SETON HALL | **LAW**

Healthcare Compliance
Certificate Program

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Scott Danzis is a partner in Covington's Food, Drug, and Device Practice Group and chairs the Firm's Medical Device Industry Group. Scott is a leading expert on the regulation of medical devices, diagnostics, and digital health. He regularly helps clients navigate their most complex regulatory challenges, including strategies for premarket review, postmarket compliance, and enforcement actions. Scott counsels many of the world's preeminent medical device companies on a range of matters, including advertising and promotion, recalls, quality system issues, medical device reporting, clinical and non-clinical testing, FDA inspections, and other regulatory matters.

Scott previously served in FDA's Office of the Chief Counsel where he served as the Special Assistant to the Chief Counsel of FDA. At FDA, Scott was involved in a wide range of legal and regulatory matters, including significant rulemaking, enforcement actions, and legislative initiatives.

Scott speaks regularly at conferences regarding FDA regulation of devices and diagnostics, and since 2010 serves as an Adjunct Professor of Law at the Georgetown University Law Center, where he teaches a course on FDA law.

Scott 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 Coif. He also holds a Master's Degree from George Washington University and a Bachelor of Science from Cornell University.

From 2006 to 2008, Scott 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.

Scott has significant experience in the following areas:

- 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;
- Compliance with antifraud statutes, including the anti-kickback statute and the False Claims Act.

Scott recently 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.

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