



Ensign Alexander Novin

USPHS Active Duty 4 May 2008 – 23 August 2008

Duty Station: Food and Drug Administration (FDA)

Rockville, Maryland



I spent this summer with the United States Public Health Service (USPHS) as a Pharmacy Junior Commissioned Officer Student Training and Extern Program (JRCOSTEP). Along with ENS Michael Ruggero, I was assigned to the Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER). With the help of my preceptor, Captain William A. Hess, I worked on and experienced a wide variety of things during my time there. Officially, I was part of



The USPHS helped staff a medical tent had been set up by the National Park Service on the National Mall during the Independence Day 2008 Celebration. ENS Novin is in the back row, second from the left, and CAPT Hess, the PHS-1 RDF Team Commander, is also in the back row, third from the right. In addition, CAPT Hirschfeld, the PHS-1 RDF Chief Medical Officer, in the back row, second from the right.

the CDER's Medical Informatics Staff with my preceptor; however our projects brought us to other groups that were well beyond both CDER and FDA. The vast majority of my work encompassed the initiatives that had been set in place by the federal government to facilitate the move towards electronic health (eHealth).

I wore the PHS khaki uniform Monday through Thursday, and then wore the PHS battle dress uniform (BDU) as part of our 'casual Friday' attire. I worked in both the Parklawn building in Rockville, Maryland and in the newer White Oak building in Silver Spring, Maryland. The

number of PHS officers walking around in the White Oak building was substantially higher than the Parklawn building. One thing the uniform does convey is that you are visibly part of something larger than yourself, and it sometimes helps to break the awkward silences in elevators. Throughout the summer I had to make numerous trips to the National Naval Medical Center (NNMC) in Bethesda, Maryland to obtain additional uniform components. While moving around on the NNMC, you are treated by the active duty armed forces as though you were just like them, receiving salutes and returning them in kind. There are customs and courtesies you are required to know while wearing the uniform which between my preceptor and my prior knowledge weren't difficult to master at all. Things like how to salute, how to address everyone, the different ranks, etc.

My work at FDA/CDER started with the Substance Registration System (SRS) database which allows companies to electronically list both active and inactive ingredients in a standardized format in Structured Product Labeling (SPL). A big part of all the work involving eHealth is standardization and harmonization of terminology and information so that the computers can effectively utilize it. My main job with the SRS was to determine whether particular ingredients were in the public domain, and then setting a public domain "flag" to either "Yes" or "No". We



did this to prevent inadvertently revealing confidential chemical information. A drug manufacturer might invest millions of dollars in drug research and development, and the success of their product often depends upon a degree of secrecy prior to approval. In addition to getting the SRS ready for all of the new submissions, we needed all of the existing drugs, devices, and biologics in it as well. So, I assisted the Center for Biologics Evaluation and Research (CBER) in entering their vaccine substances into the SRS. This involved lengthy meetings with CBER vaccine experts to reach consensus on an Extensible Markup Language (XML) description schema, and then me entering the various vaccine schema components vaccine data into SRS as these vaccine experts looked on.



The other major FDA project I worked on was the pharmacologic class designations with the Study Endpoints and Labeling Division (SEALD). They are working on standard pharmacologic classes and terminologies to index drugs for Structured Product Labeling (SPL). We worked closely with a firm named Apelon, which is a contractor for the Department of Veterans Affairs, who manages the National Drug File Reference Terminology (NDF-RT) jointly with the FDA, the Center for Medicare and Medicaid Services (CMS), the National Cancer Institute



(NCI), and the National Library of Medicine (NLM). My work was that of a liaison between Apelon and drug experts in FDA review divisions. To that end, I compiled data into spreadsheets, looked for potential solutions to problems in current medical literature and the NDF-RT, and met with the drug experts from the review divisions to discuss the issues with them. I found that review division experts will sometimes tell you more than you'd ever want to know about a particular drug, it's a very academic experience.

I had many other PHS collateral duties during the summer that went beyond my work at FDA. A collateral duty is an assignment that is beyond that which appears in one's official position description. I did not get any extra pay for performing these duties – they were just expected of me no matter how long it took. Captain Hess is the Team Commander for Public Health Service-1 Rapid Deployment Force (PHS-1 RDF), which consists of 105 officers from the various PHS professional categories. The PHS-1 RDF is one of five teams throughout the nation that must be prepared and ready to deploy within 12 hours to deal with both natural and man-made disasters.



While everyone in the PHS is required to keep up with their basic readiness status, as a JRCOSTEP I was exempt from this because of my short tour of duty. Readiness has many aspects, such as having all necessary gear (e.g., sleeping bag, poncho, and canteen), having a complete battery of immunizations, being able to perform sit-up, push-ups, and run, and successfully completing on-line training modules. My preceptor strongly recommended that still attempt to achieve basic readiness status just in case the PHS-1 RDF was deployed. I was taking online learning modules from the Federal Emergency Management Agency (FEMA) about disasters, terrorism, and emergency response as well as submitting medical history/physical information to become basic ready myself. The PHS-1 RDF was put on alert status in July for Hurricane Dolly, and it

was somewhat nerve-wracking waiting for word as to whether tomorrow we'd pack our bags and head to Texas or not. We were never deployed, so I didn't go out to Texas; however I was deployed during the 4th of July. The National Park Service (NPS) requested our assistance staffing their medical tents for all the people who would be on the National Mall during the celebration. While deployed, I helped to rehydrate some patients and passers-by, as well as assist with medical records for those patients whom we were treating. I had a spectacular view of the fireworks since we were just south of the Lincoln Memorial. I also got to drive a golf cart, which we used for transportation, on the National Mall at one point! Medical treatment in the field is much different than what one is used to seeing in hospitals. I found that field medicine is quite exciting and I've developed a bit of a taste for it (or that could just be the camouflage talking).



The entire summer wasn't spent working however. I lived in a great apartment in Silver Spring, Maryland which was close to the metro stop. Being near the metro allows one great access and I got to do all the sight-seeing I could handle on the weekends. There were other COSTEPs, interns, post-docs, and rotation students in the metropolitan D.C. area, so we got together on numerous occasions and it was a great time. I even got to play softball on the Office of New Drug's (OND) team 'Brand X'. The FDA also has a program by which different people from the various offices will hold presentations and talk to all the students who're at the FDA about what they do and answer questions you might have. By the end of the summer I had attended twenty of those



lectures. Not all of them were at the FDA either, the United States Pharmacopeia (USP), National Institutes of Health (NIH), American Pharmacists' Association (APhA), and American Society of Health-System Pharmacists (ASHP) all have their headquarters in the D.C. area and are part of the program. There wasn't even enough time to do everything available, other things I couldn't do in my limited time there were a Capital tour and Pentagon tour.

I have to say that my experience as a JRCOSTEP was unparalleled. I could not think of a better way to spend a summer. For those who are considering a career in the PHS, I would highly recommend doing whatever you can to be selected as a JRCOSTEP so that you can "get your feet wet" with these medical professionals. Even for those students who aren't looking for a career in the PHS, I highly recommend a JRCOSTEP experience because it'll give you a unique perspective on the profession of pharmacy that you won't get in school.

Ensign Alexander Novin

PharmD Candidate

Philadelphia College of Pharmacy Class of 2010