



Kai Peters

PARTNER

San Francisco

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RELATED SERVICES

- Pharmaceutical & Medical Device
- Business Transactions
- Food & Beverage
- Product Liability
- Real Estate
- Healthcare, Regulatory Transactions & Telehealth

OFFICES

- San Francisco

OVERVIEW

Kai Peters is a Partner who acts as outside general counsel for businesses, advising on a broad range of corporate, commercial and litigation matters, and in representing businesses in simple and complex litigation.

Kai has significant experience in litigation, including product liability, mass torts, class actions, breach of contract, and business disputes. He has a particular emphasis in complex commercial litigation representing pharmaceutical, medical device, and other FDA-regulated companies, solar companies, and hi-tech and new media companies.

Kai acts as national and local litigation counsel for companies of all sizes in state and federal courts, including in MDL's and in coordinated proceedings. He has recovered significant sums in breach of contract matters as well. He also advises corporate clients in the area of avoidance of potential liability

and litigation, from training and organization of sales representatives to the form and content of internal and external documents.

Kai has extensive experience in all phases of litigation, including the initial phases of litigation; development and preparation of witnesses for testimony; depositions of experts and company witnesses of all backgrounds (including special emphasis on working with sales representatives, regulatory employees, and company executives); analysis and development of defenses, including those based on medical and scientific causation issues, labeling, and preemption; motion practice; written discovery; major document organization and review (including e-discovery); summary judgment motions; alternative dispute resolution including mediation; evaluation of cases with experts; and the trial phase.

As outside general counsel, Kai advises clients of all sizes in a variety of business matters, including:

- Entity formation and business liability protection;
- Contract drafting, review, and negotiation, including service, purchase and sale, licensing, lease, distribution, co-marketing, executive employment, independent contractor, loan, and clinical trial agreements;
- Non-disclosure, confidentiality, and invention agreements;
- Clinical trial agreements – drafting, negotiation, informed consents, and regulatory consulting – including review of FDA submissions;
- Intellectual property and trade secret protection;
- Legal advice on operations, business strategy, and risk avoidance;
- Privacy policies and terms of use for websites;
- Pre-litigation business dispute resolution;
- Reorganizations, conversions, and acquisitions.

Kai is an Adjunct Professor of Law for University of California College of the Law, San Francisco (formerly known as University of California, Hastings College of the Law), currently teaching a course entitled “Practical Civil Litigation.”

Kai is frequently quoted in legal and industry publications, including extensive comments in the Daily Journal, and presents at conferences nation-wide.

PUBLICATIONS

Kai Peters' publications include:

- *Those Involved in Compound Pharmaceuticals Beware: Law Enforcement Is Focused on You*, The Food and Drug Law Institute Update Magazine (November/December 2017) (shared with the permission of FDLI)

- *What Happens When A Medical Device Manufacturer is Embroiled in Allegations of Improper Advertising and Promotion?*, The Food and Drug Law Institute Update Magazine (September/October 2015)
- *Defense Lawyers Cheer High Court's Ruling on Generic Drugs*. Quoted on US Supreme Court Decision on Key *Bartlett Decision*, *Daily Journal* (June 25, 2013)
- *The Caronia Decision: Will The Truth Set You Free?*, *DRI Happenings* (May 2, 2013)
- *The Corporate Responsibility Doctrine: Handling Matters When Corporate Executives Are Involved in Criminal or Civil Matters*, *Inside the Minds*, Aspatore Books (January 2013)
- *Lessons from GlaxoSmithKline's \$3 Billion Settlement in the US*, *Scrip Regulatory Affairs* (August 2012)
- *How Can Manufacturers Avoid Off-Label Promotion of Medical Devices?*, *Medical Law Perspectives* (April 2012)
- *Legal Risks to Consider in Virtual Trials*, *Applied Clinical Trials Online* (April 2012)(Interview)
- *Off-Label Promotion: What Should Pharmaceutical Companies Watch Out For in 2012?*, *Medical Law Perspectives* (March 2012)
- *Drugmakers Look to FDA for Guidance on Off-Label Marketing*, *Daily Journal* (January 2012)(Interview)
- *Drugmakers Rely on First Amendment and First Amendment Defense*, *Daily Journal* (November 2011)
- *What Every Pharmaceutical and Medical Device Company Should Know: False Claims Act Cases Based on Off-Label Promotion Promise to Increase with the Healthcare Act and the Bad Ad Program*, *IADC's Defense Counsel Journal* (July 2011)(Co-author)
- *Virtual Clinical Trials Raise Legal and Ethical Questions*, *The Daily Journal* (June 2011)
- *Drug & Medical Device Defense: 10 Tips When Criminal Activity is Involved* For The Defense (October 2010)
- *Name-Brand Manufacturers Liable for Ingestion of Generic Products?: An Analysis of The Nation's Response to California's Conte v. Wyeth Decision*, *IADC Drug, Device and Biotechnology Committee Newsletter* (February 2010)

