Richard Klein recently left FDA after more than 41 years with the agency. He served as director of the FDA’s Patient Liaison Program in the agency’s Office of Health and Constituent Affairs, the primary agency interface with patients and patient advocate communities. He interacted extensively with outside communities and within the agency’s scientific and policy offices to advocate for patient interests, and facilitate patient engagement. He actively addressed issues and concerns of patients in a variety of areas, including treatment access to unapproved drugs, product safety, and clinical trial design.

Mr. Klein has worked in various capacities at FDA providing him with a well-rounded understanding of the regulatory issues that affect patients. He participated in the development of revised expanded access regulations and guidelines, and led the creation of the FDA expanded access website, and played an active role in the development of the streamlined application for individual patient access, and the Expanded Access Navigator.

Prior to working in patient engagement, he helped to develop policies and regulations for the protection of human research subjects, and provided guidance for institutional review boards (IRBs).