



NAME: Kimberly Struble, Pharm.D.

JOB TITLE: Medical Team Leader, Division of Antiviral Drug Products, Office of New Drugs, Center for Drug Evaluation and Research

AGENCY: Food and Drug Administration (FDA)

EDUCATION/DEGREES/CERTIFICATES/INSTITUTIONS:

Dr. Kimberly Struble received her Baccalaureate of Science Degree from the University of Connecticut School of Pharmacy in 1993. She obtained her Doctor of Pharmacy Degree in 1999 from the University of Arkansas for Medical Sciences.

CURRENT JOB DESCRIPTION:

Dr. Struble is a Medical Team Leader in the Division of Antiviral Drug Products (DAVP) in the Office of New Drugs (OND) at the Food and Drug Administration (FDA) in Silver Spring, Maryland. She is an expert in human immunodeficiency virus (HIV) drug development and was the first non-physician Medical Team Leader in OND and DAVP. As the Medical Team Leader, her responsibilities include assigning and reviewing work of her team related to the evaluation of safety and efficacy data from Investigational New Drug (IND) and New Drug Application (NDA) submissions for drug products used in the prevention of HIV infection, treatment of HIV infection, herpes, hepatitis B and C, influenza, and other emerging viral infections. These submissions require application of complex scientific expertise and often include collaborative evaluation throughout FDA and coordination with other Agencies. As the Medical Team Leader, Dr. Struble provides advice, counsel, instruction, and scientific expertise for the team and the work she oversees. She also serves as the Division's HIV and hepatitis Focus Group Leader where she identifies topics and leads discussions with other Medical Officers and Team Leaders regarding current issues in HIV and hepatitis drug development.

In addition, Dr. Struble is a member of the Department of Health and Human Services HIV Treatment Guidelines Panel. In this capacity she serves as the co-leader of drug interaction table format revisions and member of the therapeutic drug monitoring and treatment-failure subgroup.

She also serves as the FDA representative for the following cross-Agency workgroups: the executive committee for the Forum for Collaborative HIV Research and Women's Research Initiative; Centers for Disease Control and Prevention occupational and nonoccupational post-exposure prophylaxis public health service working group; and Lead Medical Officer for a project funded by the Office of Women's Health entitled, *Women in HIV Issues: Safety and Efficacy Analyses*.

QUALIFYING SKILLS FOR CURRENT POSITION:

Dr. Struble was commissioned in the USPHS and joined the FDA in 1993 as a Drug Information Officer in the Division of Drug Information Resources where she was responsible for serving as the AIDS Database Coordinator. She then became a Regulatory Management Officer in DAVP where she coordinated and managed the review of IND and NDA submissions for drug products in the Division. Based on her expertise in the area of HIV drug development, she became a Regulatory Review Officer/ Clinical Reviewer responsible for the scientific review of IND and NDA submissions related to antiviral drug treatment.

In 2002, Dr. Struble separated from the USPHS and FDA to join a pharmaceutical company as Director of U.S. Regulatory Affairs and Director of Global Research and Development. She rejoined FDA in 2003 as a Senior Clinical Analyst in DAVP.

Dr. Struble has extensive research experience, authored publications, and has been recognized by numerous FDA awards. She served as a Disaster Medical Assistant Team (DMAT) Member, and volunteer pharmacist at the National Institutes of Health HIV outpatient clinic and Elizabeth Taylor Medical Center, Whitman-Walker Clinic in Washington, DC.

REASONS FOR CHOOSING THE FDA AS A CAREER:

Dr. Struble is committed to advancing public health and chose FDA as a career because her daily work has a national public health impact. She is a champion for HIV drug development and is committed to sharing her knowledge and experiences with others through mentoring and further contributing to scientific advances in drug development and knowledge of antiretroviral drug interactions.

PREVIOUS USPHS ASSIGNMENTS:

- Drug Information Officer (1993-1994), Division of Drug Information Resources, CDER, FDA
- Regulatory Management Officer (1994-1997) and Senior Regulatory Review Officer (1997-2002), Division of Antiviral Drug Products, Office of New Drugs, CDER, FDA

MOST REWARDING PROFESSIONAL EXPERIENCE:

Dr. Struble has had many rewarding professional experiences during her career in public health. She especially enjoyed the opportunity to work with the National Institutes of Health to train pharmacists in South Africa on pharmaceutical care for HIV-infected patients, antiretroviral drug interactions, and clinical trial conduct.

by CDR Richardae T. Araojo