Hogan Lovells

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Biography

With more than 40 years of legal experience, Jonathan Kahan is an industry leader in obtaining FDA market clearance of novel medical devices for medical technology and diagnostics companies. He also advises on post-market compliance matters.

Jonathan helps clients navigate complicated regulatory processes, including those related to combination products such as combinations of devices, drugs, biologics, and human tissues. He authored the leading text on medical device law, *Medical Device Development: Regulation and Law* (Parexel 2020).

Jonathan is the former director of the firm's Medical Device and Technology practice group and an adjunct professor at the George Washington University Law School teaching medical device law. He presently serves as a member of the George Washington University President's Leadership Advisory Council and he is also the general counsel of the Association of Medical Diagnostics Manufacturers.

Jonathan is highly ranked by *Chambers* as well as other legal directories. He has been consistently included in Washington, D.C. *Super Lawyers* and *Washingtonian* magazine's Top Lawyers in D.C. He also received the Food and Drug Law Institute (FDLI) Distinguished Service and Leadership Award, recognizing his

Practices

Medical Device and Technology Regulatory

Industries

Life Sciences and Health Care

Areas of focus

Postmarket Compliance and Enforcement Actions

Advisory Panel Preparation

Combination Products

Medical Devices

Advertising and Promotion

contribution in promoting public health, advancing the medical device and technology law field, and ensuring a robust and innovative regulatory environment.

Representative experience

Assisted client in obtaining premarket approval (PMA) for a novel medical device to treat brain cancer.

Assisted client in obtaining a Humanitarian Device Exemption approval for a novel device that brings sight to patients blinded by retinitis pigmentosa.

Represented a medical device client in resolving a civil money penalty proceeding brought by the FDA.

Assisted client in obtaining de novo reclassification for a novel pill camera for imaging lesions in the colon.

Assisted clients in obtaining 510(k) clearance for multiple proton beam therapy systems.

Assisted client in obtaining PMA for a novel gastric balloon system for the treatment of obesity.

Assisted numerous clients in the filing of a Requests for Designation with the FDA OCP and obtaining a favorable device jurisdictional rulings.

Advised client regarding whether clinical decision software was regulated by the FDA as a medical device.

Awards and rankings

- Healthcare: Pharmaceutical/Medical Products Regulatory (District of Columbia), Senior Statespeople, *Chambers USA*, 2019-2020
- Healthcare: Pharmaceutical/Medical Products Regulatory (District of Columbia), *Chambers USA*, 2006-2020
- Healthcare: Life Sciences, Recommended, *Legal 500 US*, 2020
- Distinguished Service and Leadership Award, *Food and Drug Law Institute*, 2020

Compliance

Premarket Review

Education and admissions

Education

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

B.A., The George Washington University, with honors, Phi Beta Kappa, 1970

Memberships

General Counsel, Association of Medical Diagnostics Manufacturers

Member, American Bar Association

Member, Editorial Advisory Board, MD&DI

Bar admissions and qualifications

District of Columbia

Court admissions

U.S. Supreme Court

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

U.S. District Court, District of Columbia

- Life Sciences: Regulatory/Compliance (Nationwide), Recognised Practitioner, *Chambers USA*, 2017-2019
- Hall of Fame, *LMG Life Sciences*, 2019
- Food and Drugs, *Super Lawyers*, 2009-2018
- FDA Law, *Best Lawyers in America*, 2015
- Most Highly Regarded Firms for Life Sciences, *Who's Who Legal*, 2013-2015
- Washington's Top Lawyers: Food and Drug, *Washingtonian*, 2009-2014
- Handbook, Recommended Specialist in 'Life Sciences: Regulatory', *PLC Which Lawyer?*, 2011
- Regulatory Star, *LMG Life Sciences*, 2013, 2016-2018
- Regulatory: Medical Devices, *PLC Life Sciences Cross-border Handbook*, 2011-2012
- Leading Lawyer in Regulatory: Medical Devices, *PLC Life Sciences Cross-border Handbook*, 2009
- Medical Device & Diagnostic Industry, Hundred Notables of the Medical Device Industry, 2004

Latest thinking and events

- News
  - After a long and winding road, FDA finalizes much-debated “intended use” rule
- Hogan Lovells Publications
  - Podcast: Talking the cure
- Press Releases
  - Hogan Lovells leads NONAGON to FDA 510(k) clearance for smartphone compatible telehealth device
- Press Releases
  - Hogan Lovells advises Lucira Health in securing Emergency Use Authorization for over the counter at-home COVID-19 test
- Media Mention
  - Lucira Health's unexpected sprint to a first-

of-its-kind EUA from FDA: The inside story

- Press Releases
  - Hogan Lovells steers Memic to De Novo FDA authorization for a surgical robotic system