



NAME: CAPTAIN (CAPT) JUSTINA MOLZON

JOB TITLE: ASSOCIATE DIRECTOR FOR
INTERNATIONAL PROGRAMS

AGENCY: FOOD AND DRUG ADMINISTRATION (FDA)

Education/Degrees/Certificates/Institutions:

CAPT Justina Molzon received her B.S., with honors and distinction, and M.S. in Pharmacy, with an emphasis on pharmaceuticals and pharmacognosy, from the University of Rhode Island. She also earned a law degree from the Chicago-Kent College of Law/Illinois Institute of Technology and is a Fellow in the American Society for Pharmacy Law, serving on its Board of Directors from 1989-1997.

Current Job Description:

CAPT Molzon is a member of FDA's Center for Drug Evaluation and Research's (CDER) Senior Management Team and currently the Associate Director for International Programs. One of her primary responsibilities is to serve as the CDER lead and Steering Committee representative for the International Conference for Harmonization (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use.

ICH is a joint initiative involving both regulators and industry representatives of the European Union, Japan and the United States in scientific and technical discussions of the testing procedures required to assess and ensure the safety, quality and efficacy of medicines. The objective of ICH is to increase international harmonization of technical requirements to ensure that safe, effective and high quality medicines are developed and registered in the most efficient and cost-effective manner. These activities have been undertaken to promote public health, prevent unnecessary duplication of clinical trials in humans, and minimize the use of animal testing without compromising safety or efficacy.

CAPT Molzon's other responsibilities include working with international drug regulatory authorities, the global scientific community, and other US Government agencies. She is directly involved in setting international regulatory standards by working with regional harmonization efforts and representing CDER at Bilateral (EU/US) and Trilateral (Mexico/Canada/US) initiatives and meetings with other foreign regulatory bodies. She had recently developed the CDER Forum for International Drug Regulatory Authorities which is offered twice a year to explain CDER's review process and to promote safe, effective and quality drug products globally. Furthermore, CAPT Molzon serves as an intra/interagency liaison on international matters and works with the World Health Organization (WHO), serving on several of its technical committees, as well as the Pan American Health Organization (PAHO) where she oversees efforts on good manufacturing practices, bioequivalence and good clinical practices. One of her most recent assignments is the coordination of CDER's activities related to the President's

Emergency Plan for AIDS Relief (PEPFAR), where she is involved in technical outreach to the 15 PEPFAR focus countries

Qualifying Skills for Current Position and Previous USPHS Assignments:

CAPT Molzon has a broad scope of experience as a USPHS officer and as a civilian pharmacist. After teaching at the University of Rhode Island, she started her PHS career as a staff pharmacist at the USPHS Indian Hospital on the Navajo Indian Reservation in Tuba City, Arizona. She was soon promoted to Acting Chief of Pharmacy Services and was administratively and professionally responsible for the provision of pharmacy services within the Tuba City Service Unit with a catchment area of 4,400 square miles and a population of over 40,000 people. After five years in Arizona, CAPT Molzon continued her USPHS career as a regional pharmacist consultant and inspector in Chicago, IL with the Health Care Financing Administration's (HCFA) Survey and Certification Review Branch, Division of Health Standards and Quality (HCFA is now named the Centers for Medicare and Medicaid Services (CMS)). As the pharmacist consultant, her primary responsibilities included coordinating pharmacy standards for Medicare and Medicaid providers for federal and state agencies. She also planned monitoring activities for health care providers, provided consultation for state agencies on pharmacy related issues and assisted the FBI in cases involving fraud. After 3 years as a pharmacist consultant, CAPT Molzon left the USPHS and worked as a clinical pharmacist in the critical care areas of Northwestern Memorial Hospital while she pursued her law degree. While in Chicago, she also worked with a pro bono legal program for persons with HIV/AIDS. After receiving her Juris Doctor, she returned to the USPHS and FDA as a labeling reviewer with the Labeling Review Branch in the Office of Generics Drugs (OGD) in Rockville, MD. As a result of her hard work and dedication, she soon became the Special Assistant to the Director of OGD, and later was promoted to Special Assistant to the Deputy Center Director for Pharmaceutical Science and International Programs, CDER, FDA, where she continued to excel in coordinating special projects, assisting in implementation of CDER's discipline specific coordinating committees, representing the Center on the Research Involving Human Subjects Committee, and facilitating, planning, and coordinating national and international meetings related to Center initiatives. She now holds the position of Associate Director for International Programs.

Reasons for Choosing the USPHS as A Career:

In 1976 CAPT Molzon was an instructor and graduate student at the University of Rhode Island's School of Pharmacy responsible for the 5th year pharmacy student's dispensing class and lab. As part of her teaching responsibilities, she invited various lecturers to give presentations on employment possibilities in pharmacy. One of the presentations was by a PHS Commissioned Officer from the USPHS Hospital in Boston. He did such a good job explaining the opportunities and advantages of being a pharmacist in Public Health Service that she decided to submit her own application. At that time she was contemplating joining the Peace Corps after graduate school, but quickly realized that by working in the Indian Health Service she could achieve the same goals of helping to provide health care to underserved areas. She specifically requested working in IHS west of the Mississippi and was pleased to be offered the position of staff pharmacist in the IHS hospital in Tuba City.

Most Rewarding USPHS Professional Experience:

Working on the Navajo reservation in a small IHS hospital was CAPT Molzon's most rewarding experience until her current involvement in Presidential Emergency Plan for AIDS Relief (PEPFAR). Both address urgent public health needs and she feels that her efforts have made a difference. In Tuba city, she had to rethink everything she had taught pharmacy students about dispensing and counseling. She could no longer merely say "take this medication every six hours" because the Navajo's did not generally wear watches. She often needed to work through a Navajo translator because many of the older patients did not speak English. CAPT Molzon explained that it was a very rewarding experience to be working with a culture very different than her own. Currently CAPT Molzon is responsible for coordinating CDER's PEPFAR activities. PEPFAR is a five year U.S. Government program with goals to treat 2 million HIV-infected people, prevent 7 million new infections and care for 10 million people infected with or affected by HIV/AIDS, including orphans and vulnerable children. CDER is helping to meet these treatment goals by encouraging pharmaceutical sponsors worldwide to submit U.S. marketing applications for single entity, fixed-dose combination (FDC), and co-packaged versions of previously approved antiretroviral (ARV) therapies. These efforts ensure the availability of safe, effective and high-quality ARVs to meet the in-country treatment goals of global agencies and governments engaged in the treatment and care of patients living with HIV/AIDS. Further, CAPT is very grateful that she has the opportunity to work with international drug regulatory authorities in assuring the safety, efficacy and quality of pharmaceuticals worldwide.

What advice would you give to Junior Officers?

CAPT Molzon would advise Junior Officers to start their career in IHS or Bureau of Prisons to get a good foundation in the profession of pharmacy. They should then work for another PHS agency to gain broader experience and, if they so choose, work their way towards headquarters as the capstone to their career. Often Junior Officers start at headquarters, specifically the Washington DC area. They then find it difficult to leave the metropolitan area and as a result have a difficult time showing diversity in geographical mobility and work assignment history which is helpful for promotion.