



Paul T. Kim

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INDUSTRIES

Life Sciences
Healthcare

SERVICES

Government Strategies
Medicare Coverage &
Reimbursement
Biodefense and Pandemic
Preparedness

HONORS/AWARDS

WASHINGTON, D.C. SUPER
LAWYERS 2010
Named one of the top Food and
Drug lawyers in the Washington,
DC annual review of attorneys by
WASHINGTONIAN magazine
(2009, 2007 and 2004)
Commissioner of Food and Drug
Special Citation
Sloan Foundation Fellow
Harvard College Scholar

EDUCATION

Harvard College, A.B., cum laude,
1988
Harvard University, John F.
Kennedy School of Government,
M.P.P., 1990
Georgetown University Law
Center, J.D., 1998

Regarded as one of the top food and drug lawyers in Washington, Paul Kim draws on his extensive governmental experience to advise clients on legal, legislative and regulatory issues in food, drug and device law, Medicare and Medicaid coverage and reimbursement, and the conduct of clinical research. He represents leading biotechnology, pharmaceutical and medical device companies before the Food and Drug Administration (FDA), the Centers for Medicare and Medicaid Services (CMS), and Congress.

Paul uses his Capitol Hill experience in the enactment, amendment and implementation of the Food, Drug, and Cosmetic Act, and such landmark legislation as the Public Health Security and Bioterrorism Act, the Hatch-Waxman Amendments and the Orphan Drug Act to advise clients on compliance issues and regulatory approvals. He also assists with general FDA regulatory matters, collaborating with clients to develop comments, petitions, presentations and regulatory submissions for agency rulemakings, advisory committee proceedings, early collaboration and pre-submission meetings, and other meetings with key Federal decision-makers. Clinical research compliance, FDA product approval, CMS coverage and reimbursement issues, and bioresearch monitoring are additional areas of focus in Paul's regulatory practice.

Paul also develops effective legislative and media strategies for industry clients, manages advocacy coalitions, and helps clients develop constructive relationships with key federal regulators and congressional decision-makers. He also represents clients before congressional committees and with in their dealings with individual members of the United States Senate and the House of Representatives, defends their interests in congressional oversight and investigations, and helps them prepare for hearings.

Before joining Foley Hoag Paul was Deputy Staff Director for health policy for Senator Edward M. Kennedy, who chairs the U.S. Senate Health, Education, Labor and Pensions Committee. Major laws enacted while Paul served with Senator Kennedy include The Public Health Security and Bioterrorism Response Act of 2001 (whose food safety protections were deemed "the most significant expansion of federal authority over the food industry in more than six decades" by the New York Times), the Reauthorization of the Prescription Drug User Fee Act, The Medical Device User Fee and Modernization Act of 2002, The Rare Diseases Act of 2002 (amending the Orphan Drug Act), The Best Pharmaceuticals for Children Act, and Senate passage of the Greater Access to Affordable Pharmaceuticals Act of 2001.

Paul also was Counsel to Congressman Henry A. Waxman (serving as staff in both the House of Representatives and the Senate, as well as in conference, on the Food and Drug Administration Modernization Act of 1997) and as a professional staff member to Senator David Pryor on the U.S. Senate Special Committee on Aging and the U.S. Senate Finance Committee. His other public policy experience includes positions as Assistant Director for Government Relations with the American Foundation for AIDS Research (amFAR), the largest private funder of HIV/AIDS research, as a Policy Analyst with the Office of the Commissioner, Food and Drug Administration, and with Ciba-Geigy Pharmaceuticals in Basle, Switzerland.

BAR AND COURT ADMISSIONS

Y Maryland
Y District of Columbia

REPRESENTATIVE EXPERIENCE

The following is a brief summary of Paul's experience and accomplishments:

- Y Hatch-Waxman Act - Provides advice on the latest developments affecting product approvals and market exclusivities, including generic biologics, FDA and court decisions, FTC investigations and legislative activity
- Y Orphan Drug Act - Counsels clients on FDA and CMS policies affecting orphan product approval and reimbursement, helps secure orphan designations, market exclusivities and tax credits, as well as

humanitarian device exemptions

- Ÿ Coordinating product approval, coverage and reimbursement - Advises clients on managing and coordinating the timely development of clinical and pharmacoeconomic data for both FDA product approval and CMS coverage and reimbursement
- Ÿ Biodefense and bioterrorism - Advises biotechnology and medical device clients on post-September 11 laws and funding programs promoting the development of biodefense countermeasures; provides guidance on the proper implementation of new food safety and select agent regulations under the Public Health, Security and Bioterrorism Preparedness and Response Act
- Ÿ Premarket applications - Assists in preparing and reviewing fast track and accelerated approval applications, as well as other innovative NDAs, PMAs and supplements undergoing priority review at FDA
- Ÿ Device reforms, reprocessed devices and combination products - Aids medical device clients in working with the Office of Combination Products, and provides guidance on implementation of policies on reprocessed devices and qualification for and use of the CDRH third-party device review and inspection programs
- Ÿ Clinical research compliance and bioresearch monitoring - Assists in achieving compliance with FDA and Common Rule requirements for human research subject protections, including guidance on legislative initiatives and the new Federalwide Assurance of Protection for Human Subjects (FWA), and legal support in response to oversight by the FDA and the HHS Office for Human Research Protections (OHRP)

