

# Jennifer A. Romanski Principal

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Ms. Romanski, chair of the firm's Life Sciences Legal, Regulatory, and Compliance Practice Group, has broad experience counseling pharmaceutical, biotech and medical device companies in regulatory and compliance matters, including preparation of corporate compliance programs, advertising and promotion activities, medical publication planning, interactions with healthcare practitioners, grants and continuing medical education programs, FDA enforcement activity, and sample accountability and PDMA requirements. She worked for many years in Porzio's Key Client program where she served as part of the in-house legal team for various pharmaceutical companies several days a week. She has also served as acting compliance director at a large pharmaceutical company, where she was involved in over twenty compliance reviews and investigations.

She has drafted contracts with co-promotion partners, direct mail companies, medical publication facilitators, and market research organizations. She has provided counsel on implementation of compliance measures for research and development companies, with emphasis on pre-market requirements, clinical trial registration and disclosure, and patient recruitment. In addition, she regularly counsels clients on compliance with state marketing disclosure reporting laws and the new requirements under the Patient Protection and Affordable Care Act, including compliance with healthcare practitioner transparency requirements.

# Recognitions

No aspect of this or any advertisement has been approved by the Supreme Court of New Jersey. For ranking methodologies, please see **here**.

Law360 - Distinguished Legal Writing Award, Burton Awards (2023)

#### News

- Porzio, Bromberg & Newman Named Winner of Financial Times Innovative Lawyers in Healthcare & Life Sciences Award, 12/05/2023
- Porzio, Bromberg & Newman Principal Jennifer Romanski Wins Law360 Distinguished Legal Writing Award, 4/06/2023

#### **Articles**

Prepare For Scrutiny In Marketing Contraception After Dobbs, 8/01/2022



- Texas Introduces Legislation To Amend Current Drug Cost Transparency Law, 3/11/2021
- OPDP Issues Untitled Letter For Kardashian DTC Video, 3/11/2021

#### **Events**

- Privacy in Life Sciences: The Why's and How's for Incorporating Privacy into Your Healthcare Compliance Program,
  2/27/2024
- Puerto Rico Pharmaceutical Summit 2024, 2/06/2024
- OPDP Year in Review: Highlights and Key Takeaways from 2022 FDA Enforcement Letters, 01/26/2023
- Porzio Life Sciences Webinar: State Drug Price Transparency Laws: Anticipating Reporting Responsibilities and Making Sure Your Company is Prepared, 9/15/2021
- Porzio Life Sciences Webinar: Enforcement Action Trends: Compliance Takeaways from the Incyte Complaint, 6/15/2021

## **Speaking Engagements**

- "Privacy in Life Sciences: The Why's and How's for Incorporating Privacy into Your Healthcare Compliance Program,"
  Porzio Webinar, 2/27/2024
- "Conducting Internal Investigations: Best Practices to Address Compliance Concerns, Reduce Risk, and Access Results,"
  Porzio's 3rd Annual Puerto Rico Pharmaceutical Summit, 2/06/2024
- "Illuminating the Role of FTC in Healthcare Advertising Enforcement," Food and Drug Law Institute (FDLI) Advertising & Promotion for Medical Products Conference, 11/02/2023
- "Med Device Compliance 101," Porzio Life Sciences, Life Sciences Palooza, 9/27/2023
- "Enforcement Action Update," Porzio Life Sciences, Life Sciences Palooza, 9/26/2023
- "Don't Slack on the States Refresh and Updates on State Compliance and Legal Requirements," Pharmaceutical Compliance Congress 2023, McLean, VA, 4/27/2023
- "OPDP Year in Review, Highlights and Key Takeaways from 2022 FDA Enforcement Letters," Webinar Presenter, Porzio Bromberg & Newman & Porzio Life Sciences, Morristown, NJ, 1/26/2023
- "Healthcare Compliance Considerations, Marketing Prescription Products in the United States," Association of Corporate Counsel, Israel, ACC Webinar, Morristown, NJ, 10/31/2022
- "Compliance Considerations with Industry Educational Endeavors: Grants, Publications and Scientific Exchange" Twenty-Third PCF Pharmaceutical and Medical Device Ethics and Compliance Congress, Washington, D.C, 10/25/2022
- AdvaMed & Porzio Life Sciences MedTech Compliance 101 Bootcamp, 9/14/2022



