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EA/EOU

Greetings from the Department Head



Dear Alumni and Friends;

Greetings from Purdue! December is about change. The semester draws to a close, fall gives way to winter, and we'll soon welcome a new year. Change is in the air here at Purdue, too. At the University level, we're searching for our 12th president, to succeed President France Córdova when her term ends next July. In IPPH, we're completing searches for a full professor and an assistant professor. We're getting ready to renovate our ground floor laboratories. The plans are complete, the old labs have been cleaned out (Alumni: Yes, we threw out your stuff!) and construction is scheduled to begin in the spring.

Take a minute to catch up with our changes in this newsletter. Read about the awards and honors received by our faculty and students. Meet the department's new Lecturer and our new Communications Coordinator. Learn about our Sustainable Medicines in Africa program, and follow two of our graduate students who climbed to the top of Mt. Kilimanjaro. Check out our newsletter border, too – it shows images of pentamidine isethionate crystals from Dr. Steve Byrn's group. Above all, know that our good wishes for you are unchanging. A joyous holiday season, a peaceful and prosperous New Year from all of us in IPPH!

Liz Topp
Dane O. Kildsig Chair and Department Head

Department Highlights

Alumni Highlights

- **Dr. Robert Sepelyak, Ph.D.** (1982), received the 2011 Distinguished Alumnus Award from the College of Pharmacy on Nov. 4. Dr. Sepelyak is currently the Project Director of Pharmaceutical Development at AstraZeneca Pharmaceuticals LP. During his visit, Dr. Sepelyak also spoke at a graduate student roundtable on "Pharmaceutical Career Opportunities".

Faculty Highlights

- **NIPTE** has received a grant of up to \$35 million from the FDA to improve pharmaceutical manufacturing and drug safety. Dr. Stephen Byrn, Charles B. Jordan Professor of Medicinal Chemistry, currently serves as the president of the NIPTE faculty committee, and College of Pharmacy Dean Craig Svensson is a member of the Board of Directors. The award was featured in *Purdue Today* (<http://www.purdue.edu/newsroom/research/2011/111004SvenssonNIPTE.html>). (October)
- **Dr. Greg Knipp** has received funding from Eli Lilly and Company to support a research project entitled "Pharmacokinetic studies on intravenous and oral formulations of Glipizide and immediate and modified release formulations of metformin in pigs". (October)

Post Doc Highlights

- **Dr. Andrew Otte** (Pinal group) participated in this year's AAPS Graduate Student Symposium in Analysis and Pharmaceutical Quality, and gave a podium presentation entitled "Surface Energy Distributions for the Prediction of Fine Particle Fraction from Dry Powder Formulations" at the October 2011 annual meeting.

Faculty and Student Highlights

Graduate Student Highlights

- **Yi Ling Hsieh** (Taylor group) participated in this year's AAPS Graduate Student Symposium in Analysis and Pharmaceutical Quality, and gave a podium presentation entitled "Utilization of pH-Metric Titration to Evaluate Supersaturation Behavior of Weakly Basic Drugs" at the October 2011 annual meeting.
- **Wyatt Roth** (Knipp group) has won the Excellent Student Poster Award for the I/ODG symposium which was held in Indianapolis on August 9. His poster is entitled "Development and testing of novel pediatric formulations of rifampicin for the treatment of tuberculosis (TB) in infants and young children". (August)
- **Wyatt Roth** has also been selected to receive a 2011-2012 Ronald W. Dollens Graduate Scholarship in the Life Sciences from Purdue University. The scholarship will provide partial stipend support for him for the upcoming year. (August)
- **Wyatt Roth** has also been selected as this year's recipient of the Kienly Award for the outstanding graduate student teaching assistant in the Department of Industrial and Physical Pharmacy. The award recognizes Wyatt's many contributions as a TA, notably in IPPH 562 and in the Sustainable Medicines in Africa program. (October)
- **Zohreh Amoozgar** (Yeo group) has received a Bilsland Dissertation Fellowship from the College of Pharmacy, which will provide her with a stipend for the period August 1 to December 31, 2011, to assist her in completing her dissertation. (August)
- **Zohreh Amoozgar** has also been selected to receive a 2011-2012 Ronald W. Dollens Graduate Scholarship in the Life Sciences from Purdue University, which will provide partial stipend support for her for the upcoming year. (August)
- **Zohreh Amoozgar** has also been selected as a winner of the Jenkins-Knevel Award for Outstanding Graduate Research. Zohreh presented her work during a special Graduate Student Awards Symposium on November 3. (October)
- **Zohreh Amoozgar** received this year's graduate student award from the Iranian Pharmaceutical Scientists Association, presented at the AAPS meeting in Washington, DC. (October)
- **Lavanya Iyer** (Topp group) has been selected to receive a 2011-2012 Ronald W. Dollens Graduate Scholarship in the Life Sciences from Purdue University, which will provide partial stipend support for her for the upcoming year. (October)

