

**“Drug Information, how may I help you?”**  
**My Summer Jr. COSTEP Experience**  
**Ensign, Johanna Beznak: Duquesne University Pharm. D Candidate, Class of**  
**2010**

*“I'm calling to report these severe hallucinations I got after I took Lyrica and Celexa...I took acid in the 70's and never hallucinated this much!”*

Just one of the many consumers, health professionals, clinical researchers, and countless other callers I spoke with during my eight weeks at the FDA's Division of Drug Information (DDI). DDI serves as the hub for the majority of public inquires regarding drugs; who knew that the FDA number that is printed everywhere leads to this office in the FDA White Oak campus! DDI is composed of a team of pharmacists and other health professionals (known as Consumer Safety Officers (CSO)) who provide expert advice and guidance regarding all aspects of CDER activities.

Some examples of public inquires DDI gets on a daily basis include consumers requesting information on side effects and drug interactions, policies on importing drugs, and even clinical researchers with questions regarding Investigational New Drug Applications. The beginning of my COSTEP experience coincided with a Class I Digitek recall and I assumed the responsibility of a CSO sooner than I expected. Class I recalls are the most serious classification, this one arising from a manufacturing glitch that produced Digitek tablets double in size, essentially containing twice the amount of active ingredient. As you would expect, the release of this information was followed by an immediate surge in calls throughout the month. I educated callers on the basis of the recall, common side effects that may occur with increased digoxin levels, subsequent steps to take regarding their medication and overall health, and of course referred them to fill out a Medwatch form to report any adverse reactions. There were a number of distressed callers, which one can only expect with a recall of this severity, and I did my best to enlighten them on the situation and allay their anxiety- although sometimes there is only so much you can do over the phone. Contaminated heparin was also a hot topic, as were the killer tomatoes in June that warranted the public to have one less ingredient on their salads and sandwiches.

May and June proved to be a busy time for FDA renovations. I had the opportunity to get a first hand account of the proposal to eliminate current pregnancy labeling categories and replace them with three sections (risk summary, clinical considerations, and a data section), that would potentially be more informative and specific to those relying on such labeling. Additionally, I was present when the FDA discussed issuing a public health advisory to alert patients, caregivers and health care professionals to switch to hydrofluoroalkane (HFA)-propelled albuterol inhalers, as chlorofluorocarbon (CFC)-propelled inhalers will no longer be available in the United States after Dec. 31, 2008. I consider both the pregnancy labeling and CFC phase-out to be major milestones, affecting not only myself as a pharmacy student but the general public as well. The significance of the CFC-phase out was recognized by our division, and it gave DDI COSTEPs the chance to develop an outreach for state pharmacy boards

across the country, creating a tutorial pharmacists could potentially use to inform and educate patients on this change in their therapy.

The FDA coordinates numerous presentations and excursions for all the students and COSTEPS, many taking place at various FDA campuses while others are scattered around D.C. I met around 20 other interns during my stretch at FDA, a mixture of students on rotation and COSTEPs representing states all over the country, with some even coming as far as France. We were able to get a taste of how things work at other divisions and offices in FDA, such as Drug Advertising, Generic Drugs, Antimicrobials, and OTC Products. In addition, PHS pharmacists spoke about their experiences as officers, describing the career opportunities and benefits available with the PHS. Throughout the month, a few metro trips here and there gave us the chance to see BOP headquarters, APhA headquarters, and even go on a tour of the Pentagon. In June, we attended the FDA Cardiovascular & Renal Drugs Advisory Committee held at the nearby Washington D.C Hilton, and we were able to observe as this panel discussed a new drug application with its sponsors. It's not everyday you get to be in the same room with elite doctors and clinical experts from around the country and get a behind-the-scenes look at what takes place before a drug is approved.

Working at FDA provided me with experience that will undoubtedly help me develop as a student and future pharmacist, providing me with skills I would not have acquired in a typical pharmacy setting. I had the opportunity to network with other students, pharmacists, and PHS officers, all while getting an inside perspective of one of the most essential agencies in the country.

### **DDI Interns and COSTEPS, Summer 2008**

