

The ECP Monthly



An Internal Digest for the Department of Experimental and Clinical Pharmacology

Department News

- **Mike Brown (PI), Jeannine Conway** and Todd Sorenson received a Technology Enhanced Learning (TEL) small grant to study tablet PC use in the PC lab course. The grant is entitled "Improving Teaching and Learning of Parenteral Product Preparation Skills Through the Development and Implementation of Online Instructor Training and Student Evaluation Systems."
- **Pam Clemens** and **Susan Marino** attended the American Society of Clinical Pharmacology and Therapeutics meeting
- **Jim Cloyd** will receive the 2005 Research Achievement Award at the American Pharmacist Association annual meeting on April 3rd. He has been invited to be the keynote speaker at this event.
- **Jim Cloyd** will also be presenting a poster entitled, "Zonisamide Does Not Affect the Pharmacokinetics of an Oral Contraceptive in Healthy Females," at the American Academy of Neurology on April 12.
- **Mark Kirstein** is presenting a poster on April 22nd at the American Association of Cancer Research meeting in Anaheim, CA, entitled, "Development of an In Vitro Cell Culture Hollow Fiber System to Evaluate Anti-Neoplastic Drug Regimens."
- **Tim Tracy** received confirmation of the competing renewal of his NIH grant "Mechanisms of Atypical Drug Kinetics and Interactions" for 5/05-4/09 for \$982,423!

Dr. Kotlyar Awarded a NIH K23 Grant

Many smokers report that they smoke in response to stress and stressful events often lead to relapse when they try to quit smoking. Both smoking and stress lead to similar physiological responses such as increases in blood pressure, heart rate and plasma catecholamine concentrations and both smoking and an exaggerated response to stress result in an increased risk of the development and progression of heart disease. When stress is combined with smoking the increases in blood pressure and heart rate are additive, therefore combining stress with smoking likely results in greater cardiovascular harm than either smoking or stress individually. Identifying medications that decrease the physiological response to mental stress during cigarette smoking may therefore reduce the negative cardiovascular effects in smokers and may lead to new approaches to help people quit smoking.

Dr. Kotlyar, received a 5-year NIH K23 award entitled "Smoking, Antidepressants and Response to Mental Stress" to study the affect of Paxil (paroxetine) on the body's response to stress while smoking and to gain additional knowledge and skills related to this area of research. This 5-year award for \$692,849 is a Mentored Patient-oriented Research Career Development Award involving a research project, a training plan, and a mentoring plan.

(Dr. Kotlyar, continued on back)

Dr. Sioris and Dr. Kingston Promote Product Safety and Adverse Incident Management Internationally

Dr. Sioris and Dr. Kingston, along with Dr. Dean Filandrinos and Dr. John Gaultieri, have shared many practice ventures and successes. SafetyCall International is their latest innovation. The company began in late July 2004 and is an interdisciplinary medical practice functioning as a human and animal poison control center employing clinical toxicologists, pharmacists, nurses, veterinarians, physicians, medical toxicologists, and experts in post-market surveillance. To date, SafetyCall is the only firm in the country that offers both human and veterinary toxicological services and it is also the only industry poison control center affiliated with the American Association of Poison Control Centers.

The unique corporate niche that SafetyCall occupies grew out of an industry-wide need for incident management of their products. Industries outsource this responsibility to practices like SafetyCall who have the necessary expertise and credentialing to handle any adverse incidents and to provide post-market surveillance. For example, if a consumer believes he or she is having a reaction to a product they would of course go to their

(SafetyCall, continued on back)

Upcoming Events

- April 6th – Seminar, **Manisha Lamba**, ECP graduate student, “Pharmacokinetic – Pharmacodynamic Modelling in Epilepsy”
- April 13th – Department Meeting 12:15
- April 20th – Seminar, **Heather Venezia**, Assistant Professor, ECP and Lab Medicine and Pathology, “An International Bioequivalence Study of Generic and Brand Formulations of the Antiretroviral Agents: Nevirapine, Zidovudine, Lamivudine”
- April 27th – Seminar, **Wonkyung Byon**, ECP graduate student, “Developmental Pharmacology in Pediatrics”

(SafetyCall, continued from front)
doctor or an emergency room. The 1-800 number on the back of the actual product can link the consumer and the consumer’s physician (or veterinarian) to SafetyCall, which has a list of the product’s ingredients and clinical toxicology expertise to provide information that may be critical and life-saving in the event of an acute reaction.

In addition to the 24/7 call center, SafetyCall also maintains a consulting group called “Science Strategies” which compiles incident data to assist in product safety. As a result of handling multiple incidences, SafetyCall is able to compile an extensive database to determine the risks and

safety profile associated with particular products, since “The absence of reliable evidence of risk should not be mistaken for reliable evidence of the absence of risk” (SafetyCall International). This product safety and incident management service offers corporations the opportunity to proactively manage risk, take proper care of their customers, and promote safe use of their product.

Not only does SafetyCall function to protect the consumer, but in the process identifies potential areas of concern for the client to improve product safety. In turn, this process engenders increased consumer confidence in industry, fewer unnecessary lawsuits, and a healthier more protected consumer. All in all, SafetyCall is an invaluable link in the chain of incident management, product safety, better business, innovation, and consumer protection.

(Dr. Kotlyar, continued from front)

The research project will commence this summer and will continue until 60 subjects have completed the study which will be a double-blind crossover trial in which subjects will receive one month of Paxil (an SSRI effective in treating social phobia, anxiety disorder and several other psychiatric conditions) or one month of placebo prior to each of two laboratory session. The night before each session participants will be instructed not to smoke and to come into the general clinical research center (GCRC) the following morning. Subjects will be asked to relax for a ½ hour period after which blood will be drawn and will then be instructed to smoke a single cigarette. After smoking the subject will be asked to give a brief speech regarding a scenario that will be presented to them and to perform some mental arithmetic calculations. Blood pressure will be measured throughout the visit and blood will be drawn several times during the stress tasks. The goal of the research is to compare participant’s physiological response to stress while taking Paxil to the measures obtained while taking placebo.

The training aspect of Dr. Kotlyar’s grant involves earning a Master’s Degree in Clinical Research through the School of Public Health. Throughout the duration of the grant, Dr. Dorothy Hatsukami, the Director of the Tobacco Use Research Center, will serve as Dr. Kotlyar’s primary mentor with additional mentorship provided by an interdisciplinary advisory group consisting of Drs Cynthia Gross, Joseph Hanlon, Mustafa al’Absi and Anne Joseph.



Recent Publications



- **Straka, R.J.**, Taheri, R., Cooper, S., and Smith, J.C. Achieving Cholesterol Target in Managed Care Organization (ACTION- Trial). *Pharmacotherapy* 2005; 25 (3): 360-37.
- Kolwankar, D., Glover, D., Ware, J.A., and **Tracy, T.** Expression and Function of ABCB1 and ABCG2 in Human Placental Tissue. *Drug Metabolism and Disposition* 2005; 33: 524-529.
- **Tracy, T.S.**, Venkataramanan, R., Glover, D.D., Caritis, S.N. Temporal Changes in Drug Metabolism (CYP1A2, CYP2D6, and CYP3A Activity) During Pregnancy. *American Journal of Obstetrics and Gynecology* 2005; 192: 633-9.
- **Brundage, R.C. and Mann, H.J.** General Principles of Pharmacokinetics and Pharmacodynamics. Chapter 185 in *The Textbook of Critical Care* 5th Edition, 2005.

