Judith L. O’Grady

Partner

Washington, D.C.

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Judy is a sought-after regulatory strategist for clients navigating the complexities of FDA regulations. Her clients appreciate her comprehensive, proactive approach and deep knowledge of the life sciences sector.

OVERVIEW

Judy leads the firm’s FDA regulatory team. She advises prescription and over-the-counter pharmaceutical, biologic, biosimilar, and medical device companies on a wide variety of complex regulatory issues governed by the Food and Drug Administration (FDA). Judy counsels clients on the full range of issues they face in areas such as OTC monographs, INDs, NDAs, 505(b)(2)s, BLAs, 510ks, de novo applications, PMAs, facility registration, product listings, product labeling, good manufacturing practices, clinical trials, adverse event reporting, recalls, inspections, and audits. She also counsels cosmetic, dietary supplement and food companies regarding FDA regulatory compliance. Judy has extensive experience reviewing marketing and promotional materials under FDA and FTC regulations and guidance for a wide range of regulated products, including drugs, medical devices, foods, cosmetics, and dietary supplements.

Judy guides clients on all aspects of responding to FDA enforcement actions, assisting in responses to Warning, Untitled and Complete Response Letters, 483s, 4003s, and FDA import holds. She also provides support to her litigation and white collar colleagues on cases and investigations involving allegations of FDA regulatory violations.

In addition to her counseling work, Judy assists clients on their corporate filings and key transactions. She prepares the regulatory sections of SEC filings and other transaction documents, and leads due diligence teams in conjunction with securities offerings, mergers and acquisitions, asset and stock purchase agreements, and a wide variety of other life science transactions.

Judy’s practice also spans compliance counseling for clinical laboratories related to the Clinical Laboratory Improvements Amendments of 1988 as well as state clinical laboratory laws and regulations. As chair of the Defense Research Institute’s Medicare Secondary Payer Task Force, she also counsels a diverse range of clients on compliance with the Medicare Secondary Payer Act and Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007.

Judy draws from her background as a litigator for pharmaceutical and medical device manufacturers to preemptively identify and address FDA regulatory issues that may present an issue in future litigation. She has experience with all aspects of state and federal litigation, including pre-litigation risk assessments, document collection and production, preparing company witnesses, developing experts, and deposing parties, key witnesses

and experts. Before transitioning to her counseling practice, Judy worked on pharmaceutical and medical device product liability federal multidistrict (MDL) litigations, state consolidated matters, and individual plaintiff cases appearing in numerous state and federal courts throughout the United States.

Judy's medical research and scientific background enables her to firmly grasp the complex scientific issues involved in representing pharmaceutical and medical device manufacturers. She served as a laboratory assistant at the Stanley Laboratory of Brain Research in Bethesda, MD, where she researched the normal development of the brain and the neuropathology of major mental illnesses. Judy also spent time as a laboratory technician in the Anesthesiology Department of the Hospital of the University of Pennsylvania.

AWARDS

- Named a "Rising Star" by *Washington, D.C. Super Lawyers* (2014-2016)

TOP AREAS OF FOCUS

- FDA Regulatory + Risk Management Counseling
- Health Care + Life Sciences
- Life Sciences Transactions
- Pharmaceutical + Medical Device Litigation + Counseling

ALL AREAS OF FOCUS

- FDA Regulatory + Risk Management Counseling
- Health Care + Life Sciences
- Health Care Regulatory
- Hemp + Hemp Derivatives Industry
- Life Sciences Transactions
- Litigation + Trial
- Pharmaceutical + Medical Device Litigation + Counseling
- Product Liability

PROFESSIONAL/COMMUNITY INVOLVEMENT

- Member, Defense Research Institute Medicare Secondary Payer Task Force
- Member, American Bar Association
- Board member, Rollingwood Citizens Association

EDUCATION AND CERTIFICATIONS

EDUCATION

- University of Maryland Francis King Carey School of Law, J.D., *with honors*, 2004, health law certificate recipient
- University of Pennsylvania, B.A., 1996, biological sciences with neuroscience concentration

BAR ADMISSIONS

- District of Columbia
- Maryland

COURT ADMISSIONS

- U.S. District Court, District of Columbia
- U.S. District Court, District of Maryland

