetaminophen should not take acetaminophen, but use other non-steroidal anti inflammatory drugs (NSAIDS) for treatment of pain or fever. Even though some NSAIDs carry similar warnings for serious skin reactions, cross-reactivity is not common. This means that one will not necessarily have adverse skin reactions with NSAIDs if he/she has adverse reactions against acetaminophen.[2]

Acetaminophen labeling has always been subject to change due to safety reasons. In April of 2009, the FDA required all manufacturers of OTC acetaminophen products to include a warning for potential internal bleeding and liver damage.[1] In 2011, the FDA required black box warnings for severe liver damage and allergic reactions on all prescription products containing acetaminophen.[1] Other

changes include changes in the concentration of acetaminophen in liquid dosage forms for infants, and attempts to reduce the acetaminophen dose in prescription products to 325mg.[1,8] There are no strength changes to OTC products as of yet.

Lisa Kubaska, PharmD, a spokesperson for the FDA, says that the Division of Nonprescription Regulation Development is still gathering information before proposing any changes.[1]

The new changes for acetaminophen might be alarming for many patients and health professionals. However, this does not mean that people should avoid using the medication. Because serious skin reactions are rare, the benefits of taking acetaminophen still outweigh the risks. Nonetheless, all health professionals must be aware of the newly established adverse effect, be mindful when evaluating any skin conditions for possible association with acetaminophen, and report any medication adverse effects to the FAERS.

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NEWS

HIV Test: Making a Difference

By: Sang Hyo Kim, Staff Editor

On June 27, 2013, the Centers for Disease Control and Prevention (CDC), AIDS.gov, and other national and local entities organized the 19th annual National HIV Testing Day. On this day, the theme of "Take the Test, Take Control" was employed to spread awareness of testing and prevention methods to those at risk of contracting HIV.[1]

The National HIV Testing Day was launched in 1995 and was created by the National Association of People with AIDS in response to the growing number of HIV infections in communities of color and other heavily impacted communities.[2] Approximately 1.1 million people in the United States are living with HIV, one in five of whom do not know they are infected.[1]

HIV testing is a crucial first step in taking control and responsibility of one's health. The U.S. Preventive Services Task Force (USPSTF) recommends that everyone from the ages of 15 to 65 should be screened for HIV. Those younger than 15 and older than 65 years of age should also be screened if they are at a high risk of infection. The CDC also recommends that homosexuals and bisexuals, people with multiple partners, or those who use intravenous drugs get tested at least once a year. Further data from the CDC suggests that sexually active gay and bisexual men can benefit more if they get tested every three to six months. Getting tested allows people to know their HIV status and, if infected, get proper medical treatment and prevent HIV transmission to others.[3]

Getting tested is simple because primary doctors can perform the test. There are also two FDA-approved tests that can be used at home: Home Access HIV-1 Test System and OraQuick in-Home HIV Test.[4,5] The Home Access HIV-1 Test System, the only current home kit to be clinically proven more than 99.9% accurate, can be found in most drug stores and involves collecting a finger stick blood sample, sending it to a licensed laboratory, and calling in later for results.[4] Customers are given an identification number and can speak to a counselor while waiting for results. If an individual is tested positive, he or she is provided with referral for a follow-up confirmatory test, and is also provided with other treatment and support services.[4]

The OraQuick in-Home HIV Test, found online and in stores, is a rapid home-use HIV test kit that does not require sending a sample to a laboratory for analysis. It provides results in 20-40 minutes by using a swab of oral fluid from the gums.[4] The test is not as efficient as the Home Access HIV-1-Test system because it can give false negatives if tested within three months of infection.[5] People who test positive must perform a follow-up confirmatory test before a final diagnosis of infection can be made.[5]

The CDC's effort to increase HIV testing is not only made on an annual National HIV Testing Day. In 2010, the CDC implemented new phases of its successful Expanded Testing Initiative by funding thirty health departments to focus on increasing HIV testing among African Americans, Latinos, gays and bisexuals, as well as injection users of all ethnicities. Additionally, the CDC's "Act Against AIDS" (AAA) aims to expand HIV testing by raising awareness to all Americans and reducing infection among the hardest hit populations.[3]

With the emphasis on HIV testing by the CDC and other local and national organization, everyone should be proactive and opt to be tested. By getting tested and encouraging friends and families to do the same, transmission can be prevented and early

treatment is possible. With a collaborative effort, everyone can be closer to an AIDS free generation.

For more information on HIV testing, and HIV/AIDS related question, please visit the site:

http://hivtest.cdc.gov/faq.aspx#tested

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NEWS

Olmesartan Medoxomil Label Revision

By: David Ong, PharmD Candidate Class of 2014

Manipulating the renin-angiotensin system is one of the many ways drugs are used to treat hypertension. By blocking key steps in the renin-angiotensin cascade, a decrease in blood pressure may be achieved. Angiotensin II receptor blockers (ARBs) represent one of the drug classes that utilize the aforementioned mechanism. ARBs displace angiotensin II from the angiotensin I receptor, which in turn lowers blood pressure by decreasing angiotensin II-induced vasoconstriction, aldosterone release, catecholamine release, arginine vasopressin release, water intake, and hypertrophic response.[1]

ARBs were originally developed to overcome the shortcomings of its predecessor- angiotensin converting enzyme inhibitors (ACE inhibitors). Angiotensin converting enzyme is a relatively nonspecific enzyme with substrates ranging from angiotensin I to bradykinin. Therefore, ACE inhibitors have a larger range of side effects compared to ARBs. Cough and angioedema are examples of side effects that may be exhibited from the use of ACE inhibitors. The more selective mechanism of action displayed by ARBs has been speculated to reduce side effects and improve clinical efficacy.[1] Side effects of ARBs include but are not limited to hyperkalemia, hypotension, and dizziness.[2]

An example of an ARB is olmesartan medoximil, more commonly known as Benicar®. Unlike the other agents in its class however, olmesartan has been linked to the development of a serious intestinal disorder: sprue-like enteropathy. Sprue-like enteropathy is a form of intestinal problem characterized by symptoms of chronic severe diarrhea with substantial weight loss. The enteropathy has been linked to the usage of olmesartan medoximil and may develop months to years after the initiation of drug therapy.

When such symptoms develop and other causes are ruled out, the drug should be discontinued and an alternative anti-hypertensive medication should be started.[3] Upon discontinuation, clinical improvement of the sprue-like enteropathy has been observed. Symptoms of sprue-like enteropathy recurred in patients who restarted the medication.[4] The FDA stated in July 2013 that the labeling of olmesartan

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will reflect the new safety concern.[1] There have been 23 reported cases of sprue-like enteropathy, some involving hospitalization, in patients using olmesartan medoximil.[3]

The FDA has advised clinicians to ensure that patients on olmesartan are aware of the symptoms of sprue-like enteropathy, and to seek medical attention it they experience symptoms. If no other causes of the symptoms are identified, olmesartan should be discontinued.[1]

