# Pamela Furman Forrest (Pam)

PARTNER


## CONTACT

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## PRACTICES

FDA & Life Sciences

Healthcare Industry

## MEMBERSHIPS

American Health Lawyers Association

Advisory Board of BNA's Medical Devices Law & Industry Report

## EDUCATION

J.D., Stanford University

B.A., summa cum laude, Phi Beta Kappa, Yale University

## ADMISSIONS

District of Columbia

New York

## PROFILE

Pamela Furman Forrest is a partner in King & Spalding's FDA & Life Sciences Practice Group. Ms. Forrest joined the firm in 2007, bringing with her more than 12 years of experience in advising clients on a broad range of FDA regulatory issues. Her practice focuses on FDA medical device matters, including premarket notification, premarket approval, product recalls, Medical Device Reporting (MDR), Quality System Regulation (QSR) compliance, establishment registration and device listing, labeling and promotion, reclassification, import/export issues and Investigational Device Exemption (IDE) requirements. In addition, Ms. Forrest frequently assists medical device manufacturers, investment banks, and private equity funds with due diligence evaluations of FDA-regulated companies.

Ms. Forrest has written and spoken extensively on various aspects of FDA regulation of medical devices, and has testified before several State legislative committees regarding medical device legal and regulatory issues.

Ms. Forrest graduated *summa cum laude*, *Phi Beta Kappa*, from Yale University in 1988, with a Bachelor of Arts in political science. She received her law degree from Stanford University in 1994. Ms. Forrest currently serves on the Advisory Board of BNA's Medical Devices Law & Industry Report.

**Recent Publications**

**Published Works**

- "*Ensuring Effectiveness of Voluntary Medical Device Recalls,"* Medical Device and Diagnostic Industry, March, 2011
- "*Introduction to the Regulation of Medical Devices*," The Fundamentals of Life Sciences Law: Drugs, Devices, and Biotech, April, 2007
- *"How FDA Hopes to Decrease Medical Errors with the Help of Bar Code Technology,"* Health Lawyers News, December, 2005
- *"How to Avoid an MDR Disaster: Set Up an Effective Reporting System,"* Medical Device and Diagnostic Industry, June, 2005
- *"FDA Considerations Related to Maintaining Clinical Trial Records in Electronic Form,"* Health Lawyers News, December, 2004
- *"The Increasing Impact of FDA Regulation on Hospitals and Related Institutions,"* Health Lawyers News, December, 2003
- "*The Impact of FDA Medical Device Regulation on Hospitals*," Health Law Digest, Volume 29, Number 1: 3-13, January, 2001

**Presentations**

- "Post-Market Information: New Uses and Challenges," King & Spalding Medical Device Summit, Boston, Massachusetts, October 2010
- "Medial Device Essentials: Premarket and Postmarket Requirements," FDA Boot Camp, Boston, Massachusetts, September, 2010
- "Building Effective Systems for Medial Device Reporting and Corrections/Removals," King & Spalding Medical Device Summit, Menlo Park, California, June, 2009
- "How to Avoid an MDR Disaster: Setting Up an Effective Medical Device Reporting System," FDAnews Audioconference, July, 2008

- “Building an Effective and Streamlined Medical Device Reporting System,” King & Spalding Medical Device Summit, Chicago, Illinois, April, 2008 and San Francisco, California, October, 2007
- “Perspectives on Using FDA Counsel,” Orthopedic Surgical Manufacturers Association, St. Petersburg, Florida, January, 2008
- “FDA’s Postmarket Regulation of Medical Devices: Requirements, Common Pitfalls, and Recent Developments,” FDA Boot Camp; Basic Training for Products Liability and Patent Lawyers, San Francisco, California, May, 2007 and New York, New York, March, 2007
- “Classification of Medical Devices and the Essentials of the Device Approval Process,” FDA Boot Camp; Basic Training for Products Liability and Patent Lawyers, Boston, Massachusetts, July, 2007; San Francisco, California, May, 2007; New York, New York, March, 2007; Chicago, Illinois, September, 2006; and New York, New York, March, 2006
- “Postmarket Issues,” The Food and Drug Law Institute’s (FDLI) Introduction to Medical Device Law and Regulation, Washington, D.C., January, 2007
- “Off-Label Promotion -- Current FDA Policies and How to Comply,” Regulatory Affairs Professionals Society’s Advertising, Promotion & Labeling Conference, Denver, Colorado, May, 2006
- “MDRs -- An Industry Perspective,” North Central Association of Food and Drug Officials’ Spring 2006 Drug-Device Education Conference, Chicago, Illinois, March, 2006
- “FDA Awareness for Hospitals,” American Health Lawyers Association Conference on Legal Issues Affecting Academic Medical Centers and Other Teaching Institutions, Washington, D.C., January, 2006
- “Off-Label Promotion - Current FDA Policies and How to Comply,” The Institute of Medical Technology’s Seminar on Disseminating Off-Label Information, Washington, D.C., December, 2005
- “Establishing an Effective MDR System,” Medical Design and Manufacturing (MD&M) Conference, Minneapolis, Minnesota, November, 2005
- “Avoiding Pitfalls in Your Complaint-Handling and MDR System,” Medical Design and Manufacturing (MD&M) Conference, New York, New York, June, 2005
- “International Issues,” The Food and Drug Law Institute’s (FDLI) Introduction to Medical Device Law and Regulation, Washington, D.C., May, 2005 and November, 2004
- “Research and FDA-Related Issues,” American Health Lawyers Association (AHLA) Fundamentals of Health Law Seminar, Chicago, Illinois, November, 2004
- “FDA Medical Device Regulatory Issues Affecting Hospitals,” American Health Lawyers Association (AHLA) Annual Meeting, Orlando, Florida, June, 2001

