TRANSNATIONAL
STRATEGY GROUP

Mr. Fred Richman — Washington
Senior Advisor for Pharmaceuticals and Medical Devices

Mr. Richman's background, expertise and extensive knowledge of the U.S. Food and Drug Administration (FDA) permit clients to achieve compliance with drug GMP regulations, including assistance in interacting with FDA during compliance inspections, preparing comprehensive responses to FDA's FD-483 observations, and in attending regulatory meetings with FDA. In his work, Mr. Richman reviews and advises firms on applicable ICH and FDA guidance documents and GMP regulations regarding quality systems, stability data, process validation, and laboratory controls. He routinely provides assistance on import-export issues.
Mr. Richman served as a Senior Case Review Officer in FDA's Office of Enforcement, where he was responsible for reviewing and clearing for the Office of the Commissioner, legal action recommendations submitted by FDA field offices nationwide. In 1996, Mr. Richman took on the position of Team Leader for the Adverse Drug Reaction and Pharmacy Compounding Team in FDA's Center for Drug Evaluation and Research (CDER). In his subsequent CDER position as Deputy Director, Division of New Drugs and Labeling Compliance, he supervised regulatory operations relating to Rx and OTC drugs. He was instrumental in developing a regulatory strategy to address the marketing of unapproved drug products.

In 2005, Mr. Richman became the Director of the Division of Compliance Management and Operations (DCMO) in FDA's Office of Enforcement. Mr. Richman has made numerous presentations to groups such as the Regulatory Affairs Professionals Society (RAPS), the Drug Information Association (DIA), the Pharmaceutical Education Research Institute (PERI), and the Food and Drug Law Institute (FDLI) on diverse drug and device compliance issues. Most recently, he presented a webinar for PERI on "FDA Regulatory Actions: The Consequences of Non-Compliance" and gave a presentation on "Violations and Enforcement" at an FDLI seminar on drug regulation.

Mr. Richman was recently selected by the Food and Drug Law Institute (FDLI) to serve on its new Global Committee. This committee is charged with assisting FDLI staff in developing and delivering educational conferences and publications. He and the other committee members will provide input to staff on legal, regulatory, and policy activities and developments in food and drug law in countries of interest and suggest ways to further the strategic goals of FDLI's global initiative.

Mr. Richman obtained a B.A. degree in Chemistry from Queens College of the City University of New York, Flushing, New York, and an M.S. degree in Chemistry from St. John's University, Jamaica, New York.