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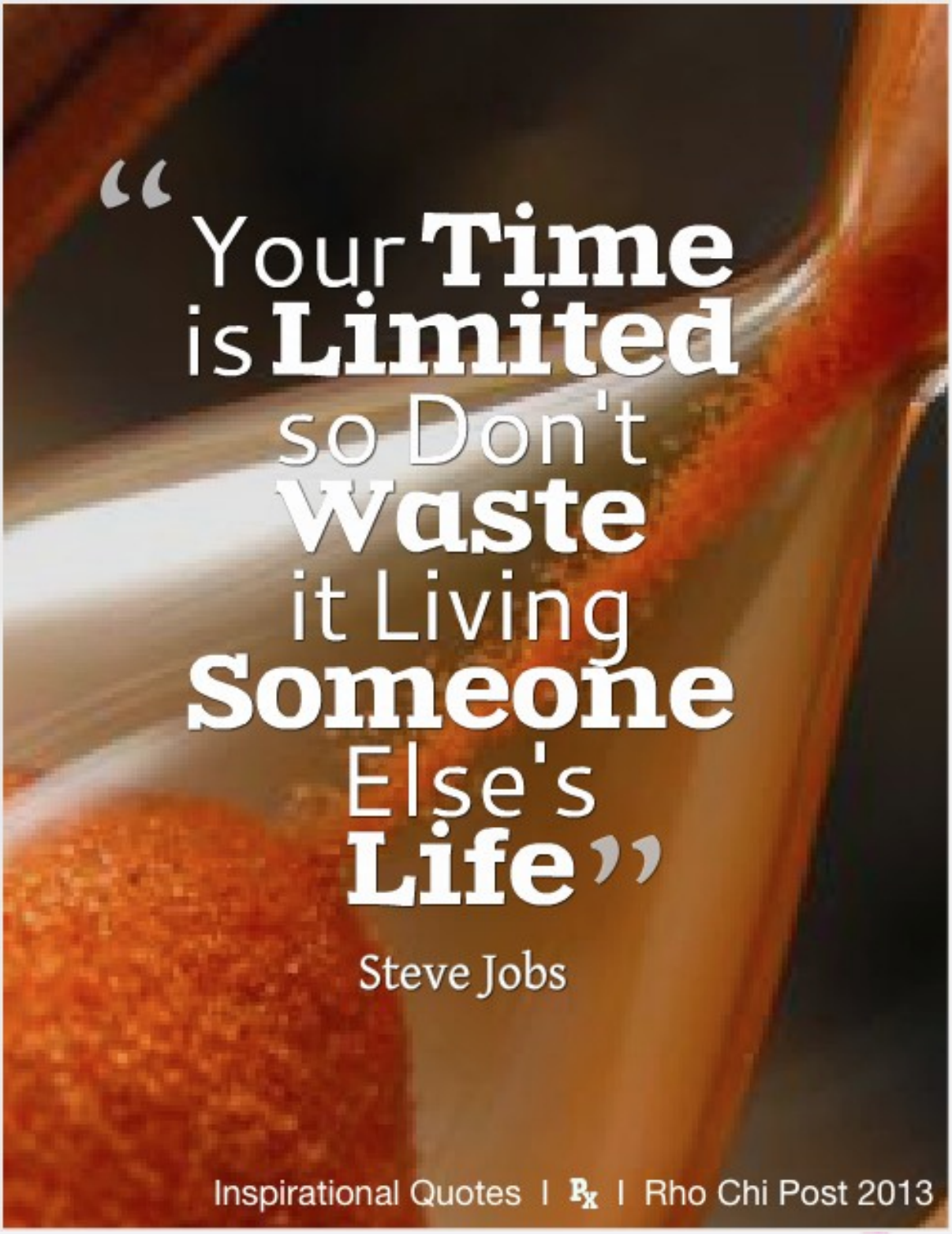
Quote of the Month

By: Melissa Roy, Co-Copy Editor [Graphics-Focused]



CLINICAL

Children, Codeine, and Cytochrome P-450

By: Davidta Brown, Staff Editor

For post-operative pain treatment, few drugs are as trustworthy, and as tried-and-true, as codeine. Prescriptive confidence in the analgesic has promoted its use in children recovering from uncomplicated surgeries, but the spate of injuries and deaths of young children who had been given codeine after undergoing adenotonsillectomies has provoked a second, more calculating look at it. In light of new revelations in the relationship between genetic variation and pharmacology, specifically with regards to a gene known as *Cytochrome 2D6*, the FDA has instituted a boxed warning for all codeine-containing drugs, as well as a contraindication for all children who have had either an adenoidectomy or a tonsillectomy.[1]

Codeine is an opioid analgesic used to treat mild to moderate pain. It's also used for coughs and colds in conjunction with acetaminophen.[1] The biological activity of codeine depends on its conversion to morphine by an enzyme called Cytochrome P-450 isoenzyme 2D6 (CYP2D6) in the liver.[2] After this transformation, morphine is metabolized into its active form, morphine-6-glucuronide.[1,2] Only 15% of ingested codeine is actually demethylated into morphine, but the effects of the drug are still of clinical significance because of morphine's 200-fold greater affinity for the μ opioid receptor over codeine.[3]

"The FDA has instituted a boxed warning for all codeine-containing drugs, as well as a contraindication for all children who have had either an adenoidectomy or a tonsillectomy."

The gene that codes for CYP2D6 is highly polymorphic, with more than ninety known allelic variations.[4] An individual's phenotype for this gene is reported as a diplotype: 1 maternal and 1 paternal allele.[5] The clinical significance of these allelic variations comes from their classifications as wild-type (also called normal function), reduced-function, or nonfunctional, and the biological effects of these allelic classifications are multiplied by the number of copies of each allele, which can be more than two in rare cases.[5]

Enzymatic activity directly affects drug efficacy and metabolism, and it is this metabolic activity that interests health care providers. About 75% – 92% of the population have allelic combinations that produce a normal range of CYP2D6 enzymatic activity, and these individuals are known as "extensive metabolizers".[2]At the lower extreme are the "poor metabolizers", the 5% – 10% of the population who have low enzymatic activity, and in whom codeine displays little to no analgesic efficacy.[2] Finally, there are the "ultra-rapid" metabolizers who, with two or more functional alleles, convert standard codeine doses into disproportionately large, potentially dangerous amounts of morphine, in a short period of time.[2]

Toxic effects due to such opioid excesses have been reported sporadically over the past decade, culminating in a report published in April 2012. This publication detailed one case of respiratory depression and two cases of death in children aged three to five; the two children who died were discovered to have been ultra-rapid metabolizers of codeine, while the one with respiratory depression was an extensive metabolizer.[2] The two fatal incidents occurred during the recovery period of a surgery to address obstructive sleep apnea, and in all cases; there were signs of morphine toxicity within two days of the start of codeine administration.[1,2]

After analysis of these data, the FDA released a Safety Communication document in which it was conjectured that pre-existing breathing difficulties, for which these children received treatment, may have rendered them particularly sensitive to the type of respiratory distress that can result when codeine is suddenly converted to high levels of morphine.[1]Ciszkowski et al. also suggest that the recurrent hypoxemia that can occur in children with chronic breathing difficulties may alter existing mu-opioid receptors, potentially leading to increased morphine sensitivity.[6] In other words, genetic predisposition to ultra-rapid metabolism of codeine, pre-existing respiratory abnormalities, and the type of surgeries

often prescribed to treat these abnormalities are potentially a perfect storm of respiratory failure and tragedy.

When the FDA first announced warnings about the risks of codeine in children who had been treated for obstructive sleep apnea with adenotonsillectomy, they urged health care providers to prescribe codeine at the lowest effective doses, for the shortest time possible, as needed.[7] In late February 2013, these warnings were upgraded to a contraindication for codeine use in sensitive patients, and a requirement for a new warning on all products containing codeine, as previously mentioned.[1,2] Instead of codeine, it was suggested that analgesics like morphine, methadone, or a non-opioid treatment be prescribed to both poor and ultra-rapid metabolizers.[5]

Since genetics are the most significant determining factor in whether codeine treatment will endanger a patient, and as these genetic traits can be analyzed in a laboratory, one might reasonably wonder why genetic testing is not performed prior to surgery as means of determining appropriate post-op treatment. Unfortunately, genetic disposition doesn't guarantee an individual's reaction to codeine. Recall that one of the three children who suffered serious complications from post-op codeine administration was at the normal, extensive metabolizing, enzyme activity level.[1] And perhaps the simpler truth is that genetic analysis is just not a part of the traditional health examination. However, as the intricate ties between genetics, protein functions, and pharmacology become less nebulous, health care could be on the verge of a brave new world of personalized medicine, of which codeine and a gene called *CYP2D6* are just the beginning.

