



## Peter S. Reichertz

Partner

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### PRACTICE AREAS

- Food and Drug Regulatory
- Intellectual Property
- Litigation

### INDUSTRIES

- Advertising
- Food and Beverage
- Life Sciences

## OVERVIEW

Mr. Reichertz is a partner in the Washington D.C. office, and is leader of the firm's Food and Drug Law Group. He also serves as co-leader of the firm's Life Sciences group.

### Areas of Practice

Mr. Reichertz concentrates in both food and drug regulatory law and intellectual property law. He counsels companies whose products are regulated by the FDA under the Federal Food Drug and Cosmetic Act. He represents manufacturers and distributors in obtaining approval to market drugs, medical devices, food, dietary supplements and cosmetic products, and counsels on all aspects of marketing of such products, including providing advice on labeling, advertising, manufacturing and distribution issues. He also counsels on related federal and state regulatory statutes.

Mr. Reichertz's practice also includes advising advertising agencies, clinical investigators, research organizations and other non-manufacturers on compliance with the Federal Food Drug and Cosmetic Act. He represents clients in FDA rulemaking proceedings, and in enforcement proceedings brought by the U.S. on behalf of the FDA. Mr. Reichertz also represents clients in advertising disputes related to FDA-regulated products, both at the FDA and in false advertising litigation under Section 43(a) of the Lanham Act and before the National Advertising Division of the Better Business Bureau.

In addition, Mr. Reichertz practices in intellectual property, specifically in trademarks, copyrights, trade secrets and licensing. His trademark expertise includes counseling and advising clients on the selection and adoption of trademarks, as well as the prosecution of trademark applications in the United States Patent and Trademark Office. He also prepares and negotiates trademark licensing and distribution agreements.

## EDUCATION

- J.D., The National Law Center, George Washington University, *with honors*
- A.B., Brown University

## ADMISSIONS

- District of Columbia
- U.S. Supreme Court
- U.S. Court of Appeals for the Federal Circuit
- U.S. Court of International Trade

## EXPERIENCE

### Representative Matters

- Representing clients in purchase and sale of FDA-regulated companies and products. Some recent transactions include:
  - Represented Luitpold Pharmaceuticals, Inc. in connection with its acquisition of Roxro Pharma, Inc.
  - Represented C.B. Fleet Co., Inc. in connection with the sale of a gastrointestinal pharmaceutical product, under development, to a private-equity backed portfolio company.
  - Represented Luitpold Pharmaceuticals, Inc. in connection with its acquisition of all of the stock of PharmaForce, Inc.
  - Representation of U.S. pharmaceutical company in connection with its acquisition of gastro-intestinal care products.
  - Representation of Luitpold Pharmaceuticals, Inc. in connection with its acquisition of the dental business of BioMimetic Therapeutics, Inc.
- Preparation of numerous distribution and licensing agreements involving FDA-regulated products, and advising clients on FDA and other regulatory concerns regarding same.
- Preparing, filling and obtaining acceptance of 510(k) notifications for a variety of device products, for new uses and changes to products.
- Reviewing ANDA's once NDA's prior to submission, preparation of the administrative documents as part of the the ANDA and the NDA, and advising clients on issues relating to priority review and filing issues.
- Advising clients on issues relating to 505(b)(2) applications.
- Representing a client involved in multiple product liability lawsuits on FDA issues and risk minimization.
- Advising clients on acceptable off-label promotional activities and review of advertising for compliance with FDA and FTC requirements.
- Prosecution and defense of false advertising claims in the federal courts and before the NAD involving drugs, cosmetics and dietary supplements, and advice to clients to minimize risk of advertising challenges.
- Conducting due diligence review of a medical device company prior to a public offering and conducting GMP/QSR inspections of medical device and pharmaceutical manufacturers.
- Advising clients on product recalls.
- Representing clients importing products with Notices of Detention relating to registration and labeling issues.

