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New Research Examining Quality Issues for Essential Drugs, Emerging Botanicals Supported by USP Awards

Six Students Awarded USP Fellowships for 2009–2010

Rockville, Md., October 20, 2009 — New research focused on the quality of key medicines and their use as well as increasingly popular botanicals is being sponsored by the U.S. Pharmacopeial (USP) Convention under its 2009–2010 Fellowship Program. USP fellowships are awarded to graduate students enrolled in chemistry, pharmacy, or other health care/scientific doctoral or post-doctoral programs to support research related to quality standards for medicines, dietary supplements and food ingredients.

USP's six fellowship recipients for 2009–2010 are:

- **Paul Gavaza**, The University of Texas at Austin, College of Pharmacy

Area of Research — Using the theory of planned behavior to predict Texas pharmacists' intention to report adverse drug events (ADEs). ADEs are unintended, undesirable and harmful events that are associated with the use of a drug. Some ADEs are the result of errors caused by medical staff, and most are preventable. In what is understood to be the first research of U.S. pharmacists' attitudes or willingness to report ADEs, this research will identify pharmacists' beliefs concerning reporting; identify critical factors that influence attitudes and willingness to report ADEs; explore the utility of the theory of planned behavior models in predicting intentions to report ADEs; and examine the relationship between demographic and practice characteristics and the theory of planned behavior model constructs.

- **Tanja Gödecke**, University of Illinois, Department of Medicinal Chemistry and Pharmacognosy

Area of Research — Method development for identity and quality control of an *Angelica sinensis* extract by Nuclear Magnetic Resonance (NMR). Quality control of botanical dietary supplements that contain single or mixed herbs or herbal extracts presents considerable challenges. This research will focus on developing an innovative analytical methodology for the quality control of herbal materials and extracts, applying state-of-the-art NMR. It will focus on *Angelica sinensis* (Dong quai), which is widely used as a dietary supplement in the United States. The newly developed NMR method would allow the simultaneous authentication, the identification of adulterants, and the quantitation of biologically active compound markers, and thus facilitate rational quality control of the plant material and extracts in a dietary supplement.

- **Kristyn Greco**, University of Connecticut, School of Pharmacy

Area of Research — Establishing best practices in dissolution testing for drug salts that undergo solvent mediated conversion: Effect of biorelevant dissolution media and its implications to bioavailability. Salt form selection is an integral part of the drug development process. For poorly soluble compounds, appropriate salt selection can result in higher dissolution rates, which are expected to lead to higher bioavailability of a drug. In a continuation of research from 2007–2008, this research will investigate the effect of different synthetic

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surface active ingredients as well as of some bile salts on the solution mediated phase transformation. This may lead to a better understanding of bioavailability.

- **John Limitiaco**, The University of California, Riverside

Area of Research — Development of new analytical approaches for analysis of heparin. In 2007–2008, hundreds of Americans and citizens worldwide died as the result of heparin intentionally adulterated with over sulfated chondroitin sulfate. This research will explore new approaches for the characterization of pharmaceutical heparin leading to simple high performance liquid chromatography (HPLC) and CE methods that can be easily implemented in quality assurance laboratories utilizing UV and/or refractive index detection. At the same time, the establishment of hyphenated LC-NMR and cITP-NMR methods will enhance the arsenal of techniques available for the rapid identification of new natural or intentional contaminants that may be introduced into the heparin supply chain in the future.

- **Vanisree Mulabagal**, Auburn University Department of Pharmacal Sciences, Harrison School of Pharmacy

Area of Research — Liquid Chromatography/Mass Spectrometry (LC-MS)-based fingerprint profile and quantitative analysis of *Euterpe oleracea* (acaí) dietary supplements and raw materials. The acaí berry is traditionally consumed in Brazil but has gained popularity in the United States, both as a food and as a botanical dietary supplement. Dietary supplements containing berries are abundant sources of anthocyanins that are associated mainly with antioxidant properties reported to provide health benefits. This research will address accurate and precise quantitation of all anthocyanins present in acaí dietary supplements and raw materials based on high resolution LC-MS method. The sample preparation procedure for acaí dietary supplements and raw materials will also be established.

- **Archana Rawat**, University of Connecticut, School of Pharmacy

Area of Research — *In vitro* release method for microsphere stability and performance testing. Poly lactitde-co-glycolide (PLGA) microspheres are under intense investigation for controlled and targeted drug delivery. PLGAs are one of the popular synthetic polymers for clinical applications as a consequence of their biodegradability, biocompatibility and resorbability. At this time there are no compendial methods available for the *in vitro* release testing of controlled release microsphere formulations. This research will seek to develop a standard method for parenteral controlled release microsphere formulations for incorporation into the *USP–NF* that can be used to minimize variations in the *in vitro* drug release profile and to make inter- and intra-laboratory comparisons possible.

USP’s Fellowship Program

USP’s Fellowship Program supports research in drug and food standards and their use. Each student is awarded a \$25,000 award, a portion of which is used to help support the fellow and research costs. Since the program’s inception in 1981, USP has invested more than \$3.7 million in 224 fellowship awards.

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USP—Advancing Public Health Since 1820

The United States Pharmacopeial (USP) Convention is a scientific, nonprofit, standards-setting organization that advances public health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods. USP’s standards are recognized and used worldwide. For more information about USP visit <http://www.usp.org>. **FY1014**