SETON HALL | **LAW**

Healthcare Compliance
Certificate Program

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Nikki Reeves is an FDA and health care regulatory compliance lawyer with more than twenty years of experience. She co-chairs the firm's Life Sciences and Healthcare Industry Group, which is comprised of more than 350 lawyers across fifteen practice areas in the firm. A partner in the firm's FDA & Life Sciences practice, she advises pharmaceutical and medical device companies on pre- and post-market FDA regulatory compliance and enforcement matters ranging from clinical trials to good manufacturing practices to labeling, advertising, and promotion of FDA-regulated products. She has been the lead FDA regulatory advisor to her clients on 150+ transactional matters. She is an expert on federal Sunshine, state, and international transparency/disclosure laws and leads two industry compliance coalitions.

Ms. Reeves counsels pharma and device companies on FDA inspections, Form 483s, Warning Letters, product recalls, import detentions, clinical holds, and other FDA compliance and enforcement matters. She conducts risk assessments and internal investigations into allegations of FDA and health care program noncompliance. She routinely advises company executives and board members and represents her clients before federal agencies. She has established robust compliance programs and policies for numerous life sciences companies. She has also served as an interim General Counsel and as a Chief Compliance Officer for her life sciences clients.

Ms. Reeves leads two pharma and device industry coalitions on transparency and disclosure laws. The *Ad Hoc Sunshine and State Law Compliance Group* is a coalition she advises on federal Sunshine Act and state transparency/disclosure and gift ban laws. The *International Marketing and Disclosure Compliance Group* is a separate coalition of companies she advises on the growing area of transparency and disclosure laws and industry codes of conduct in the EU, Australia, Japan, and numerous other countries and regions.

Ms. Reeves was named an LMG Life Sciences Star for FDA Pharmaceutical and FDA Medical Device in 2019. She is a frequent speaker and author on FDA advertising/promotion, clinical trials, compliance, and transparency law matters. She currently serves on the Advisory Board for FDAnews. She was formerly on the Food and Drug Law Institute (FDLI) Editorial Advisory Board for the *FDLI Food & Drug Law Journal* and a member of the FDLI Medical Device Committee. She has also served on the Leadership Advisory Board for the National Women's Law Center and on the Special Gifts Committee for the Arlington Free Clinic.

Ms. Reeves was elected by her partners to serve a three-year term on the firm's Management Committee in 2017. In addition to chairing the firm's Life Sciences and Healthcare Industry Group,

she served for three years on the firm's Lateral Partner Committee and for three years on the firm's Partners Committee. She was the Hiring Partner for the Washington, D.C. office for two years.

Ms. Reeves received a B.A. from North Carolina State University, an M.P.A., *cum laude*, from North Carolina State University, and her J.D. from the University of Maryland, where she graduated with high honors and Order of the Coif.