### HONORS

- Washington SmartCEO, Legal Elite, Readers Pick Top Local Attorneys, December 2009 and December 2010
- Which Lawyer?, Life Sciences/Regulatory law, Nationally ranked by Practical Law Company, 2007

### MEMBERSHIPS

- Member, American Bar Association
- Member, Federal Circuit Bar Association

- Member, International Trademark Association
- Member, Food and Drug Law Institute

## ARTICLES

- Physician Payment Sunshine Act: Requirements And Unresolved Questions, *The Metropolitan Corporate Counsel*, January 2012
- Clinical Investigators Beware: Greater FDA Review, *Law360*, February 17, 2010
- A National, Uniform Paper Trail for Drugs?, October 9, 2006
- Reichertz, P., and Friend, M., "Hiding Behind Agency Discretion: The Food and Drug Administration's Personal Use Drug Importation Policy", (Cornell J. of Law and Pub. Pol. 493) (2000).
- Reichertz, P., "Understanding Government Regulation of the Marketing and Advertising of Medical Devices, Drugs, and Biologics: The Challenge of the Internet", (52 Food & Drug L.J. 303) (1997).
- Reichertz, P., and Halpern, N., "FDA Regulation of Telemedicine Devices", (52 Food & Drug L.J. 517) (1997).
- Reichertz, P., "Legal Issues Concerning the Promotion of Pharmaceutical Products on the Internet to Consumers," (51 Food & Drug L.J. 355) (1996).

## SPEECHES

- "The New Drug Approval Process: NDA Submission and Review", Food and Drug Law Institute Workshop on "Introduction to Drug Law and Regulation: Understanding How the Government Regulates the Drug Industry", New Brunswick, New Jersey, October 5, 2011
- "FDA Guidelines: Now and the Future", IBC Conferences "Biosimilars Asia 2011", Shanghai, China, May 24, 2011
- "Anticipating and Managing Emerging Issues Relating to Recalls of OTC Products and Supplements", American Conference Institute conference on "Drug and Device Recalls", Philadelphia, PA, March 22, 2011
- "Post-Approval Regulations, Post Marketing Surveillance, Imports and Exports, and Topics to Watch-TPDs and Drugs" and "Approval Pathways and Exclusivity Consequences for Approved and Licensed Protein Products and Other Biologically-Derived Products", FDA Center for Drug Evaluation and Research Training, March 8, 2011
- "The Shifting Regulatory Landscape & The Future of Devices", Medical Device Innovation, Panel Moderator, Landmark Ventures Life Sciences Summit, New York, New York, February 9, 2011
- "FDA Enforcement Initiatives: Clinical Investigations", Strategic Issues Facing Emerging and Established Life Sciences Companies, Silicon Valley, CA, November 2010
- "FDA Enforcement Initiatives: Clinical Investigations", Strategic Issues Facing Emerging and Established Life Sciences Companies, Del Mar, CA, November 2010
- "FDA Enforcement Initiatives: Clinical Investigations", Strategic Issues Facing Emerging and Established Life Sciences Companies, New York, NY, October 2010
- "Training the Sales Force: Minimizing the risk of Sending Your Sales Team Into the Field", American Conference Institute Conference on "OFF LABEL COMMUNICATIONS", Philadelphia, PA, July 15, 2010

