

To: Professor T. Michael Duncan  
From: Alix Mizoue  
Date: April 6, 2015  
Subject: Tara Gooen Bizjak

LCDR Tara Gooen Bizjak is an officer in the United States Public Health Service (PHS) and a lead investigator for the United States Food and Drug Administration (FDA). In 2002, she ~~received~~ earned her B.S. in Chemical Engineering from Cornell University with a Bioengineering option. At Cornell University, Ms. Gooen Bizjak studied Chinese Hamster Ovary cells as a research assistant in Professor Lee's lab, and she completed two co-op internships. After graduation, she worked as a civilian in the FDA and at the same time ~~received~~ earned her Masters of Biomedical Science from the University of Medicine and Dentistry of New Jersey focusing on biodefense and stem-cell biology. She worked for the FDA for six years before joining the Public Health Services, though she has stayed with the FDA.

Ms. Gooen Bizjak began her presentation by discussing her career path. Following graduation, she joined the FDA as a Consumer Safety Officer, or Investigator, in New Jersey. She strongly supported the FDA's mission "to protect and promote public health." As Consumer Safety Officer, she inspected manufacturing facilities both nationally and abroad.

Ms. Gooen Bizjak then described the process of drug manufacturing inspections at the FDA. Investigators inspect drug manufacturing sites on a routine basis for Current Good Manufacturing Practices. The FDA Headquarters reviews the applications and, when appropriate, ~~takes~~ acts to enforce ~~ment actions~~. She emphasized that every inspection is unique because there are many different processes.

Later, Ms. Gooen Bizjak detailed her experience in the U.S. Public Health Service and the benefits of working for the United States Military. When Hurricane Katrina struck New Orleans in 2005, she volunteered to offer aid, but was not selected because of her civilian status. As a result, Ms. Gooen Bizjak decided to join the PHS and became a Lieutenant Commander. She is now on ~~tier-tier-~~ one deployment. She highlighted the benefits of working for the PHS such as the salary, job security, health insurance, paid vacation days, and paid maternity leave. She also mentioned that the PHS encourages mobility and deployment; however, candidates must medically qualify and meet the age requirements. Ms. Gooen Bizjak pointed out the diversity of PHS officers, including physicians, dentists, engineers and therapists.

Next, Ms. Gooen Bizjak reported on how the FDA ensures quality. She stated that manufacturers must understand their processes and consistently perform each step well. The FDA expects manufacturers to use statistics as well as small and ~~large-large-~~ scale tests. She listed some of the typical tests done such as appearance and an assay of the amount of active ingredient.

Ms. Gooen Bizjak concluded her presentation by listing the lessons she has learned while working for the government. She emphasized that challenges and risks are opportunities, not road blocks. She also advised us to get our hands dirty and help out where needed in any job. Finally, Ms. Gooen Bizjak stated that every day is a new learning opportunity and supported continuing education. "If you don't change and improve, the world will change around you."

Ms. Gooen Bizjak's presentation was interesting and provoking. I had not previously considered a career in the government, but there seems to be many benefits. I appreciated that she listed not only the advantages of working for the government but also the disadvantages. Additionally, I thought the section on lessons learned was helpful.

Reviewed by Elizabeth Guilherme Excellent memo!