- "State of the Industry A Closer Look at the Drug Pricing Transparency Landscape," Drug Pricing Transparency Congress, Philadelphia, PA, 3/29/2022
- "HCP Engagement & Transparency: Best Practices for Managing Risk and Avoiding Enforcement Action" Transparency & Aggregate Spend Conference, 12/06/2021
- "Risk Reduction in a New Generation of TV Ads Saving Time and Increasing Consumer Comprehension," FDLI Advertising and Promotion for Medical Products Conference, 10/15/2021
- "Anticipating Reporting Responsibilities and Making Sure Your Company is Prepared," Porzio Life Sciences Webinar, 9/15/2021
- "Enforcement Action Current Trends: Compliance Takeaways from the Incyte Complaint," Porzio Life Sciences Webinar, 6/30/2021
- "Compliance Challenge: Federal, State and International Transparency, Disclosures and Reporting; Part 4 of Four-Part Series, Culture, Effective Compliance Program Development and Implementation, Government Expectations and Assessing Your Risk Profile," Medtech Compliance Virtual Bootcamp, 3/11/2021
- "Compliance Challenge: Grants, Donations and Other Funding; Part 3 of Four-Part Series, Culture, Effective Compliance Program Development and Implementation, Government Expectations and Assessing Your Risk Profile," Medtech Compliance Virtual Bootcamp, 3/09/2021
- "Compliance Challenge: Healthcare Professional Engagements; Part 2 of Four-Part Series, Culture, Effective
  Compliance Program Development and Implementation, Government Expectations and Assessing Your Risk Profile,"
  Medtech Compliance Virtual Bootcamp, 3/04/2021
- "Compliance Framework; Part 1 of Four-Part Series, Culture, Effective Compliance Program Development and Implementation, Government Expectations and Assessing Your Risk Profile," Medtech Compliance Virtual Bootcamp, 3/02/2021
- "State Law Considerations When Advertising Pharmaceuticals; Law Over Lunch," Food and Drug Law Institute (FDLI), 1/14/2021
- "State of the Industry Drug Pricing Transparency Landscape Address," 6th Edition Drug Pricing Transparency, 11/16/2020
- "Before and Beyond Advertising: Healthy Partnerships with Disease and Patient Experts," FDLI Advertising and Promotion for Medical Products Conference, 10/30/2020
- "What you say matters: Communication Pitfalls and Whistleblower Risks," AdvaMed Bootcamp MedTech Compliance 101/201, 10/21/2019
- "Patient Engagement: Challenges of Engaging Patients and Patient Groups," FDLI Advertising and Promotion for Medical Products Conference, 10/17/2019



- "Designing a Proactive Monitoring Program as New Risks Emerge," CBI's 7th Annual Compliance Monitoring Conference, 2/27/2019
- "Dive into the Legal Implications of Nurse Educator Programs," Bio/Pharma Compliance Congress on Non-Promotional Activities, 12/04/2018
- "Nontraditional Venues: Are They Promotional?" FDLI Advertising & Promotion for Medical Products Conference, 10/16/2018
- "Assess Your Organization's Training Strategy for Executing Speaker Programs," CBI's Speaker Programs Conference,
  2/13/2018
- "A Checkpoint on Regulatory and Enforcement Updates," CBI's 3rd Annual Medical Affairs & MSL Excellence Forum, 1/30/2018

#### **Practices**

• Life Sciences Legal, Regulatory, and Compliance

### **Area of Focus**

- Compliance and Regulatory Counseling
- Pharmaceutical, Medical Device, Biotech

#### **Industries**

Life Sciences

# **Industry Focus Areas**

- Medical Device
- Pharmaceutical

# **Bar Admissions**

- New Jersey, 1997
- New York, 1998

#### **Court Admissions**

- United States District Court, District of New Jersey, 1998
- United States District Court, Southern District of New York, 1999



United States District Court, Eastern District of New York, 1999

# **Education**

- University of Pennsylvania
  B.A. in Biological Basis of Behavior, 1994
  cum laude
- University of Pennsylvania Carey Law School J.D., 1997

