Hogan Lovells

Jodi Scott

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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 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, and developing systems to mitigate the risks associated with the unapproved use of approved products (AKA off-label uses).

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.

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

Postmarket Compliance and Enforcement Actions

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

Awards and rankings

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

Latest thinking and events

- Hogan Lovells Publications
  - Podcast: Talking the cure
- News
  - HHS withdraws proposal to exempt 84 medical device types from FDA 510(k) process
- Hogan Lovells Publications
  - Life sciences and health care horizons 2021
- News
  - Biotech & Digital Medicine Showcase: Life sciences firms advised on regulatory concerns, investing
- News
  - HHS proposal to exempt medical devices from

Advertising and Promotion 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 and Chair of the Board Governance Committee, Girl Scouts of Colorado

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

510(k) process halted

- News
  - Five highlights from FDA's new AI device regulation Action Plan