



NAME: ISSAM ZINEH, PHARMD, MPH, FCP, FCCP

JOB TITLE: DIRECTOR, OFFICE OF CLINICAL PHARMACOLOGY, OFFICE OF TRANSLATIONAL SCIENCES, CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)

AGENCY: U.S. FOOD AND DRUG ADMINISTRATION (FDA)



Dr. Zineh is an expert in the fields of drug development and evaluation, clinical pharmacology, pharmacotherapy, and precision medicine, and is the Director of the Office of Clinical Pharmacology, Center for Drug Evaluation and Research (CDER), FDA. Dr. Zineh has held various leadership positions at the FDA including Associate Director for Genomics (2008-2012), Co-Director of the CDER Biomarker Qualification Program (2009-2015), and voting member of the CDER Medical Policy Council (2016-present).

EDUCATION/DEGREES/CERTIFICATES/INSTITUTIONS:

Dr. Issam Zineh received a Doctorate of Pharmacy (Pharm.D.) from Northeastern University in 2000. He completed a pharmacy general practice residency at Duke University Medical Center (2000-2001), and completed a Cardiovascular Pharmacogenomics Fellowship at the University of Florida (UF) Center for Pharmacogenomics (2001-2003). Dr. Zineh also obtained a Master of Public Health (MPH) with a concentration on health management and policy from the UF College of Public Health and Health Professions in 2008. In 2011, Dr. Zineh was among the CDER Inaugural Leadership Cohort in the Program for Authentic Leadership. He has a broad range of professional certifications, numerous research publications and speaker engagements as well as professional honors and awards.

CURRENT JOB DESCRIPTION:

Dr. Zineh is the Director of the Office of Clinical Pharmacology (OCP) at CDER in FDA. OCP is a dynamic, multidisciplinary organization whose stated goals are to enhance drug development, promote regulatory science and innovation, and inform the optimal use of medications.

He is also member of the CDER senior management team and currently leads a staff of 230 regulatory, research, program/project management, and administrative staff in FDA's efforts to enhance drug development and promote regulatory innovation through clinical pharmacology and experimental medicine.

QUALIFYING SKILLS FOR CURRENT POSITION:

Prior to joining FDA in 2008, Dr. Zineh was trained as a clinical pharmacist who practiced in both inpatient and outpatient settings. After receiving his Pharm.D., he completed an extensive clinical practice residency at Duke University Medical Center (2000-2001) which spanned ambulatory and critical care, general medicine, drug information, and several therapeutic areas. Dr. Zineh then completed extensive training and education at the University of Florida Center for Pharmacogenomics (2001-2003), and continued to serve on faculty where he had an active

research program in cardiovascular pharmacology and pharmacogenomics (2003-2008). While on faculty, he completed an MPH (2005-2008) and later served as the Associate Director of the Center for Pharmacogenomics. Dr. Zineh has held several adjunct faculty positions including at the University of Florida and the University of North Carolina at Chapel Hill.

Research focused and academically engrained, Dr. Zineh has spoken extensively at national and international meetings. He has also published over 80 papers on patient-oriented original research, public health policy, drug development, and regulatory science. He serves on multiple editorial review boards, is an active manuscript reviewer, and has contributed heavily to the understanding of patient drug response variability. Throughout Dr. Zineh's career, he has had a broad range of unique professional experiences, significant training, and lectured and authored publications with numerous recognitions and awards both domestic and abroad. He maintains pharmacist licenses in Florida and Massachusetts.

REASONS FOR CHOOSING THE PUBLIC HEALTH SERVICE AS A CAREER:

When Dr. Zineh was on faculty at UF, he focused heavily on research with therapeutic individualization for patients. In addition, he obtained an MPH with a concentration in public health policy and administration. He started thinking about long-term goals, and wanted to focus on the direct impact on patients and the overall population. Dr. Zineh notes, "It's very challenging in academic research to translate the science into successful, impactful discoveries". After meeting Dr. Larry Lesko, who was formerly the Director of the Office of Clinical Pharmacology at FDA, Dr. Zineh was convinced that a career at FDA could afford him opportunity to positively impact patients at a high level. Dr. Zineh got a unique opportunity to head up the genomics group at the FDA Office of Clinical Pharmacology, and utilize the administration portion of his education. He is excited for the future of clinical pharmacology to influence drug development and enable the safe and rational use of new therapeutics in patients. Being able to participate in regulatory policy setting and decision making, Dr. Zineh is excited to continue to work with great people across the multiple Centers at FDA.

PREVIOUS AND CONCURRENT FDA ASSIGNMENTS:

Director, CDER/Office of Clinical Pharmacology, FDA, Silver Spring, MD
Co-Director, Biomarker Qualification Program, CDER/Office of Translational Science, FDA
Associate Director for Genomics, CDER/Office of Clinical Pharmacology, FDA

MOST REWARDING PUBLIC HEALTH SERVICE PROFESSIONAL EXPERIENCE:

The most impactful experience from Dr. Zineh's career at FDA is when he was able to partake in extensive year-long negotiations to integrate innovative scientific approaches (biomarkers, precision medicine, model-informed drug development, and others) into the FDA Prescription Drug User Fee Act (PDUFA). Dr. Zineh is excited about the growing integration of innovative science and technology into FDA policy and oversight.

OTHER PROFESSIONAL INTERESTS/ACTIVITIES:

Dr. Zineh is involved with a wide array of professional pharmacy activities, associations, and federal agencies with a key theme deeply rooted in patient-focused drug development, rational therapeutic use, and clinical trial research. However, Dr. Zineh also takes time to work with his local community; he serves as a member of the board of directors for the nonprofit, Downtown

Baltimore Child Care, Inc. (DBCC), which focuses on the early educational needs of children in Baltimore city.

*By LT Maryam Khazraee
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