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CLINICAL

A Close Concurrence on Certolizumab (Cimzia®)

By: Sang Hyo Kim, Staff Editor

This year, on July 23rd, FDA advisers voted 7 to 6, with one abstention, in favor of approving the drug certolizumab (Cimzia®) for the indication of axial spondyloarthritis (axSpA). axSpA is a chronic inflammatory condition that includes ankylosing spondylitis (AS) and non-radiographic axial spndyloarthristis (nr-axSpA).[1,2] axSpA, AS and nr-axSpA, are forms of inflammatory arthritis that mainly affects the spine and pelvic joints.1 The main feature that distinguishes axSpA from nr-axSpA is that nr-axSpA cannot be diagnosed by utilization of radiographic imaging.[2]

Certolizumab (Cimzia®), marketed by UCB Inc., belongs to the tumor necrosis factor (TNF) inhibitor class of drugs, which are used to treat autoimmune diseases such as rheumatoid arthritis (RA) and Crohns

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Disease.[2,3] Rheumatoid arthritis is a form of inflammatory arthritis, while Crohn's Disease is a form of inflammatory bowel disease that usually affects the intestines.[4,5] Certolizumab, approved for Crohn's disease and RA in 2008 and 2009, respectively, is administered by subcutaneous injection every four weeks for Crohn's disease and every other week or every four weeks for RA as maintenance therapy.[3] Certolizumab is a breakthrough drug because although there are four other TNF inhibitors that are approved for ankylosing spondylitis (AS), these medications are not approved for treating nonradiographic axial spondyloarhtritis (nr-axSpA).[3]

The approval of certolizumab came from a study of 325 patients: 178 patients with AS and 147 patients with nr-axSpA.[3] The pivotal study compared two dosing regimens of certolizumab against placebo for patients who had an inadequate response or a contraindication to NSAIDS.[3] Like the regimens currently approved to treat rheumatoid arthritis, the recommended dosing is 400 mg in weeks 0, 2, and 4, followed by either 200 mg every 2 weeks (Q2W) or 400 mg every 4 weeks (Q4W). 58% of patients on the Q2W regimen and 64% on the Q4W regimen had achieved an ASAS (Assessment of SpondyloArthritis International Society) 20 response, a primary endpoint at 12 weeks, compared with 38% of those on placebo; ASAS 20 response is defined as an improvement of at least 20% and absolute improvement of at least 10 units on a 0-100mm scale in at least 3 of the following domains (See for criteria: (http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003425.pdf).[3,6] The differences also remained significant at 24 weeks, in which the ASAS20 response in the two subpopulations, AS and nr-axSpA, also favored those treated with certolizumab.[3] The rates of serious adverse events were similar in the certolizumab-treated and placebo groups, and the safety profile of certolizumb corresponded to that of other TNF inhibitors.[3]

Although with the approval, many concerns were raised. Advisory panels of the FDA, who voted against it, say that the indication is too broad, especially for those treated with nr-axSpA, since the number of patients in the clinical trial was too small.[3]Additionally, the panels believe that there is a lack of clear definition of active disease in the nr-axSpA indication, as well as the possibility of primary care physicians prescribing the biologic drug for patients with lower back pain.[3] However, panelists supporting the approval say that adequate prescribing information will result in appropriate use for patients with active disease in clinical practice.[3] Dr. Janet Maynard, a clinical team leader in the FDA's Division of Pulmonary, Allergy, and Rheumatology Products, further states that the FDA did not base the efficiency of the drug solely on the subgroups and that the data for AS appear reasonable.[3] With its debate, certolizumab will be keenly observed.

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RHO CHI POST CLINICAL CORNER

DIABETES MELLITUS

By: Aleena Cherian, Co-Copy Editor [Graphics-Focused]

DIAGNOSIS CRITERIA

- HEMOGLOBIN A1C ≥6.5%
- FASTING PLASMA GLUCOSE (FPG)≥126 MG/DL FOR TWO READINGS
- 2H PLASMA GLUCOSE ≥200 MG/DL (11.1 MMOL/L) DURING AN ORAL GLUCOSE TOLERANCE TEST (75G OGTT)
- RANDOM PLASMA GLUCOSE ≥ 200 MG/DL (WITH CLASSIC SYMPTOMS OF HYPERGLYCEMIA OR HYPERGLYCEMIC CRISIS)

TESTING/SCREENING FOR DIABETES

- ADULTS OF ANY AGE WHO ARE OVERWEIGHT/OBESE (BMI ≥ 25 KG/M2) WITH ADDITIONAL RISK FACTORS FOR DIABETES OR AFTER AGE 45 (REPEAT EVERY 3 YEARS IF NORMAL)
- CHILDREN AND ADOLESCENTS WHO ARE OVERWEIGHT AND WHO HAVE TWO OR MORE ADDITIONAL RISK FACTORS FOR DIABETES
- PREGNANT WOMEN NOT PREVIOUSLY KNOWN TO HAVE DIABETES AT 24-48 WEEKS FOR GDM USING 72G 2H OGTT
- WOMEN WITH GDM FOR PERSISTENT DIABETES AT 6-12 WEEKS POSTPARTUM (OGTT)

PREVENTION/ DELAY OF TYPE 2 DIABETES

Impaired glucose tolerance (IGT), impaired fasting glucose (IFG) or A1C of 5.7-6.4%
- Lifestyle modifications
  - Weight loss of **7% body weight**
  - Increased physical activity to at least **150 min/week** (after consultation with healthcare provider)
  - Dietary strategies:
    - reduced calories, reduced dietary fat, foods containing whole grains, dietary fiber of 14g fiber/1000 kcal (USDA recommendations), limited intake of sugar sweetened beverages, limit alcohol intake to <1 drink/day (adult women) or 2drinks/day (adult men)
    - Smoking cessation
  - Consider metformin therapy for prevention, especially in patients with BMI>35 kg/m2, age <60 and women with prior gestational diabetes (GDM)

Screen and treat modifiable risk factors for CVD

GLYCEMIC GOALS

- **A1c < 7% :** for most nonpregnant adults- reduces microvascular complications of diabetes and long term reduction in macrovascular disease (if implemented soon after diagnosis)
- **A1C < 6.5%** (more stringent goals): for patients with short duration of diabetes, long life expectancy, no significant CVD, if this can be achieved without significant hypoglycemia
- **A1C < 8%** (less stringent goals) : for patients with history of severe hypoglycemia, limited life expectancy, advanced vascular complications, extensive comorbidities, long-standing diabetes

PHARMACOLOGIC AND OVERALL APPROACHES TO TREATMENT

Type 1 Diabetes

Insulin therapy
- MDI injections (3-4 injections/day of basal or prandial insulin)
- Continuous subcutaneous insulin infusion (CSII)

Patient education: match prandial insulin to carb intake, premeal glucose, anticipated activity

Consider screening for other autoimmune illnesses: thyroid, vitamin B12 deficiency, celiac disease

Type 2 Diabetes

First line
- Metformin (if tolerated and not contraindicated): preferred initial agent
- Insulin therapy (with or without additional agents): consider in some patients with newly diagnosed T2DM- markedly symptomatic and/or elevated blood glucose or A1C

Second line
- If noninsulin monotherapy at maximal tolerated dose does not achieve or maintain the A1C over 3-6 mo: add additional oral antihyperglycemic, GLP-1 agonist or insulin
  - Sulfonylurea (glyburide, glipizide, glimepiride)
  - Thiazolidinedione (pioglitazone)
  - DPP-4 inhibitor (sitagliptin, saxagliptin, linagliptin)
  - GLP-1 agonist (exenatide, liraglutide)
- Use patient centered approach (consider efficacy, cost, potential side effects, effects on weight, comorbidities, risk of hypoglycemia, patient preferences)

