SETON HALL | **LAW**

Healthcare Compliance
Certificate Program

Christopher Hanson

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Christopher Hanson assists clients in tackling their most sophisticated and high-stakes regulatory issues involving medical devices, in vitro diagnostics, clinical laboratories, and radiation-emitting electronic products. For nearly a decade, he has aided clients in interactions with federal, state, and foreign regulatory agencies, including the U.S. Food and Drug Administration (FDA), the Centers for Medicare and Medicaid Services (CMS), the Federal Trade Commission (FTC), and the Substance Abuse and Mental Health Services Administration (SAMHSA). His broad range of clients include large multinational companies, venture capital firms, industry associations, and development-stage companies.

Mr. Hanson takes a hands-on approach in crafting creative and practical solutions for clients. His work includes drafting legislation as well as preparing public comments for agency rulemakings, guidance documents, advisory committees, and other public policy venues. He provides strategic advice and regulatory due diligence to support corporate transactions and securities filings. He also has experience advising in enforcement matters and conducting global internal investigations and audits of the firm's life science clients in the United States, Asia, Australia, Europe, and Latin America.

During the course of the COVID-19 pandemic, Mr. Hanson has supported medical device manufacturers and clinical laboratories in drafting Emergency Use Authorization (EUA) submissions for in vitro diagnostic (molecular and serology) tests as well as decontamination systems for personal protective equipment (PPE). He has assisted dozens of clients in developing domestic and global COVID-19 testing strategies across a variety of industries, including professional sports leagues, higher education, entertainment and technology companies, and the mining and manufacturing sectors. In particular, he has guided clients through the web of federal, state, and local public health reporting obligations and clinical laboratory laws, including the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

Mr. Hanson is an active and dedicated firm member, having served twice as Vice Chair of the Summer Associate Program. Additionally, he pursues extensive pro bono work related to the lesbian, gay, bisexual, and transgender (LGBT+) community and speaks across the country on issues of LGBT+ diversity and inclusion in the legal community. He also authored the chapter,

"Overview of the Legal Framework for Medical Device Regulation in the United States," in Practising Law Institute's *Medical Devices Law and Regulation Answer Book* (2019). He is a graduate of Northwestern University School of Law, where he was elected to the Order of the Coif and graduated in two years. He holds a Masters of Divinity degree from Harvard University, where he was a Presidential Scholar, and an honors undergraduate degree from Yale University. Mr. Hanson previously served as the Chairperson of the Harvard Divinity School Alumni/ae Council.

Mr. Hanson's representative matters include advising global health care company GSK on FDA and CLIA regulatory components of the company's $300 million equity investment and collaboration with 23andMe; co-drafting legislation signed into law in California and New Jersey concerning the regulation of state clinical laboratories; and successfully petitioning FDA for removal of certain Class II medical devices from an import alert.