

## Jodi Scott

Partner

Denver

### 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 MDSAAP audits.



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### Practices

Medical Device and Technology  
Regulatory

Investigations, White Collar, and  
Fraud

Administrative and Public Law

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### Industries

Life Sciences and Health Care

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### Areas of focus

Medical Devices

Adverse Event Reporting  
Vigilance Reporting

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

- 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

- ■ Virtual health Whats on the horizon for telehealth and remote monitoring
- Announcements
  - Hogan Lovells advises Joe and Clara Tsai Foundation in shipping thousands of ventilators and millions of units of PPE to the US from China
- Hogan Lovells Publications
  - Virtual health horizons 2020
- News
  - FDA temporarily postpones all domestic routine facility inspections in response to COVID-19 pandemic
- News
  - SweynTooth cybersecurity vulnerabilities: considerations for medical device manufacturers

Advertising and Promotion  
Compliance

Combination Products, FDA  
Jurisdictional Issues, FDA  
Postmarket Compliance Issues

Unique Device Identifiers

State Medical Device Distribution &  
Manufacturer Licensing

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## 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

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## 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

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- News

- FDA postpones foreign inspections amid growing concerns over coronavirus (COVID-19)

## Bar admissions and qualifications

Colorado

District of Columbia

ISO 13485 Certified Auditor

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