If target A1C not achieved after ~3 additional months, consider adding a third agent

If 3 drug combination (including basal insulin) does not achieve target A1C after 3-6 months, move to a more complex insulin regimen (multiple daily doses) with 1-2 non insulin agents. sulfonylureas/meglitinides generally avoided in these patients

HYPOGLYCEMIA

Preferred treatment: glucose 15-20 g
- repeat if hypoglycemia continues 15 minutes after treatment
- consume meal/snack to prevent recurrence

Prescribe glucagon for all individuals at severe risk

Reviewed by: Dr. Jodlowski and Dr. Zito, Clinical Pharmacy Practice Department

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MANAGEMENT OF COMORBIDITIES			
HYPERTENSION/ BLOOD PRESSURE CONTROL	Goal: SBP/DBP <**130-140/80** Pregnancy: 110-129/65-79 (ACEI/ARB contraindicated)	Lifestyle modifications: weight loss, DASH diet (reduce sodium, increase potassium), moderation of alcohol, increased physical activities	Pharmacologic therapy: (DM + HTN) include **ACEI or ARB** Monitor: SCr/eGFR and serum potassium levels
DYSLIPIDEMIA/ CHOLESTEROL MANAGEMENT	Goals: (if at goal, reassess lipids every 2 years) LDL <100 mg/dL (<70 mg/dL with CVD) Alt therapeutic goal if target not reached: ~30-40% reduction from baseline HDL >50 mg/dL TG <150 mg/dL	Lifestyle modification: reduction of trans fat, saturated fat and cholesterol intake, increased fiber/ plant sterol intake, physical activity, weight loss	Pharmacologic therapy: add **statin** therapy (target LDL) All patients with dyslipidemia and diabetes regardless of baseline lipids for diabetes with overt CVD or without CVD over the age of 40
ANTIPLATELET AGENTS	Consider aspirin 75-162 mg as primary prevention for patients at increased CVD risk Secondary prevention in patients with diabetes and history of CVD (combination therapy with ASA + clopidogrel 75 mg up to a year following ACS) CVD + documented ASA allergy- clopidogrel 75 mg		
MONITORING CHRONIC COMPLICATIONS	Nephropathy (annual assessment of urine albumin excretion, consider ACEI/ARB and lowering protein intake) Retinopathy (optimize glycemic and BP control, eye exam within 5 years of diagnosis) Neuropathy Foot care (comprehensive exams to identify risk of ulcers/amputations)		

AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS / AMERICAN COLLEGE OF ENDOCRINOLOGY CONSENSUS STATEMENT

- LIFESTYLE MODIFICATION, INCLUDING DIET AND EXERCISE ARE NECESSARY FOR ALL PATIENTS WITH DIABETES.
- ALTHOUGH THE RECOMMENDED **A1C** GOAL IS **6.5%**, IN SOME PATIENTS, THIS GOAL MAY BE TOO STRINGENT (E.G., HISTORY OF HYPOGLYCEMIA UNAWARENESS, LACK OF MOTIVATION, LIMITED LIFE EXPECTANCY, ETC).
- EFFECTIVENESS OF THERAPY SHOULD BE EVALUATED FREQUENTLY, FOR EXAMPLE EVERY TWO TO THREE MONTHS, AND THERAPY SHOULD BE ADJUSTED IF NECESSARY.
- SAFETY AND EFFICACY SHOULD BE GIVEN A HIGHER PRIORITY THAN COST BECAUSE COST OF MEDICATIONS IS ONLY A SMALL PART OF THE COST OF CARE OF DIABETES. EMPHASIS SHOULD BE PLACED ON AVOIDING HYPOGLYCEMIA AND WEIGHT GAIN.
- RAPID-ACTING INSULIN ANALOGUES ARE SUPERIOR TO REGULAR HUMAN INSULIN AND PROVIDE A BETTER, SAFER ALTERNATIVE.
- **NPH** INSULIN IS NOT RECOMMENDED FOR USE BECAUSE THE SYNTHETIC INSULIN ANALOGS, INSULIN GLARGINE (***LANTUS***) AND INSULIN DETEMIR (***LEVEMIR***), PROVIDE A RELATIVELY PEAKLESS PROFILE AND PRODUCE MORE REPRODUCIBLE AND CONSISTENT EFFECTS.

The American Association of Clinical Endocrinologists (AACE) prefers GLP-1 agonists (e.g., *Byetta*, *Victoza*) over DPP-4 inhibitors (e.g., *Onglyza*, *Januvia*) because GLP-1 agonists are associated with a greater decrease in postprandial glucose and weight.

Reviewed by: Dr. Jodlowski and Dr. Zito, Clinical Pharmacy Practice Department

CLASS / PHARMACOLOGY	A_1C	AGENTS & DOSING	NOTABLE ADVERSE EFFECTS	COMMENTS / ROLE IN THERAPY
ORAL ANTIHYPERGLYCEMIC AGENTS				
Alpha Glucosidase Inhibitors **competitively blocks α-glucosidase in brush border of small intestines, slowing breakdown of carbohydrates to glucose**	0.5-1%	**Acarbose** (*Precose®)* **Miglitol** *(Glyset®)* INITIAL 25 mg TID MAX 300 mg/day	Weight: neutral GI: Gas, bloating, nausea	Take with meals considered 3rd line (lower efficacy) – ADA
Biguanide **Inhibits hepatic glycogenolysis, gluconeogenesis and enhances insulin sensitivity in muscle and fat.**	1% to 1.5%[3]	**Metformin** (*Glucophage*, *Glucophage XR*) INITIAL 500 mg PO BID or 850 mg PO once daily MAX: 2550 mg/day	Weight: neutral Low hypoglycemia risk GI (abdominal discomfort, stomach upset, diarrhea; less with XR) Lactic acidosis, metallic taste, impaired B12 abs.	Do not use in patients with renal dysfunction (SCr>1.4-5) First line: as initial therapy after lifestyle modification.
Dipeptidyl peptidase-4 (DPP-4) inhibitor **Inhibits degradation of endogenous incretins which increases insulin secretion, decreases glucagon secretion.**	0.5% to 1%[3]	**Linagliptin** (*Tradjenta*) INITIAL: 5 mg PO once daily MAX: 5 mg/day **Saxagliptin** (*Onglyza*) INITIAL: 2.5 or 5 mg PO once daily MAX: 5 mg/day **Sitagliptin** (*Januvia*) INITIAL: 100 mg PO once daily MAX: 100 mg/day	Weight: neutral Hypoglycemia (rare), reports of acute pancreatitis, facial edema Common: headache, nasopharyngitis (generally well tolerated)	With or without food May need dose reduction in renal impairment ADA: second line, add on to metformin (first line if metformin C/I) or part of 3 drug combination
Meglitinide **Stimulates pancreatic insulin secretion.**	0.5% to 1%[3]	**Nateglinide** (*Starlix*) INITIAL: 120 mg PO TID with meals MAX: 120 mg PO TID **Repaglinide** (*Prandin*) INITIAL: 0.5 mg PO TID with meals if A1C <8%, 1 or 2 mg TID with meals if A1C ≥8% MAX: 16 mg/day	Weight: neutral/gain May case hypoglycemia Bloating, abdominal cramps, diarrhea, and flatulence	Caution: hepatic impairment Can be used in renal insufficiency Monitor carefully when glucuronidation inhibitors are given with repaglinide Repaglinide more effective for lowering A1C than nateglinide.
Sulfonylurea-second generation **Stimulates pancreatic insulin secretion from beta cells by closing ATP-sensitive K+ channels**	1% to 1.5%[3]	**Glyburide** (*Diabeta*, *Glynase*, *Micronase*, others) INITIAL: 2.5 mg PO once daily MAX: 20 mg/day **Glipizide** (*Glucotrol*, *Glucotrol XL*, others) INITIAL: 5 mg PO once daily MAX: 40 mg/day **Glimepiride** (*Amaryl*, others) INITIAL: 1 mg PO once daily MAX: 8 mg/day	Weight: gain high hypoglycemia risk (less with glimepiride versus glyburide). Rash, hemolytic anemia, cholestasis	Reduced efficacy over time. second line, add on to metformin or part of 3 drug combination take with meals risk for hypoglycemia greater in liver disease or renal insufficiency monitor with CYP 2C9 inhibitors
Thiazolidinedione (TZD) **Enhances insulin sensitivity in muscle and fat by increasing glucose transporter expression (binds peroxisome proliferator activator receptor-γ, PPARγ and stimulates lipid uptake)**	1% to 1.5%[3]	**Pioglitazone** (*Actos*) INITIAL: 15 mg PO once daily MAX: 45 mg/day **Rosiglitazone** (*Avandia*) INITIAL: 4 mg PO once daily (only available from certified pharmacies) MAX: 8 mg/day	Weight: gain Low hypoglycemia risk volume retention /peripheral edema, heart failure, and fracture risk. *Actos:* may increase the risk of bladder cancer. *Avandia: increased risk of MI*	Take with or without food Highly bound to albumin, metabolized via 2C9 Maximal glycemic lowering effect not until 3-4 mo of therapy Avoid in symptomatic CHF patients, patients on insulin therapy (requires sufficient insulin production for efficacy) C/I : NYHA Class III and IV HF combination of pioglitazone and insulin can result in significant edema.