- "Approval Pathways and Exclusivity Consequences for Approved and Licensed Protein Products and Other Biologically-Derived Products", FDA Center for Drug Evaluation and Research Training, May 10, 2010
- "Product Recalls", Basham Ringe y Correa SC Seminar on "Product Liability", Mexico City, December 4, 2008
- "Clinical Trial Databank and Postmarket Safety Reporting Requirements under FDAAA", Food and Drug Law Institute, "Introduction to Biotechnology Law and Regulation", Washington, DC, June 5, 2008
- "Patent and Non-Patent Exclusivities", Food and Drug Law Institute, "Introduction to Biotechnology Law and Regulation", Washington, DC, June 5, 2008
- "Clinical Trials Databank Requirements and Other Important Provisions of FDAAA", Sheppard Mullin Life Sciences Seminar, Del Mar and Orange County, April 2008
- "U.S. FDA Regulation of Medical Devices: Current Requirements and Future Trends", the Second National Forum on Innovation and Technology Trends, Tijuana, Mexico, (June 2, 2006)
- "The New Drug Approval Process: NDA Submission and Review," Food and Drug Law Institute, Introduction to Drug Law, Washington, D.C., (January 23, 2006)
- "Marketing Compliance in Pharmaceutical Labeling and Packaging," Food and Drug Law Institute/Center for Business Intelligence Pharmaceutical Marketing Compliance Congress, Washington, DC (January 26, 2004)
- "Post Approval Issues" and "Over-the-Counter Drugs," Food and Drug Law Institute Introduction to Drug Law and Regulation, Washington, DC (November 18, 2003)
- "Assess the Risks and Benefits Associated with Off-Label Communications," Center for Business Intelligence Guidelines for Disseminating Off-Label Information, Washington, DC (October 21, 2003); Moderator
- "Understand the Role that Product Liability Plays in Handling of Pharmaceutical Complaints," Center for Business Intelligence Effective Handling of Pharmaceutical Product Complaints, Philadelphia, PA (June 13, 2003)
- "Enforce PDMA, FDA, State and Healthcare Fraud Regulations," Center for Business Intelligence Sample Accountability, Alexandria VA (May 19, 2003)
- "Assess the Costs and Benefits Associated with Off-Label Communication," Center for Business Intelligence Guidelines for Disseminating Off-Label Information, Washington, DC (October 22, 2002); Moderator
- "Enforce PDMA, FDA, State and Healthcare Fraud Investigations," Center for Business Intelligence Sample Accountability, Washington, DC (May 20, 2002)
- "Liability Associated with Promotional Materials," Center for Business Intelligence Pharmaceutical Promotional Labeling, Galloway, NJ (March 1, 2002)
- "Regulatory Issues When Providing Drug Information on the Internet," Drug Information Association Pharmacoeconomic and Quality of Life Labeling and Promotional Claims; A Global Update, Philadelphia, PA (October 29, 2001)
- "Assess the Costs and Benefits Associated with Off-Label Communications," Center for Business Intelligence Guidelines for Disseminating Off-Label Information, Washington, DC (October 19, 2001)
- "FDA/FTC Regulation of the Internet," Barnett International Pharmaceutical Business via the Internet, Woodcliff Lake, NJ (August 16, 2001)
- "Compliance with FDA Labeling and Advertising Requirements," Health Care Compliance Association/Food and Drug Law Institute Second Annual Pharmaceutical Industry Regulatory and Compliance Summit, Arlington, VA (June 11, 2001)

- “FDA Perspectives”, Arent Fox The Bayer Corporation Settlement. What Does It Mean to You?, New York, NY (March 20, 2001)
- Reichertz, P., “Benefits of Advertising and Promoting Off-Label Information,” Center for Business Intelligence Disseminating Off-Label Information, Washington, DC (October 14, 2000); Moderator
- “Regulatory Issues When Providing Drug Information on the Internet”, Drug Information Association Pharmacoeconomic and Quality of Life Labeling and Marketing Claims, New Orleans, LA (October 2, 2000)
- “Benefits of Advertising and Promoting Off-Label Information,” Center for Business Intelligence Disseminating Off-Label Information, Washington, DC (March 31, 2000)

**EVENTS**

- Strategic Issues Facing Emerging and Established Life Sciences Companies - San Diego
- Strategic Issues Facing Emerging and Established Life Sciences Companies - Silicon Valley
- Strategic Issues Facing Emerging and Established Life Sciences Companies - New York