Hogan Lovells

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Biography

Jodi Scott developed and honed her practical, real-world sensibility and business acumen during the time she spent as an in-house FDA counsel with Medtronic PLC, the world's largest medical device manufacturer.

Today, she uses that background to solve the challenges that confront her clients in areas that include MDRs, regulatory due diligence, importing and exporting medical devices, advertising and promotion, preparing for and managing FDA inspections, developing systems to mitigate the risks associated with the unapproved use of approved products (AKA off-label uses), developing digital health technology, and securing the necessary state medical device manufacturer and distributor licenses.

Jodi assists the medical device industry in navigating the complex requirements so as to maintain compliance with the U.S. Food and Drug Administration's (FDA) quality system (QSR) and other post-market regulatory rules. She spends much of her time developing and implementing strategies to manage FDA-initiated enforcement actions, such as FDA inspections that result in FDA Form 483s, untitled letters, Warning Letters, investigations, and consent degrees of permanent injunction. She has received ISO 13485 auditor certification and assists companies in preparing for managing and responding to ISO and MDSAP audits.

She also guides her clients through complex medical device recalls by helping them work through the

Practices

Medical Device and Technology Regulatory

Investigations, White Collar, and Fraud

Administrative and Public Law

Industries

Life Sciences and Health Care

Areas of focus

Medical Devices

Digital Health

Postmarket Compliance and Enforcement Actions

Advertising and Promotion

difficult decisions of whether a recall is warranted and, if so, how to execute it in a way that best achieves a balance between patient and customer risk and the agency's interests, while also demonstrating the company's commitment to safety and its regulatory obligations.

She also applies her regulatory knowledge in assisting clients with regulatory due diligence related to mergers and acquisitions and funding, such as private equity deals, initial public offerings, and other financial transactions.

Jodi co-leads the firm's cross-functional Digital Health Working Group and regularly assists clients in navigating the complexities of FDA regulation of digital health technologies with an eye to helping them meet their business objectives while being mindful of the potential for regulatory obligations.

Awards and rankings

- Outstanding Women in Business, Law, *Denver Business Journal*, 2020
- Life Sciences Star, *LMG Life Sciences*, 2013-2019
- Leading Life Sciences Lawyer, *LMG Life Sciences*, 2021
- Lawyer of the Year, *Law Week Colorado*, 2017
- Best Life Science Lawyer - Colorado, *The Corporate America M&A Awards*, 2015

Latest thinking and events

- News
  - JPM2023 Trendspotting: takeaways from Biotech Showcase
- News
  - FDA expands inspection obstruction guidance to apply to device facilities
- Sponsorships and Speaking Engagements
  - Biotech Showcase and exclusive reception during the J.P. Morgan 41st Annual Healthcare Conference
- News

Compliance

Combination Products

Unique Device Identifiers

State Medical Device Distribution & Manufacturer Licensing

Education and admissions

Education

J.D., The Catholic University of America, Columbus School of Law, cum laude, 1998

B.S., Drake University College of Pharmacy and Health Sciences, 1995

Memberships

Board Member, Colorado BioScience Association

Contributing Expert to FDANews Inspection Insider

Food & Drug Law Institute

Bar admissions and qualifications

Colorado

District of Columbia

ISO 13485 Certified Auditor

- JPM2023 Trendspotting: commercializing digital therapeutics

- Hogan Lovells Podcasts
  - Podcast: Talking the cure

- News
  - FDA to regulate more AI & software tools as devices, guidance indicates