Reviewed by: Dr. Jodlowski and Dr. Zito, Clinical Pharmacy Practice Department

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CLASS / PHARMACOLOGY	A_1C	AGENTS & DOSING	NOTABLE ADVERSE EFFECTS	COMMENTS / ROLE IN THERAPY
MISC. ORAL AGENTS				
Bile Acid Sequestrant **May reduce hepatic insulin resistance leading to a reduction in hepatic glucose production. May have an effect on molecular mediators of glucose metabolism. May reduce intestinal glucose absorption**	0.5% to 1%[3]	**Colesevelam** (*Welchol*) INITIAL: 3.75 g PO per day (taken as six tablets once daily, or three tablets BID, with meals) MAX: 3.75 g/day	Gastrointestinal, nausea, bloating, constipation, increased triglyceride, pancreatitis	Lowers LDL up to 20%. Monitor for drug interactions (fat soluble vitamins, warfarin, cyclosporine)
Dopamine Agonist **May centrally reverse many of the metabolic changes that are associated with insulin resistance and obesity**	0.5% to 1%[3]	**Bromocriptine** (*Cycloset*) INITIAL: 0.8 mg PO once daily MAX: 4.8 mg PO once daily	Hypotension, syncope (*dose titration) Hallucinations, psychotic disorders	ADA: third line Role in therapy not defined by AACE/ACE
INJECTABLES				
Amylin analog **Slows gastric emptying leading to feeling of early satiety, decreases postprandial glucagon secretion.**	0.5% to 1%[1]	Pramlintide (*Symlin*) INITIAL: 60 mcg SC prior to major meals (≥250 kcal or containing ≥30 g carbohydrate) MAX: 120 mcg/meal	Weight: loss Nausea, hypoglycemia.	Local site of action SQ injection (abdomen/thigh) , given immediately before a meal Primarily renal metabolism- caution in renal insufficiency Delays gastric emptying and may delay absorption of other drugs (space admin with other meds)
Glucagon-like, peptide-1 (GLP-1) agonist or incretin mimetic **Stimulates GLP-1 receptors which increases production of insulin in response to high blood glucose levels, inhibits postprandial glucagon release, slows gastric emptying.**	1% to 1.5%[3]	**Exenatide** (*Byetta*) INITIAL: 5 mcg SC BID MAX: 10 mcg SC BID **Exenatide extended-release** (*Bydureon*) INITIAL: 2 mg SC once weekly MAX: 2 mg SC once weekly **Liraglutide** (*Victoza*) INITIAL: 0.6 mg SC DAILYx 1 wk, increase to 1.2 mg SC DAILY MAX: 1.8 mg/day	Weight: loss Low hypoglycemia risk Headache, nausea, diarrhea. Pancreatitis, acute renal failure *Victoza* may be associated with thyroid cell cancer in rodents. May be associated with renal insufficiency.	SQ injection (once daily, or ER once weekly) independently of meals Caution in impaired renal function (higher incidence of GI side effects) Delays gastric emptying and may delay absorption of other drugs (space admin with other meds)

Reviewed by: Dr. Jodlowski and Dr. Zito, Clinical Pharmacy Practice Department

INSULIN THERAPY

Mechanism: **activates insulin receptor: lowers blood glucose by stimulating glucose uptake in muscle and adipose tissue Inhibit hepatic glucose production**
Expected A1C reduction: **1.5-3.5%**
Common side effects: **hypoglycemia, weight gain (incidence increases with intensive insulin therapies**

Rapid Acting	**Humalog®** (Insulin lispro)	**Onset:** 15-30 min **Peak:** 30 min-2.5 hours **Duration of action:** 3-6.5 hours **Administration:** SC injection 15 min before or immediately after meals
	NovoLog® (insulin aspart)	**Onset:** 10-20 min **Peak:** 40-50 min **Duration of action:** 3-5 hours **Administration:** SC injection 5-10 min before meals
	Apidra® (insulin glulisine)	**Onset:** 15-30 min **Peak:** 45-48 min **Duration of action:** 4-5.3 hours **Administration:** SC injection within 15 min before or 20 min after starting meals
Short Acting	**Humulin R** (Regular Insulin)	**Onset:** 30-60 min **Peak:** 1-5 hours **Duration of action:** 6-10 hours
	Novolin R (Regular Insulin)	**Onset:** ~30 min **Peak:** 1.5-3.5 hours **Duration of action:** ~8 hours **Administration:** 30 min before meals
Intermediate Acting Insulin	**Humulin N** (NPH- insulin human isophane)	**Onset:** 1-2 hours **Peak:** 6-14 hours **Duration of action:** Up to 24 hours **Administration:** SC injection
	Novolin N (NPH- insulin human isophane)	**Onset:** 90 min **Peak:** 4-12 hours **Duration of action:** Up to 24 hours **Administration:** SC injection
Long Acting Insulin	**Lantus®** (insulin glargine)	**Onset:** 1.1 hours **Peak:** No significant peak **Duration of action:** 10.8-24+ hours **Administration:** SC injection once daily, at the same time
	Levemir® (insulin detemir)	**Onset:** 1.1-2 hours **Peak:** No significant peak **Duration of action:** 7.6-24+ hours **Administration:** SC injection once or twice daily, at the same time
Premixed Combination Insulin	**Novolin® 70/30 Humulin® 70/30** (NPH/Regular Insulin)	**Onset:** 15-30 min **Peak:** 2-16 h **Duration of Action:** 18-24 hours **Administration:** SC injection 30-60 minutes prior to meals
	NovoLog Mix® 70/30 (aspart protamine suspension/ insulin aspart)	**Onset:** 10-20 min **Peak:** 1-4hours **Duration of Action:** 18-24 hours **Administration:** SC injection within 15 minutes prior to meals
	Humalog Mix® 50/50 or 75/25 (NPL/insulin lispro)	**Onset:** 10-30 min **Peak:** 1-7 hours **Duration of Action:** 18-24 hours **Administration:** SC injection within 15 minutes prior to meals

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Reviewed by: Dr. Jodlowski and Dr. Zito, Clinical Pharmacy Practice Department

OPINIONS

Dr. Barile Interview Continued

By: Katharine Cimmino, Editor-in-Chief & Bharat Kirthivasan, Co-Copy Editor

Dr. Barile has been on the editorial board of Toxicology in Vitro for about six years now. What is the difference between being the Editor-in-Chief and working as another member of the editorial board?

