Karen C. Corallo

Skadden

Of Counsel, Washington, D.C.

Life Sciences and Health Care

T: 202.371.7522
F: 202.661.0522
karen.corallo@skadden.com

Education

J.D., South Texas College of Law, Houston, 1984 (with honors)

B.A., University of Texas, 1979 (*summa cum laude*)

Bar Admissions

District of Columbia

Texas

Karen Corallo, an experienced regulatory and litigation attorney, advises Food and Drug Administration (FDA)-regulated companies in litigation and counsels clients on administrative, regulatory and enforcement matters. Ms. Corallo has represented companies and their directors on a wide variety of cases and investigations, including those involving False Claims Act violations, breach of fiduciary duty claims, ERISA-related matters and shareholder derivative actions, among others. She assists pharmaceutical, medical device and food industry clients in navigating the complex regulatory landscape involving product approvals and clearance, recalls, quality, manufacturing and marketing.

Ms. Corallo previously served as director of the FDA Center for Drug Evaluation and Research, Division of Drug Imports, Exports, Recalls, and Shortages. In this position, she wrote and implemented the FDA's global drug imports strategy, directed key drug policy initiatives, managed operations and supervised agency staff. Ms. Corallo also previously served as associate chief counsel in the FDA's Office of Chief Counsel, where she handled both civil and criminal enforcement across all FDA-regulated commodities. She was the first FDA attorney fully dedicated to the Health Care Fraud and Abuse Control Program under the joint direction of the attorney general and secretary of the Department of Health and Human Services. In that program, Ms. Corallo worked with the Department of Justice and U.S. Attorneys' offices across the country on matters involving manufacturing quality, clinical trial fraud, and marketing and promotional enforcement issues. She also previously held positions at other global law firms.

Ms. Corallo was named as a Life Science Star in *LMG Life Sciences 2017*. She also was selected as a life fellow to the Texas Bar Foundation.