Hogan Lovells

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Jonathan Kahan is a Co-director of the firm's food, drug, medical device, and agriculture group and has been practicing in FDA law for 35 years. His practice focuses primarily on assisting medical device companies in navigating the U.S. Food and Drug Administration (FDA) regulatory process. He also has an extensive practice in combination products, which includes combinations of drugs, devices, and biologics. In addition to the daily counseling of clients in FDA-related matters, he represents many clients in administrative hearings and trials, and in the federal courts.

Jonathan has published numerous law review and other articles concerning FDA regulatory issues, and is the author of *Medical Device Development: Regulation and Law* (Parexel 2009) and *Medical Devices: Obtaining FDA Market Clearance* (Parexel 1995). He is also a co-editor of *Food and Drug Law and Regulation* published by the Food and Drug Law Institute in 2008.

Jonathan is the chair of the Dean's Advisory Board of the George Washington University Law School. He is the former Chairman of the Federal Bar Association Section on Health and Human Services, which includes the Food, Drug and Cosmetic Law Committee. He is a member of Phi Beta Kappa and Order of the Coif.

After receiving his law degree, Jonathan served as a clerk to The Honorable Oliver Gasch of the U.S. District Court for the District of Columbia.

HOGAN LOVELLS PUBLICATIONS

"FDA issues highly-anticipated Draft Guidance on the 510(k) Program." *Medical Device Alert,* Hogan Lovells (12 January 2012)

"FDA issues premarket review staff turnover SOP." *Medical Device Alert,* (11 January 2012)

"FDA issues new draft guidance on medical device product codes." *Medial Device Alert,* Hogan Lovells (11 January 2012)

PRACTICES

Food, Drug, Medical Device and Agriculture

Government Regulatory

Pharmaceutical and Biotechnology

Medical Devices

INDUSTRY SECTORS

Life Sciences and Healthcare

Medical Devices

AREAS OF FOCUS

Medical Device Premarket Clearance and Approval

FDA Enforcement Actions — Criminal/Injunction/Seizure

Investigational Device Regulation and Device Clinical Study Design

Import and Export of FDA-regulated Products

EDUCATION

J.D., *with honors, Order of the Coif,* The George Washington University Law School, 1973

B.A., *with honors*, The George Washington University, 1970

AWARDS / RANKINGS

PLC Life Sciences Cross-border Handbook, Regulatory: Medical Devices, Recommended, 2011-2012

Washington, D.C. Super Lawyers, 2009-2011

Washingtonian, Washington's Top Lawyers: Food and Drug, 2009-2011

PLC Life Sciences Cross-border Handbook, Leading Lawyer in Regulatory: Medical Devices, 2009

Chambers USA, Health Care: Pharmaceutical/Medical Products Regulatory, 2006-2011

PLC Which Lawyer? Handbook, Recommended Specialist in 'Life Sciences: Regulatory,' 2011

"FDA issues draft guidance concerning unsolicited requests for off-label information and seeks comments concerning scientific exchange of information." *Medical Device Alert,* Hogan Lovells (09 January 2012)

"FDA Issues New Draft Guidance Documents Outlining IDE Decision Pathways; New Policies and Pilot Program for Early Feasibility IDE Studies." *Medical Device Alert,* Hogan Lovells (23 November 2011)

"FDA Issues New Draft Guidance on De Novo Classification Process." *Medical Device Alert,* Hogan Lovells (21 October 2011)

"FDA issues new draft guidance documents clarifying how benefit-risk determinations are made, considerations for designing pivotal clinical studies." *Medical Device Alert,* Hogan Lovells (15 September 2011)

"FDA issues draft guidance regarding in vitro companion diagnostic devices, an area of device regulation marked by ambiguity." *Medical Device Alert,* Hogan Lovells (12 August 2011)

"FDA issues draft 510(k) device modification guidance." *Medical Device Alert,* Hogan Lovells (04 August 2011)

"IOM report regarding 510(k) clearance process released, raises more questions than it answers." *Medical Device Alert,* Hogan Lovells (01 August 2011)

"FDA finalizes long-awaited Medical Device Data Systems rule." *Medical Device Alert,* Hogan Lovells (23 February 2011)

"Former GSK lawyer moves to dismiss indictment: United States v. Lauren Stevens (D. Md. November 9, 2010)." *Medical Device Alert, Pharmaceutical and Biotechnology Alert, Health Alert, and White Collar Alert,* Hogan Lovells (10 February 2011)

"FDA releases description and timeline of initiatives for improving the 510(k) program." *Medical Device Alert,* Hogan Lovells (31 January 2011)

"Agencies seek comments regarding medical device excise tax." *Health Alert,* Hogan Lovells (13 December 2010)

"FDA Releases Highly-Anticipated Working Group Reports on 510(k) Program, New Science." *Medical Device Alert,* Hogan Lovells (06 August 2010)

Medical Device & Diagnostic Industry, Hundred Notables of the Medical Device Industry, 2004

MEMBERSHIPS

General Counsel, Association of Medical Diagnostics Manufacturers

Member, American Bar Association

Contributing Editor, *Medical Device & Diagnostic Industry* Magazine (MD&DI)

Member, Editorial Advisory Board, MD&DI

BAR ADMISSIONS / QUALIFICATIONS

District of Columbia

COURT ADMISSIONS

U.S. Court of Appeals, District of Columbia Circuit

U.S. District Court, District of Columbia

U.S. Supreme Court