"The position holds tremendous responsibility and is very rewarding. I make the final decisions on all manuscripts that are submitted. I get about 10-15 manuscripts a week. It really is a lot. On this journal there are three Editors-in-Chief. One is responsible for any manuscripts submitted from North America. Another is responsible for all research submitted from the European Union. I am responsible for the rest of the world. Out of all the submissions I get the most. The submissions that come to me make up about 60-70% of all submissions. Many come from China, India, Southeast Asia, and Africa."

"The position holds tremendous responsibility and is very rewarding."

Being a part of such a global publication, one of the biggest issues is the language barrier. Writing for most people is a difficult endeavor; writing in a foreign language can cause some communication issues between the author and the readers. Do you see any of these problems in manuscripts that are submitted to you?

"Honestly, there are a lot. Most of the problems are with the English language. If you are going to publish scientifically then the wording has to be perfect and specific. I find that with many foreign writers, the authors will have the manuscripts proofread. The funny thing is that these services only check the grammar and the syntax. It will not check or review as far as the message is concerned. Sometimes I get articles that don't make sense yet they are grammatically correct. I have to go through every paper. If I can't get through the abstract I reject it. As an editor I triage each manuscript. If I can determine that it is worthwhile then I send it to reviewers.

In essence, as the editor-in-chief of Toxicology in Vitro, you are the first read of each manuscript. This is a different approach to how some other publications work. Exactly how do you go about approving a manuscript?

"When I receive a manuscript, after I read it, I can make the decision to send it to another editorial board member or I can send it to a reviewer. If I know of an editorial board member that has specialized in that area, I will send it directly to them. But getting something published really depends on a series of reviewers. If I think it can go to the next step, I will give the manuscript to an editorial member; they will review it and send comments back to me. There are four different ways an editorial board member can classify a manuscript: accept with no changes (this is extremely rare); minor revisions; major revisions, or rejections. More than one reviewer will read each manuscript. I accumulate 3-4 sets of comments and then decide on how to proceed. "

As one can see, each manuscript goes through several reads and reviewers. How do you navigate any conflict that arises?

"That is really my job. I spend 20-30 minutes on each manuscript. So you can imagine if I get 10 manuscripts that I spend about 5-6 hours minimum each week. Not only do I check it, but I have a program that will "check relevant manuscripts" and it will search on medline any key words. Just like Google, it comes up with 1000s of hits and like "turn-it-in" it will come back with a percentage. If anything is over 50-60% then I have to examine it for plagiarism. However, there is a lot of overlap. Often people conduct experiments and just change something slightly. We do catch people though who try and double-dip. For instance, I got this one article that was discussing the effect of coal tar on lung cells. I conducted a search and got the same exact article and same exact authors, the only thing that was changed was the title. I found out that it was published in a Chinese journal. I was honestly surprised that it even came up because most of the lo-

"If you are going to publish scientifically then the wording has to be perfect and specific."

cal journals do not. Not only did I reject the article, I also contacted the author and my publisher."

Peer review is blind to the extent that the author has no idea who is reviewing it, yet the reviewer can see all of the author's credentials and affiliations. How much does this bias a reviewer's opinion?

"Some journals actually use a double blind [editing method] to prevent any sort of bias. Our journal does not. We try not to let any bias interfere but sometimes, no matter what you do, it comes through. There are many Chinese journals and universities that just don't have as much funding. So you can see how far someone has completed an experiment and if you ask them to conduct more experiments or do anything further they respond that they just can't afford it. Well honestly, that's not my problem. In a situation like this, I may like the idea but if it isn't developed enough I will not move the manuscript to the next step. Also the language barrier shows up. English is a difficult language to write in and if I can't read it I won't send it further. However, Elsevier does have a technical service that will try and work with the author or make suggestions in order to make a manuscript more readable. I send manuscripts out if I like the message but the English needs some work."

Considering how much work you go through to review a manuscript, how much do you change the manuscript?

"I don't change it at all. If we have a problem we send it back to them. Our program is written so that we can't change anything. If a reviewer wants to make a comment or add something, it will warn us that we are about to alter the manuscript. I personally don't change anything, however, a reviewer can add comments. Some people may see this as a problem but it truly is a fantastic system. What we do is true peer-review. What is upsetting now is plagiarism. It is a huge problem now and it is so easy to detect. Years ago I would have to comb through volumes and manually search through the titles of everything published that week. Now with the click of a button I can see how much is the author's own work. Honestly then it was too much to do."

"What is upsetting now is plagiarism. It is a huge problem now and it is so easy to detect."

Why did you take a more prominent role in the Toxicology in Vitro?

"I don't like to work with animals. I made it a goal in my life and career to develop methods that are alternatives to animal testing. Now I have moved in a different direction and work with embryonic cells. I teach a graduate course in cell culture. I teach them a lot of methods and this is the only time I work with animals. You get one animal and it provides you with enough cells to conduct research for a lifetime. In the class though, I will extract the cells myself, but show the students the procedure."

With research, there is often tension between in vitro and animal research. Does limiting your work to only one aspect cause any problems?

"Sometimes it is harder to get grants. When you don't do animal research it is frowned upon in the scientific community. What I often do is get a collaborator who works with the animals. I will conduct the research in vitro and I will have the collaborator do the same experiment in animals. The problem with grants is that you need to convince someone that not only is your research interesting but also that it is worthwhile; that they should part with a million dollars to conduct it. The most important thing is validation. More people now are conducting in vitro experiments. Animals are not as easy to work with or as reliable as people believe. In the scientific community, more people are coming around to using in vitro methods. Animals don't match up to humans as closely, so there is a major problem. A whole life-time for a rat is 2 years, so how could that possibly be the same as a human."

"The problem with grants is that you need to convince someone that not only is your research interesting but also that it is worthwhile; that they should part with a million dollars to conduct it. "

Besides working on several editorial boards, Dr. Barile is also a published author. His most recent publications include the textbook Clinical Toxicology: Principles and Mechanisms [2nd Edition], and the manuscripts "Effect of metals on β-actin and total protein synthesis in cultured human intestinal epithelial cells" and "Validating and troubleshooting ocular in vitro toxicology tests". How often do you publish?

"2013 has been a good year for me. I have published 3 chapters and published the 2nd edition of the Principles of Toxicology Testing. With the textbook, they asked me to do another edition, so I know it was successful. With this book I didn't want it to be too basic, but I wanted it to be useful. Besides students, I know that emergency rooms have read it and because of that I try to keep up-to-date. The pharmacy background is a great background to have. It is a clinical background. I like the pharmacotherapeutic aspect of most drugs so when I teach or write I tend to lean more towards discussing this component, but I am also interested in the research aspect of how a drug was developed. "

What is your writing process?

"Writing publications is different from writing books. Books are much more creative and it is common knowledge. It is established knowledge. So in a book I can do more editorializing and giving more of my opinion. What I often open up with in my toxicology book is more my opinion. I can't write this creatively in a research paper."

How much do you believe it is for a scientist job to make the work more interesting and palatable?

"You have to be careful; you don't want to mislead people. Often when it is an editorial, I put it in the beginning. Everything else I reference. If you don't see a reference then it is my words and my ideas. You mustn't mislead anyone. For you guys with the Post it is important that people know when it is your opinion and when it is not. It is a very fine line and you must be careful not to cross it."