SPEECHES AND CONFERENCES

- Ÿ FDA Initiatives on Follow-On Biologics, ACI Conference on Follow-On Biologics (June 2010)
- Ÿ New Landscape for Industry-Professional Relations, Drug Information Association Annual Meeting (June 2010)
- Ÿ Follow-On Biologics: Regulatory Strategies, Elsevier Business Intelligence (June 2010)
- Ÿ Health Care Reform: On the Front Lines, BIO IP Counsels Committee Conference (April 2010)
- Ÿ What FDA & Congress Are Planning for the 510(k), MassMEDIC (April 2010)
- Ÿ Plenary Panel on Health Care Reform, BIO CEO & Investor Conference (February 2010)
- Ÿ Panel on Implementation of Vaccine Reforms, National Vaccine Advisory Committee (July 2009)
- Ÿ Addressing Biosimilars: Federal Legislation for a Pathway, Massachusetts Biotechnology Council (May 2009)
- Ÿ The Business Impact of Obama and Health Reform on BioPharma, Windhover Pharma Strategic Outlook Conference (April 2009)
- Ÿ Panel on Health Care Reform, Cowen Group Annual Health Care Conference (March 2009)
- Ÿ Federal Food Safety Reforms, International Dairy Foods Association (January 2009)
- Ÿ FDA's Draft Guidance on Dissemination of Reprints, 20th Annual Advertising and Promotion Conference, Food and Drug Law Institute (September 2008)
- Ÿ Regulating the Future of Diagnostics: BIO 2008 International Convention (June 2008)
- Ÿ From Theory to Practice: FDAAA, Future FDA and Legislative Priorities, Other Enforcement Initiatives, and Beyond, American Conference Institute's FDA Boot Camp (May 2008)
- Ÿ Follow on Biologics, Windhover FDA/CMS Summit (December 2007)
- Ÿ Trends in Healthcare Policy: How They Will Affect the Medical Device Industry?, Medical Development Group (November 2007)
- Ÿ Preemption, Health and Safety, and the Supreme Court, American Constitution Society for Law and Policy (November 2007)
- Ÿ Modern Issues in Regulating Drug Development, Angiogenesis Foundation International Conference (October 2007)
- Ÿ Drug Safety and PDUFA IV: Overview of Critical Issues in Congress, BIO 2007 (May 2007)
- Ÿ Current Trends in Biotech Law & Practice, Massachusetts Continuing Legal Education (MCLE) Seminar (February 2007)
- Ÿ IVDMIA's - A New Approach to Regulating Molecular Diagnostic Tests - Overview of FDA's Draft Guidance, Massachusetts Biotechnology Council (October 2006)
- Ÿ FDA on Capitol Hill: Postmarketing Surveillance and MDUFMA Reauthorization, MassMEDIC Annual FDA

Update (December 2005)

- Y Clinical Trials: Framework for Innovation, Arthur J. Gallegher & Co. (October 2005)
- Y Managing Legal Risks in Conducting and Promoting Clinical Trials, American Conference Institute (September and February 2005)
- Y Science and Regulatory Policy Program, University of Maryland School of Public Policy and the Philip Merrill College of Journalism (May 2005)
- Y Complying with FDA Bioterrorism Requirements for Food Products, NACDS Distribution and Logistics Conference (March 2005)
- Y FDA Primer For Entrepreneurs, Women in BIO (February 2005)
- Y Drug Safety in the Post COX2 Inhibitors World, Massachusetts Biotechnology Council (January 2005)
- Y Drug Importation and Reimportation, Conference Co-Chair, American Conference Institute (November 2004)
- Y Improving Agency and Congressional Relations, Regulatory Policy Program, Food and Drug Administration (April 2004)
- Y Drug Marketing, Advertising and Promotion: A View from the Hill, Drug Information Association (February 2004)
- Y Reducing Legal Risk in Promoting and Conducting Clinical Trials, American Conference Institute (February 2004)
- Y Obesity: Science, Government and Industry Weigh In On A Growing Consumer Problem, Food and Drug Law Institute (January 2004)
- Y Legislative Agenda for Diagnostic Imaging Technologies, Washington DC symposium, Academy of Molecular Imaging (September 2003)
- Y FDA's Strategic Plan: Identifying Opportunities for Biotechnology, Massachusetts Biotechnology Council (September 2003)
- Y Project BioShield and Beyond: Promoting the Development of Bioterrorism Countermeasures, Drug Information Association Annual Meeting (June 2003)
- Y Communicating with Patients: Recognizing the Regulatory Challenges, Overcoming the Barriers, Drug Information Association Annual Meeting (June 2003)
- Y Medical Device User Fee and Modernization Act Implementation, Medical Device Manufacturers Association Annual Meeting (June 2003)
- Y Federal Government Perspectives, Board on Health Sciences Policy, Institute of Medicine (June 2003)
- Y Panel on FDA Jurisdiction, Food and Drug Law Institute Annual Education Conference (April 2003)
- Y Disaster Preparedness and Bioterrorism, National Association of Children's Hospitals (February 2002)
- Y Medical Device Reforms and User Fees, Massachusetts Medical Device Industry Council (December 2001)
- Y Informing Congress: Creating National Health Priorities, Institute of Medicine, Board of Health Sciences Policy (June 2001)