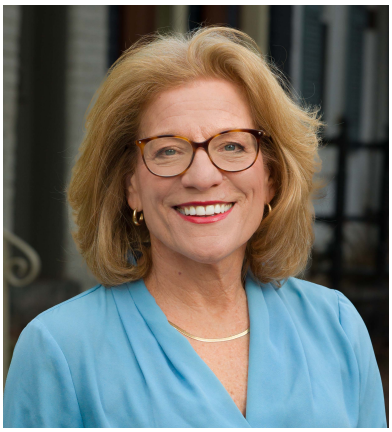
Sandra L. Kweder, M.D.

Principal, Drug and Biological Products



BACKGROUND	• 35 years of FDA experience in the U.S. and Europe
SPECIALTY	• Medical, scientific, and policy aspects of drug and biological product regulation domestically and internationally
EXPERIENCE	• 14 years as Deputy Director, Office of New Drugs, CDER • 6 years as Deputy Director, Europe Office, FDA • 33 years in U.S. Public Health Service (RADM, retired)

Dr. Sandra Kweder is an internal medicine expert with more than 30 years of experience in U.S. and international medical products regulation and policy. As Principal, Drug and Biological Products, with Greenleaf Health, she offers broad expertise accrued through multiple senior leadership roles at the FDA, where she oversaw significant regulatory developments during periods of transformation in the landscape of science policy and public health.

Sandy recently served for six years as Deputy Director of the FDA's Europe Office and Liaison to the European Medicines Agency (EMA), first in London and later in Amsterdam, working to strengthen international collaboration across all areas of FDA regulation, especially medical products. She launched new engagements with the EMA in areas including labeling and study of drugs in pregnancy, patient engagement strategy, rare disease product development, and an invigorated parallel scientific advice program. Upon returning to the U.S., she provided strategic direction and subject matter expertise to FDA leadership as Senior Medical and Regulatory Advisor in the Office of Global Strategy and Policy.

Prior to her work in Europe, Sandy spent nearly 14 years as Deputy Director of the Office of New Drugs (OND) in the FDA's Center for Drug Evaluation and Research (CDER). She guided OND through a phase of substantial maturation between 2002 and 2016, as the prescription drug user fee program (PDUFA) grew and CDER strengthened review standards and practices to incorporate scientific innovation and emerging drug development approaches such as patient-reported outcomes in clinical trials. Among other initiatives, Sandy led the taskforce responsible for developing the 2014 Pregnancy and Lactation Labeling Rule that updated the regulations on labeling prescription drugs for use in pregnant and lactating patients and helped to modernize the FDA's policies on conducting research in these populations.

Sandy joined the FDA in 1988 as a medical officer in the Division of Antiviral Drug Products, newly established to address the urgent need for treatments for HIV/AIDS. She became Acting Director of the Division of Epidemiology and Surveillance, then, after a two-year clinical fellowship, Deputy Director of the Office of Drug Evaluation IV, responsible for regulating antiviral and antimicrobial drug products. While at the FDA, she was a delegate to the American Board of Medical Examiners and a Fellow of the Drug Information Association (DIA). Sandy was often called upon to communicate complex medical and regulatory information to audiences ranging from patients and clinicians to intragovernmental and global partners. In 2022, Sandy was honored with an FDA Reward of Merit for her work to advance the Agency's mission, particularly on the global front.

For 33 years Sandy served in the U.S. Public Health Service (PHS), rising to the rank of Rear Admiral and receiving numerous PHS awards before retiring from the service in 2013.

Sandy trained in medicine at the Uniformed Services University in Bethesda, MD, and performed her two-year clinical teaching fellowship in obstetrics and consultative medicine at Brown University School of Medicine. She remains on the faculty at USUHS and continued to teach medical students and residents while at the FDA, and is known for her strong commitment to mentoring the next generation of clinicians and FDA professionals.