Greenleaf Health

Karen Midthun, M.D.

Principal, Drug and Biological Products

BACKGROUND	• 28-year career in public service, including 22 years at the FDA
SPECIALTY	• Regulation of biological products, vaccines, cell and gene therapies
EXPERIENCE	• Former Director of the FDA's Center for Biologics Evaluation and Research

Dr. Karen Midthun joined Greenleaf Health following a distinguished 28-year career in public service, of which 22 years were dedicated to the FDA. An infectious disease physician by training, Dr. Midthun served as the Director of the FDA's Center for Biologics Evaluation and Research (CBER) from 2009 to 2016.

At Greenleaf, Dr. Midthun serves as Principal, Drug and Biological Products, co-leading the firm's Drug and Biological Products Team with fellow principals Drs. John Jenkins, Bob Meyer, and Sandra Kweder. Dr. Midthun contributes specialized insight — informed by her regulatory, research, and clinical experience — to the strategic and technical guidance that Greenleaf provides to FDA-regulated entities developing products to prevent or treat infectious diseases, addressing ongoing public health needs for biologics, and advancing the growing field of cell and gene therapies.

During her FDA tenure, Dr. Midthun played a critical role in facilitating policy and technology development in the areas of blood products, vaccines, and cell, tissue, and gene therapies. Under her leadership, the FDA approved several vaccines that have had a significant public health impact, including vaccines for pneumococcal disease, meningococcal disease, and human papilloma virus. Dr. Midthun received praise for her work responding to the 2009 influenza pandemic; developing a framework for the regulation of human cell and tissue products; and, in collaboration with the Center for Drug Evaluation and Research (CDER), developing a policy for the regulation of biosimilar products.

Prior to her role as Center Director, Dr. Midthun served as the Deputy Director of CBER and the Director of the Office of Vaccines Research and Review within CBER. Before joining the FDA in 1993, Dr. Midthun was on the faculty of the Department of International Health at the Johns Hopkins Bloomberg School of Public Health, where she was involved in the clinical development of investigational vaccines and was an attending physician at the Johns Hopkins Hospital.

Dr. Midthun received her bachelor's degree from the Massachusetts Institute of Technology (MIT) and her medical degree from the George Washington University School of Medicine. She trained as a resident in internal medicine at Johns Hopkins Hospital and as a fellow in infectious diseases at Johns Hopkins Hospital and the National Institute of Allergy and Infectious Diseases (NIAID). She is a fellow of the Infectious Diseases Society of America.