SPEAKING ENGAGEMENTS

- Speaker, "FDA and HHS Activity Round-Up: An Examination of New Agency Priorities and Initiatives Impacting the Life Sciences Industry," American Conference Institute's (ACI) 2025 Women Leaders in Life Sciences Law Summit, July 30-31, 2025.
- Speaker, "FDA Policy Shifts and Leadership Changes: What Life Sciences Companies Need to Know," Troutman Pepper Locke, April 29, 2025.
- Speaker, "2025 Introduction to Medical Device Law and Regulation," Food and Drug Law Institute (FDLI), April 8, 2025.
- Speaker, "FDA Challenges and Their Impact on Biotech CEOs," Boston BioBreak – CEO Forum Dinner 2024, April 30, 2024.
- Speaker, "Paying Twice: Protecting Clients from MSP Liabilities," Defense Research Institute and Medicare Advocacy Recovery Coalition Webinar, September 30, 2021.
- Speaker, "COVID-19 Vaccine – Guidance for Employers," Troutman Pepper Webinar, January 28, 2021.
- Speaker, "Premarket Approval Application (PMA); Humanitarian Device Exemption (HDE)," FDLI's Introduction to Medical Device Law Regulation, November 7-8, 2018.
- Speaker, "Medicare Secondary Payer Act: Case Law Update," Defense Research Institute, May 8, 2018.
- Speaker, "Evolving Regulatory Pathways for Medical Devices," FDLI Annual Conference 2018, May 3-4, 2018.
- Speaker, "Premarket Approvals," FDLI/CDRH In-House Training Course, October 6, 2017.
- Speaker, "To Disclose or Not: The FDA, the SEC and Life Science," Pepper Hamilton Health Sciences Speaker Series (New York), May 16, 2017.
- Speaker, "Medicare Secondary Payer Act: Case Law Update," Defense Research Institute, April 12, 2017.
- Speaker, "To Disclose or Not: The FDA, the SEC and Life Science," Pepper Hamilton Health Sciences Speaker Series (Cambridge), March 21, 2017.
- Speaker, "To Disclose or Not: The FDA, the SEC and Life Science," Pepper Hamilton Life Sciences Speaker Series (Gladwyn), February 23, 2017.
- Speaker, "Medicare Secondary Payer: Case Law Update," February 25, 2016.

PUBLICATIONS

- Co-author, "A Model's Credibility Is in the Details: FDA Draft Guidance on the Use of AI Models in Drug and Biological Product Development," *Troutman Pepper Locke*, February 12, 2025.
- Co-author, "FDA Finalizes Guidance on Communications Regarding Unapproved Uses of Medical Products," *Troutman Pepper Locke*, January 22, 2025.
- Podcast, "AI and Pharmacovigilance Under the FDA's New Emerging Drug Safety Technology Program," *The Good Bot*, December 11, 2024.
- Podcast, "The FDA's Response to AI Medical Innovation," *The Good Bot*, June 25, 2024.
- Co-author, "FDA Issues Final Rule on Regulation of Laboratory Developed Tests," *Troutman Pepper*, May 23, 2024.

- Co-author, “FDA Issues New Draft Guidance for Unapproved Use Communications,” *Troutman Pepper*, October 25, 2023.
- Co-author, “8 Ways Life Sciences Cos. Can Adapt to the Social Media Era,” *Law360*, September 11, 2023.
- Co-author, “FDA Proposes New Rules for Prescription Drug Labeling,” *Troutman Pepper*, June 5, 2023.
- Co-author, “DC Circuit Court of Appeals Revives Medicare Advantage Overpayment Rule,” *Pratt’s Government Contracting Law Report*, December 2021.
- Co-author, “DC Circuit Revives Medicare Advantage Overpayment Rule,” *Troutman Pepper*, September 21, 2021.
- Co-author, “FDA Launches Digital Center of Excellence and ONC Updates HIPAA Security Risk Assessment Tool,” *Troutman Pepper*, October 7, 2020.
- Co-author, “U.S. PTO Initiates Expedited Review Process for COVID-19 Related Trademarks,” *Troutman Pepper*, July 20, 2020.
- Podcast, “Manufacturing Masks and Protective Equipment in the Age of COVID-19,” *Troutman Sanders and Pepper Hamilton COVID-19 Litigation Podcast Series*, May 9, 2020.
- Co-author, “HHS Issues Advisory Opinion Clarifying PREP Act Immunity,” *Pepper Hamilton Client Alert*, April 28, 2020.
- Co-author, “FDA Issues Guidance On Clinical Trial Conduct During COVID-19,” *Pepper Hamilton Client Alert*, March 23, 2020.
- Co-author, “HHS Waives HIPAA Sanctions to Facilitate Suppression of Coronavirus,” *Pepper Hamilton Client Alert*, March 19, 2020.
- Co-author, “HHS Provides Liability Immunity for Coronavirus Countermeasures,” *Pepper Hamilton Client Alert*, March 16, 2020.
- Co-author, “USDA Issues Rules for Hemp Production – Many Questions Remain for Hemp and CBD Sales,” *Pepper Hamilton Client Alert*, November 8, 2019.
- Co-author, “OIG Advisory Opinion Has Key Takeaways for Programs Designed to Assist Needy Patients,” *Pepper Hamilton Client Alert*, February 11, 2019.
- Co-author, “OIG Issues HHS Fiscal Year 2016 Work Plan,” *Pepper Hamilton Client Alert,* November 17, 2015.
- Co-author, “District Court Rules Pharmaceutical Manufacturers Are Not Required to Discount Orphan Drugs – Regardless of the Condition Being Treated – for Certain 340B Eligible Health Care Entities,” *Pepper Hamilton Client Alert,* October 26, 2015.
- Author, “Non-Group Health Plan MMSEA Section 111 Reporting Updates,” *DRI Today*, July 28, 2015.
- Author, “OIG Work Plan Midyear Update Adds Activities Related to Medicare Part D and Medicaid Rebates,” *Pepper Hamilton Client Alert,* June 12, 2015.
- Author, *DRI Defense Practitioner’s Guide to MSP Issues*, May 20, 2015.
- Author, “Revised Medicare, Medicaid and SCHIP Extension Act of 2007 (MMSEA) Section 111 Non-Group Health Plan (NGHP) User Guide,” *DRI Today*, April 17, 2015.