## MATTERS

**Representative Experience**

- Performed in-depth audits of clients’ compliance with various aspects of FDA regulation, including complaint-handling and MDR reporting requirements and conducted FDA regulatory training for relevant company personnel.
- Assisted companies in responding to FDA enforcement actions, including Warning Letters and Form 483 observations.
- Counseled companies on developing strategies for conducting product recalls.
- Shepherded clients through the FDA premarket review process, including interacting with FDA to determine the appropriate regulatory pathway and clarify data submission requirements.
- Served as FDA regulatory counsel on the due diligence team for a private equity fund’s contemplated acquisition of several FDA-regulated companies.
- Served as General Counsel for a trade association of medical device manufacturers; advocated on behalf of trade association members in negotiations with FDA, Congress, State legislatures, and State public health bodies.

**NEWS**

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| *23 Aug 2012* | King & Spalding Lawyers Earn 232 Listings in 2013 Best Lawyers in America Guide |
| *31 Aug 2011* | King & Spalding Lawyers Earn 203 Listings in 2012 Best Lawyers in America Guide |
| *30 Sep 2010* | King & Spalding Medical Device Summit Set for Oct. 13-14 |
| *15 Aug 2008* | Pamela Furman Forrest Leads Conference on Medical Device Reporting |
| *18 Mar 2008* | King & Spalding Hosts Upcoming Medical Device Summits |
| *06 Feb 2007* | King & Spalding Continues FDA/Healthcare Expansion; Adds Partner Pam Furman and Consultants Ann Graham and Anne Kelly |

**PUBLICATIONS**

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| *21 May 2013* | FDA 510(k) Rescission Authority Upheld - U.S. District Court Finds for FDA in ReGen Litigation |
| *11 Mar 2013* | FDA's Proposed Rule on Device Clinical Studies |
| *07 Mar 2013* | FDA Issues Final Guidance on Financial Disclosure by Clinical Investigators |
| *28 Feb 2013* | FDA Issues Draft Guidance on Medical Device Recalls |
| *25 Feb 2013* | Pediatric Subpopulation Information in Device Approval Applications |
| *31 Jan 2013* | FDA Issues Final Rule Regarding CGMPs for Combination Products |
| *07 Jan 2013* | FDA Issues New Guidances Regarding Its Preliminary Review of 510(k) Notices and PMA Applications |
| *07 Jan 2013* | FDA Issues Final Guidance Documents on FDA's eCopy Program for Medical Device Submissions |
| *07 Jan 2013* | FDA Announces Public Meeting to Discuss Standardization and Availability of Medical Device Labeling |
| *20 Dec 2012* | Second Circuit Vacates Off-Label Promotion Conviction on First Amendment Grounds in U.S. v. Caronia |
| *19 Sep 2012* | FDA Releases Its Proposals to Strengthen the Medical Device Postmarket Surveillance System |
| *30 Jul 2012* | FDA Issues Proposed Unique Device Identifier Rule |
| *25 Apr 2012* | FDA Issues Final Guidance Document on Benefit-Risk Determinations |
| *20 Apr 2011* | FDA Issues Draft Charter for CDRH Center Science Council |
| *24 Feb 2011* | FDA Issues Rule to Regulate Medical Device Data Systems |
| *10 Feb 2011* | FDA Announces Changes Affecting 510(k) Marketing Pathway |
| *08 Nov 2010* | FDA's Recent Remarks about 510(k) Changes |
| *22 Oct 2010* | Senior FDA Officials Share 510(k) and Enforcement Insights at King & Spalding's Device Summit |
| *22 Oct 2010* | FDA Issues Final Rule on IND Safety Reporting |
| *27 Sep 2010* | FDA and CMS Consider Parallel Review of Medical Products |
| *31 Aug 2010* | FDA's Preliminary Reports Regarding 510(k) Changes and New Science |
| *18 Aug 2010* | FDA and FCC Collaborate on the Regulation of Wireless Healthcare Technologies |
| *02 Aug 2010* | FDA Oversight of Diagnostic Tests |
| *18 Jun 2010* | Summary of the Institute of Medicine's Second Public Meeting Regarding the 510(k) Process |
| *07 Jun 2010* | New Proposed Amendments to DHHS Requirements for Investigator Disclosures |
| *26 May 2010* | FDA's New Proposals for Expanded Public Disclosure |
| *18 Dec 2009* | TMJ Implants Seeks En Banc Review of Civil Money Penalties for MDRs |
| *26 May 2009* | FDA's Outlook under the New Administration |
| *27 Nov 2007* | Medical Device Provisions of the FDA Amendments Act of 2007 |
| *09 Aug 2007* | FDA Issues a Second Guidance for In-Vitro Diagnostics Multivariate Index Assays (IVDMIA) |

**EVENTS**

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| *18 Oct 2012* | **West Coast Medical Device Summit** |
| *17 Oct 2012* | **West Coast Medical Device Summit** |