The Rho Chi Post was very fortunate to interview such a prominent member of the scientific community. We want to thank Dr. Barile for sharing his time and expertise with us.

OPINIONS

Went to an event on your campus?

Saw or learned something interesting?

SUBMIT YOUR PHOTOGRAPHS AND ARTICLES!

Send them to our editors at RhoChiPost@gmail.com

and we will feature your work in our next issue!

RHO CHI POST

Are You Smarter than a 6th Year?

Word Search: Drug Top 200 Challenge

By: Davidta Brown, Staff Editor

How well do you know the Top 200 Drugs? For each generic name listed below, find the corresponding brand name in the puzzle. Note: This puzzle contains brand names only. Good luck!

o	z	o	e	r	a	k	r	n	s	a	e	i	t
o	o	s	c	e	l	e	x	a	i	i	l	o	r
p	a	p	l	i	y	f	u	o	o	d	m	f	e
r	r	r	r	a	f	l	k	s	e	p	t	r	a
o	x	o	l	a	n	e	u	r	o	n	t	i	n
z	e	f	a	l	v	x	p	p	t	n	e	a	k
a	s	l	n	i	d	a	m	u	o	c	v	l	m
c	a	o	r	r	r	p	c	l	a	i	o	u	a
r	a	n	o	e	i	r	r	h	t	n	i	g	r
e	l	a	t	x	e	o	e	a	o	n	f	n	t
n	i	s	s	e	e	o	a	p	e	l	s	i	l
n	r	e	e	l	e	e	i	r	i	d	o	s	u
a	u	r	r	f	a	n	y	o	r	p	i	c	e
t	o	s	c	l	a	d	v	i	l	v	v	r	i

Escitalopram
Clonazepam
Sulfamethoxazole + Trimethoprim
Cephalexin
Warfarin
Albuterol HFA
Fluticasone
Lorazepam
Prednisone
Pravastatin
Ibuprofen
Rosuvastatin
Citalopram
Montelukast
Ciprofloxacin
Tramadol
Triamterene
Fluoxetine
Cyclobenzaprine
Gabapentin

PUZZLES

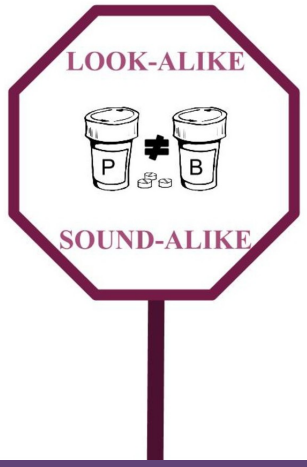
Endocrine Trivia

By: Frances Trosa, PharmD Candidate c/o 2015

Answers

Which of the following is not a rapid acting insulin?	A. Insulin lispro B. Insulin aspart C. Insulin glargine D. Insulin glulisine
Which of the following is not a diagnosis criterion for diabetes mellitus?	A. Random plasma glucose > 200 mg/dL in patients with classic symptoms of hyperglycemia or hyperglycemic crisis B. Hemoglobin A1C > 6.5% C. Two hour plasma glucose > 200 mg/dL during an oral glucose tolerance test D. Fasting plasma glucose > 100 mg/dL
Which of the following oral medications works by inhibiting degradation of endogenous incretins?	A. Metformin B. Nateglinide C. Glyburide D. Sitagliptan
Which of the following statements regarding sulfonylurea-second generation medications is true?	A. Efficacy of these medications is reduced over time B. Weight loss is a common side effect C. May increase the risk of bladder cancer D. It is important to monitor when taking with CYP1A2 inhibitors

PUZZLES



Matching Column: Look-Alike Sound-Alikes

By: Frances Trosa PharmD Candidate c/o 2015

Many drugs

LOOK – ALIKE

OR

SOUND– ALIKE

causing them to be easily mixed up in practice.

Can **YOU** match these facts with the correct medication?

1.	This drug is a prodrug which is rapidly deacetylated and oxidized in vivo to its active metabolite, penciclovir	a)	Fanapt
2.	This histamine H_2 antagonist requires dose adjustment in patients with a creatinine clearance of less than 50	b)	Femara
3.	This drug is contraindicated in patients taking a MAO inhibitor or patients who have taken an MAO inhibitor in the past 2 weeks due to the risk of serotonin syndrome	c)	Fluoxetine
4.	This drug carries a back box warning which states that if given in excessive amounts, it has the ability to cause fluid and electrolyte depletion	d)	Febuxostat
5.	This drug is not approved for the use in patients with dementia – related psychosis due to the increased risk of death in this population	e)	Famvir
6.	This drug carries a black box warning stating that it has the potential to cause serious or life threatening hypoventilation	f)	Fentanyl
7.	This medication is a xanthine oxidase inhibitor which does not require dose adjustments in patients with declining renal function	g)	Felbatol
8.	This anticonvulsant has been associated with rare and potentially life threatening liver failure	h)	Fenofibrate
9.	This drug is an aromatase inhibitor and is pregnancy category X	i)	Famotidine
10.	Absorption of this anti – lipidemic agent is increased when taken with meals	j)	Furosemide

Answers

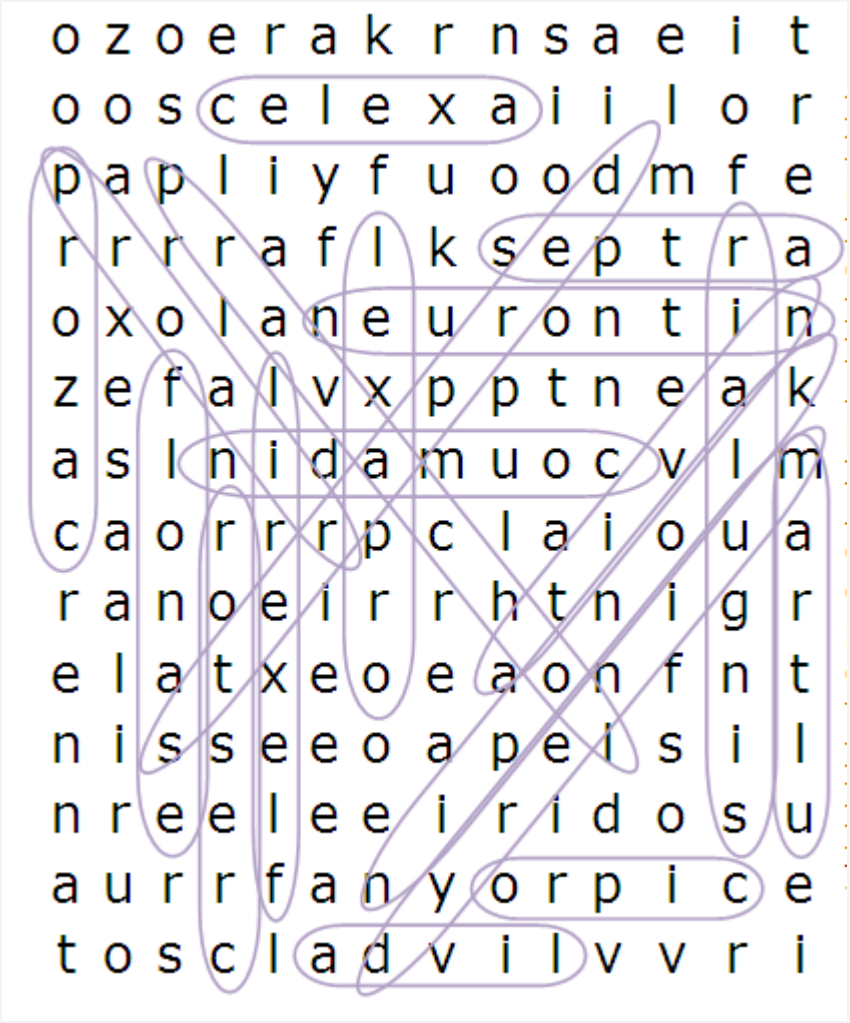
Lexi-Comp OnlineTM , Lexi-Drugs OnlineTM , Hudson, Ohio: Lexi-Comp, Inc.; July 29, 2013

PUZZLES

How Did You Do???

