

SETON HALL | LAW

Healthcare Compliance
Certificate Program



Scott Danzis

Partner

Covington & Burling LLP

sdanzis@cov.com

Scott Danzis is a partner in the firm's Food & Drug and Health Care practice groups. His practice focuses on the regulation of medical devices and diagnostics. He regularly works with companies in developing strategies for interacting with the U.S. Food and Drug Administration (FDA), including strategies for clinical development and premarket review (including appeals and dispute resolution, when needed). He also advises on compliance with post-market requirements, including advertising and promotion restrictions, quality system and manufacturing requirements, post-market reporting, recalls, and enforcement actions.

From 2006 to 2008, Mr. Danzis served as the Special Assistant to the Chief Counsel of the U.S. Food and Drug Administration. While at FDA, he was broadly involved in a wide range of legal and regulatory matters related to medical devices and drugs. He also worked on implementing key provisions of the Food and Drug Administration Amendments Act of 2007.

Mr. Danzis has significant experience in FDA regulatory strategies, including strategies for the premarket review (510(k)s, PMAs) of medical devices; appeals and dispute resolution within FDA; IDEs, INDs, and clinical trial regulation; advertising, promotion, and scientific exchange, including responding to enforcement actions and investigations; imports and exports of FDA regulated products; QSR and cGMP requirements, including responding to FDA 483s and enforcement actions; product recalls; adverse event and MDR reporting; FDA consent decrees and OIG corporate integrity agreements; regulatory due diligence; and compliance with antifraud statutes, including the anti-kickback statute and the False Claims Act.

Mr. Danzis developed and edited a book on the regulation of in vitro diagnostic products and laboratory testing, *In Vitro Diagnostics: The Complete Regulatory Guide* (FDLI, 2010). He currently serves as an Adjunct Professor at the Georgetown University Law Center, where he teaches a course on the regulation of drugs, biologics, and medical devices.

Mr. Danzis clerked for the Honorable Chester J. Straub on the U.S. Court of Appeals for the Second Circuit. He is a graduate of the University of Virginia School of Law, where he was the Editor-in-Chief of the *Virginia Law Review* and elected to the Order of the Coif. He holds a Master's Degree

SETON HALL | LAW

Healthcare Compliance
Certificate Program

from George Washington University in Health Care Management and Policy, and a Bachelor of Science from Cornell University.

Mr. Danzis has been recognized by *The Best Lawyers in America*, FDA (2011-2018); *Legal 500 US*, M&A: Commercial Deals and Contracts (2016-2017); and *Washington DC Super Lawyers*, FDA (2013-2017).