Staff Highlights

Ann Newman, Ph.D., is a limited term lecturer for Fall 2011, teaching IPPH 362 (Basic Pharmaceutics I). Dr. Newman has been an adjunct professor in IPPH for almost ten years and has served on a number of doctoral committees. She received her Ph.D. in Chemistry at the University of Connecticut, worked at Bristol-Myers Squibb in New Jersey for 10 years, and then worked at SSCI/Aptuit in West Lafayette for 10 years. Her work includes solid form screening, characterization, selection, and problem solving from late drug discovery through development and marketed products. For the past three years she has been a pharmaceutical consultant at Seventh Street Development Group (www.seventhstreetdev.com) specializing in solid state pharmaceuticals and drug development, which includes consulting, training, and webinars for the pharmaceutical industry.

DeEtte Starr, our new Communications Coordinator, began working in IPPH in July. DeEtte will help publicize IPPH through this newsletter and on the Web, by writing and taking photos, planning events and other communications projects, and serving as the CPPR Program Director. DeEtte worked in Cameroon, Africa, for 14 years as a language development missionary, in Switzerland as a staff photographer, and as a video producer in England for one year and at Purdue for four years.

Steve Byrn helps Africans make high-quality medicines for Africans.

In August 2011, IPPH's Dr. Stephen R. Byrn taught the IPPH 562 manufacturing lab course at the Kilimanjaro School of Pharmacy (KSP) in Moshi, Tanzania. About 24 students from eight African countries attended, including a dean and a department head from Nigerian universities. Three Purdue grad students and a Howard University grad student ran the labs.

Working under GMP-like conditions, African students made large quantities of Tylenol tablets. Two groups made Efavirenz anti-AIDS tablets. "We think this was the third and fourth time Efavirenz had been manufactured in [sub-Saharan] Africa," says Byrn. "Two groups also synthesized piperazine and DHA and made piperazine-DHA tablets (anti-malarials). We believe the synthesis of piperazine and DHA and the manufacture of the tablets was the first time that had ever been done in Africa."

For the past four years, Byrn has taught African pharmaceutical scientists to solve manufacturing problems to make better medicines. Currently, most African countries depend on imported medicines to treat diseases and save lives. Often the medicines are costly, or are unavailable or of poor quality.

Purdue's collaboration with the KSP began when a Nigerian medical missionary, Sister Zita Ekeocha, contacted Byrn. She ran the Industrial Pharmacy teaching unit at the KSP in Tanzania, and wanted the Purdue College of Pharmacy to send someone to install a manufacturing lab, teach good manufacturing practices (GMP), and manufacture medicines. Byrn worked with Howard University, Sister Zita and the Roman Catholic church, the St. Luke Foundation (a Lutheran organization which operates the KSP), the German government (which provides a lot of the funding and laboratory equipment), and the Tanzanian government to develop and run the program, which officially began in March 2008.

The first group of African students received Regulatory and Quality Control (RQC) certification in March 2010 after completing the four core courses: Drug Discovery, Drug Development, Manufacturing, and Documents.

The current group of students will graduate in March of 2012. By then, Byrn hopes the team will have written SOPs (Standard Operating Procedures) and will have obtained more equipment. He wants Purdue pharmacy alumni to get involved with the project. Ph.D. alumni could teach at the course, and any alumni can donate to the program. Scholarship money for African students is especially needed, as UN funding for this is no longer available. The project also needs funding to expand the program and to build a GMP facility.

Byrn's goals for the program are: to make manufacturing operational, to have a distance master's degree from Purdue approved, to provide a service for recycling expired medicines in Tanzania, to export the program to other African countries, to build up good African regulatory bodies, and to encourage the African chemical industry to manufacture high-quality ingredients in an environmentally responsible way.