PRESENTATIONS

Kai Peters has presented on numerous topics, including:

- *Nontraditional Venues: Are They Promotional?* Presented at Food Drug and Law Institute Advertising and Promotion for Medical Products Conference on October 16-17, 2018, Washington, D.C.
- *Regulation of Drug and Medical Device Marketing – Key Principles of Advertising and Promotion*. Presented at Introduction to Law and Regulation – Drug and Medical Device on November 9-10, 2015 (Presenter and Chair)
- *Generic Drug Preemption and Innovator Liability Update*. Presented at the Life Sciences Legal Summit on March 4, 2015 (Presenter)

- *Interplay Between FDA Advertising and Promotion Enforcement Activities, Product Liability, and Consumer Fraud Litigation.* Presented at the Food and Drug Law Institute's Advertising & Promotion Conference on September 29-30, 2014 (Presenter)
- *Regulatory Strategies for Life Science Companies.* Presented at the Life Sciences Legal Summit on February 27, 2014 (Presenter)
- *Regulating 3d Printing: How to Impose Limits on the Theoretically Limitless.* Presented at the *Hastings Law Journal's* symposium, "The Legal Dimension of 3d Printing" on February 21, 2014. (Panelist)
- *Advertising, Promotion, and Labeling.* Presented at the FDLI's Introduction to Medical Device Regulation and Litigation Conference, Palo Alto, CA on October 9, 2013. (Panelist)
- *Key Legal Decisions On Preemption in 2012 and 2013.* Presented at the FDLI Advertising and Promotion Conference, Washington D.C. on September, 17 2013. (Presenter)
- *Litigation: Products Liability and Key Cases in 2013.* Presented at the Strategic Considerations, and Avoidance Techniques, Medical Device Compliance, Regulation and Litigation Conference, Washington DC on March 4, 2013. (Moderator)
- *Litigation: Key Cases in 2012; Strategic Considerations: Avoidance Techniques.* Presented at The Food and Drug Law Institute's Medical Device Regulation and Litigation Conference Advance Level Program in Washington, DC on June 18, 2012. (Panelist)
- *Understanding How To Effectively Manage Risk Associated With Outsourcing Clinical Research And Trials To Drive Drug Discovery And Innovation.* Presented at ICSE USA Conference in Philadelphia, Pennsylvania on May 23, 2012.
- *Virtual Clinical Trials: Assessing the Legal Risks and Potential Liabilities In The Virtual World.* Presented at the 21st Annual Partnerships in Clinical Trials Conference, coordinated by the Institute of International Research, in Orlando, Florida on March 5, 2011.

CREDENTIALS

Admissions

- California
- U.S. District Court, Northern, Central, Eastern, and Southern Districts of California
- U.S. Court of Appeal, Sixth Circuit and Ninth Circuit
- U.S. Supreme Court

Memberships

- Food Drug & Law Institute (FDLI) Medical Device Committee (Washington D.C. chapter), Member
- Defense Research Institute, Member

Community Involvement

Kai enjoys triathlons and has competed in Ironman competitions nationally and internationally, achieved All-American honors, and competed in the Hawaii Ironman for many years. He volunteers his time to USA

Triathlon as a member of its legal committee and acts as lead judge or judge in USAT Hearings and Appeals matters.

Kai has also acted as a judge in 2012 and 2013 at a start-up competition for Central California involving hundreds of start-up companies.

Education

- J.D., University of California, Hastings College of the Law
 - Blum Foundation Scholarship recipient
 - Executive Editor, *Communications and Entertainment Law Journal*
- B.A., *honors*, Business – Economics, University of California, Santa Barbara
 - Honors Program, emphasis on international economics
 - All-American swimmer

Externship

- Honorable D. Lowell Jensen, U.S. District Court for the Northern District of California

Honors

- *Best Lawyers in America*® distinction in Product Liability Litigation – Defendants (2023-2024)

Languages

- German