Answers to Word search & Look Alike and Sound Alike

Trivia: 1. C 2. D 3. D 4. A



1. E 2. I 3. C 4. J 5. A 6. F 7. D 8. G 9. B 10. H

Do you enjoy our puzzles? Send us a suggestion for a brainteaser at:

rhochipost@gmail.com

We will feature your work in our next issue!

RHO CHI POST: EDITORIAL TEAM

@ Katharine Cimmino ***(5th Year, STJ; Editor-in-Chief)***
I have always been an avid reader and writer. As a member of the Rho Chi Post I am able to merge my passions with the professionalism that comes with aspiring to be a healthcare provider. I am eager to be a part of a publication that promotes my interests and vocation.

@ Bharat Kirthivasan ***(PhD Candidate, STJ; Co-Copy Editor [Content-Focused])***
I am a doctoral candidate in Industrial Pharmacy researching nanoparticles for delivery to the brain. The only thing I enjoy more than reading a well-written piece of work is writing it. I am glad to work for the Rho Chi Post, and I encourage others to do the same.

@ Hayeon Na ***(5th Year, STJ; Co-Copy Editor [Content-Focused])***
Hello! My name is Hayeon Na. I am a 2015 PharmD Candidate and one of the Copy Editors for the Rho Chi Post. I hope the information I present will be helpful, or at least interesting. If you have any comments regarding my contribution, feel free to contact me at any time!

@ Tasnima Nabi ***(4th Year, STJ; Co-Copy Editor [Content-Focused])***
Writing has always been my greatest outlet for experience and knowledge, through which I hope to keep you engaged and informed. It is imperative to keep up with our changing profession and community, and I look forward to bringing pertinent information to the newsletter.

@ Aleena Cherian ***(6th Year, STJ; Co-Copy Editor [Graphics-Focused])***
The Rho Chi Post has been a source of current information and great advice to students and professionals in this evolving profession. After years of experience in media and graphics-related work, it is now my privilege to be a part of this endeavor as a Co-Copy Editor. I hope you learn as much from future editions of the newsletter as I have, and I welcome your feedback!

@ Melissa Roy ***(5th Year, STJ; Co-Copy Editor [Graphics-Focused])***
We as future healthcare professionals owe it to our patients and ourselves to become aware and current on the events affecting our profession. The Rho Chi Post is our way to learn new things and stay in touch with the pharmacy world, on- and off-campus. I have gained so much from reading previous publications and feel privileged to have the opportunity be a part of the team. Feel free to reach out to me with suggestions and comments.

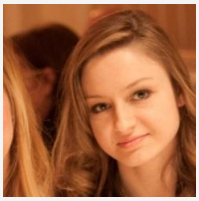
@ Erica Dimitropoulos ***(5th Year, STJ; Senior Staff Editor)***
As busy student pharmacists, we often fail to keep current with healthcare developments. My aim is to sort through the news and provide quick updates that are important to our profession. Feel free to contact me if there are any topics you would like to see covered in the next issue!

EDITORS

RHO CHI POST: EDITORIAL TEAM

@ Tamara Yunusova *(3rd Year, STJ; Senior Staff Editor)*
My name is Tamara Yunusova, and I am a 3rd year Pharm D candidate at St. John's University. I enjoy articulating information in a captivating and insightful way. I hope to make this publication more informative, student-friendly, and innovative.

@ Beatrice Popovitz *(5th Year, STJ; Staff Editor)*
I am eager to relay current information on interesting topics making waves in the world of healthcare pertinent to the advancement of our profession. As student pharmacists, we are molding the future of our profession, and the Rho Chi Post facilitates the cultivation of a relationship (between students, faculty, and other members of the healthcare community) to share ideas and spread awareness of various issues. Feel free to contact me if you would like to share your ideas with other members of the University community through this platform.



@ Ada Seldin *(5th Year, STJ; Staff Editor)*
I am thrilled to have become a new member of the Rho Chi Post team. I hope to further strengthen the goals of this newsletter and make a lasting contribution. It is important, as future pharmacists, to collaborate with our peers, as well as accomplished professionals in the field. Rho Chi Post provides a vehicle to voice our opinions and share relevant news.

@ Sang Hyo Kim *(2nd Year, STJ; Staff Editor)*
Advancements of technology and developments of new medicines, prolonging the lifespan and improving the quality of life, have increased the geriatric population. In years to come, pharmaceutical industries and healthcare systems will persistently work to find solutions to changing demands and new problems of the society. Through the Rho Chi Post, I wish to learn, educate, and prepare myself and others for the future.

@Davidta Brown *(3rd Year, STJ; Staff Editor)*
My two great loves are innovative science and quality writing, and the Rho Chi Post is an insightful combination of both. As an editor, I look forward to bringing relevant information and fresh perspectives to the student and faculty of St. John's University, as well as to making the Rho Chi Post a newsletter that offers something new to every reader.

@ *You!*

We are always looking for creative and motivated students to join our team!

If you are interested in becoming an editor for the Rho Chi Post, please visit:
http://rhochistj.org/RhoChiPost/EditorApplication

EDITORS

RHO CHI

The Rho Chi Society encourages and recognizes excellence in intellectual achievement and advocates critical Inquiry in all aspects of Pharmacy.

The Society further encourages high standards of conduct and character and fosters fellowship among its members.

The Society seeks universal recognition of its members as lifelong intellectual leaders in Pharmacy, and as a community of scholars, to instill the desire to pursue intellectual excellence and critical inquiry to advance the profession.

CURRENT EXECUTIVE BOARD

Zinnia, Majd, Moisey, Elissa, and Anh at the 2013 Induction Ceremony

President: **Moisey Rafailov**
Vice President: **Majd Ahmad**
Secretary: **Elissa Tam**
Treasurer: **Anh Nguyen**
Historian: **Zinnia L. Yu**

Faculty Advisor: **S. William Zito, PhD**

THE RHO CHI POST

MISSION
The Rho Chi Post is a monthly, electronic, student-operated, dean-approved publication that aims to promote the pharmacy profession through creativity and effective communication. Our publication is a profound platform for integrating ideas, opinions, and innovations from students, faculty, and administrators.

VISION
The Rho Chi Post aims to become the most exciting and creative student-operated newsletter within St. John's University College of Pharmacy and Health Sciences. Our newsletter continues to be known for its relatable and useful content. Our editorial team continues to be known for its excellence and professionalism. The Rho Chi Post essentially sets the stage for the future of student-operated publications in pharmacy.

VALUES
Opportunity, Teamwork, Respect, Excellence

GOALS
1. To provide the highest quality student-operated newsletter with accurate information
2. To maintain a healthy, respectful, challenging, and rewarding environment for student editors
3. To cultivate sound relationships with other organizations and individuals who are like-minded and involved in like pursuits
4. To have a strong, positive impact on fellow students, faculty, and administrators
5. To contribute ideas and innovations to the Pharmacy profession

UPCOMING EVENTS

Sept 22-24: 2013 AACP Annual Meeting
Bethesda, Maryland

Sept 24-26: 11th Annual Discovery on Target
Boston, Massachusetts

Oct 1st: iPhO Networking Event
Rutgers University

Oct 2nd: ASHP Annual Skills Competition
St. John's University

Oct 3rd: DIA Countering Counterfeit Medications in Africa
Rutgers University

Oct 16-19: Drug Discovery Re-invented
Scottsdale, Arizona