Next August, Byrn and his team will begin teaching a new round of African students. Their ground-breaking program will save more African lives in the future.

Read more about the IPPH Sustainable Medicine Program in Tanzania at: www.ipph.purdue.edu/sustain/. For more information, contact Dr. Byrn at sbyrn@purdue.edu.



Dr. Byrn teaching IPPH 562 at the Kilimanjaro School of Pharmacy (KSP)



KSP students manufacturing Tylenol in August 2011



KSP students in August 2011



IPPH Grad Students Wyatt Roth and Lindsay Wegiel atop Mt. Kilimanjaro



View of Glaciers from Kilimanjaro summit



KSP Students with tablets they manufactured



Wyatt Roth teaches KSP students how to analyze tablets

In August, IPPH graduate students Lindsay Wegiel and Wyatt Roth climbed to the top of the world – literally.

They went to Tanzania to volunteer at a manufacturing course in sustainable medicine, and planned to climb Mt. Kilimanjaro before the course started. At 19,340 ft., Kilimanjaro is the highest peak in Africa and the fourth highest peak in the world.

Wegiel and Roth spent three weeks in Tanzania this past summer, including part of one week climbing Mt. Kilimanjaro and two weeks working with IPPH's Dr. Stephen R. Byrn and the St. Luke Foundation/Kilimanjaro School of Pharmacy (KSP). In 2008, Dr. Byrn and others began a sustainable medicine program in Africa to enable Africans to produce high-quality life-saving medicines for themselves, instead of depending on imported drugs. This was the second such trip to Tanzania for both Wegiel and Roth.

The climb consisted of three days of hiking for six to seven hours and camping each night, then culminated with a six-hour "summit hike" from 11 p.m. till the next morning's sunrise atop the peak. It was so cold and windy nearing the summit that Wegiel's and Roth's water bottles froze. Many others were hiking, too, and the path ahead of them was lit by fellow hikers' headlamps. Then the sun rose and lit up the glaciers. "It was so beautiful," said Wegiel.

The hike was a highlight in a meaningful trip for both students. Wegiel wanted to participate because she "wanted the end product of what I'm doing to benefit people. I feel like this is going to help people...It changed my mentality [about] aspects of life that are important."

Both students were also pleasantly surprised with the level of student motivation. "All the students were extremely friendly and nice, and eager to learn. They're at the course because they want to be," Roth explained.

Wegiel agreed that teaching students at KSP was enjoyable. "I was amazed at how much they wanted to learn," she said. "They wanted as much information as they could get."

For students thinking about going on this trip in the future, Wegiel offers this advice: "Have an open mind to everything. Be willing to help in any way. Know they're going to want more from you if you're teaching...Take advantage of all the opportunities there." And "Try to learn a little Swahili before you go!"

Wegiel, from Steamboat Springs, CO, is part of the Taylor research group, studying interactions between polymers and the drug and amorphous formulations. Roth, from Winamac, IN, is a member of the Knipp group working on reformulating drugs into pediatric medicines.

Dr. Byrn is looking for students to volunteer at the next KSP Manufacturing course in August 2013. For more information, contact sbyrn@purdue.edu.

Kevin Boksa departed from family tradition and became a pharmaceutical researcher instead of an engineer, as his dad and brothers are. As a Purdue freshman he took the Orientation to Pharmacy course, then became more interested in the science of pharmacy rather than pharmacy practice. After completing his B.S. in Pharmaceutical Sciences, he decided to stay at Purdue for graduate studies.

This is Kevin's third year in the IPPH Ph.D. program. He is a member of Dr. Rodolfo Pinal's group, researching the use of hot-melt extrusion to explore crystalline dispersions, which are crystalline drugs suspended in a crystalline matrix. His work involves characterizing the crystalline dispersions and evaluating the effects of processing conditions on the product, as well as using thermal methods to simulate the behavior of material before the extrusion process. He also works with Dr. Stephen Byrn as the IPPH 562 Manufacturing Course teaching assistant (TA), running a lab with two other TAs, and teaching lab protocol and tablet manufacturing.



Kevin Boksa (center) working with IPPH 562 students to produce acetaminophen tablets

Kevin interned this past summer at Eli Lilly, which gave him a chance to experience the industrial side of pharmaceutical sciences. This experience was an important part of his post-graduation plans, when he hopes to go into product development at a pharmaceutical company. When he has spare time, he enjoys basketball, video games, classic cars, and heavy metal concerts.

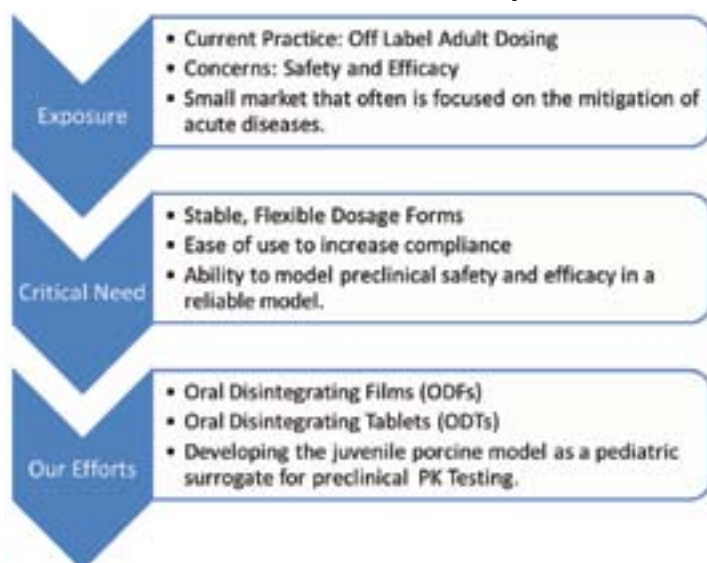
Research Spotlight: Pediatric Medicines - A Tough Pill to Swallow

Late stage clinical attrition of lead candidates remains the primary challenge facing the pharmaceutical industry today. Nowhere is this challenge (or the risk) greater than in the development of pediatric formulations. There are several concerns associated with the development of pediatric dosage forms including the relatively smaller market (10%), the need for acute as opposed to chronic therapies, the lack of information regarding the ontogeny of drug metabolizing enzymes and transporters, and

a limited number of clinical centers willing to perform trials in pediatric patients. In order to address the current challenges associated with the safe and effective development of pediatric formulations, improvements in understanding differences in drug absorption, distribution, metabolism, excretion, and toxicity (ADMET) between adult and pediatric populations must be made. Based on this unmet need, Dr. Knipp's laboratory has been working to validate the juvenile porcine model as a surrogate for human pediatric patients during preclinical pharmacokinetic (PK) studies. Moreover, one of the laboratory's research goals is to utilize the juvenile porcine model to assist in the development of novel oral pediatric formulations that will achieve targeted safe and effective exposure levels in different pediatric age populations.

Towards this aim, Mr. Wyatt Roth, a senior graduate student in the group, has focused on the development of orally disintegrating films (ODF) and tablets (ODT) for the delivery of rifampicin to infants and toddlers through a collaborative research grant with colleagues at Purdue and the Indiana University School of Medicine. During these studies, prototype ODF and ODT formulations of rifampicin have been developed and characterized. The novel ODF and ODT formulations were administered to juvenile pigs along with a commercially available capsule formulation in a crossover study design. The results of the preliminary studies revealed that PK parameters of rifampicin in the juvenile pig were very similar to those observed in human pediatric patients. It is the group's long term goal that the juvenile porcine model will be used to facilitate and expedite the development of pediatric dosage forms for the mitigation of other diseases and disorders.

Current Challenges for Pediatric Formulation Development



Challenges associated with the development of pediatric medicines will require more accurate and predictive models in order to reduce the risks of conducting trials in pediatric populations.



Peck Symposium 2011

Over 100 participants attended the 9th Annual Garnet E. Peck Symposium at Purdue on October 20. This year's Symposium focused on pharmaceutical solids, with sessions on amorphous and crystalline solids. The presentations covered cutting-edge discoveries for both types of solids, including transformations between crystal forms (polymorphs), the development of novel cocrystals, and the design of amorphous forms with enhanced solubility. Bio-sketches and abstracts of the speakers are available at www.ipph.purdue.edu/peck/ and photos of the event are at www.pharmacy.purdue.edu/features/2011-10-20.PeckSymposium/.



Amorphous Solids session speakers with Garnet Peck



Crystalline Solids session speakers with Garnet Peck

The 10th Annual Garnet E. Peck Symposium will be held on October 11, 2012.