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## EDUCATION AND HONORS

**AMERICAN UNIVERSITY WASHINGTON COLLEGE OF LAW** Washington, DC 2001
***JURIS DOCTOR:*** *CONCENTRATIONS IN HEALTH AND FOOD AND DRUG LAW*

**TECHNISCHE UNIVERSITÄT DARMSTADT** Darmstadt, Germany 1996
***MASTER CREDIT (FULBRIGHT SCHOLARSHIP)***

**MARQUETTE UNIVERSITY** Milwaukee, WI 1995
***BACHELOR OF ARTS:*** *MAJORS - POLITICAL SCIENCE & GERMAN; MINOR - THEOLOGY*

- **Fulbright Scholarship (Germany)**
  Topic of Study**: *The Political, Social, and Cultural Context of Avant Gardeism in Post World War Two German Jazz***
- Admitted to practice law in **Maryland** (inactive) and the **District of Columbia**
- **American University Law Review**, Articles Editor
- **Phi Beta Kappa**, National Honor Society
- **Pi Sigma Alpha**, Political Science Honor Society
- **Delta Phi Alpha**, German Honor Society
- **Alpha Sigma Nu**, Jesuit Honor Society
- **Dean's List**, 1991-1995
- **Eagle Scout**, 1988

## PROFESSIONAL EXPERIENCE

**HYMAN, PHELPS & McNAMARA, P.C.** Washington, D.C. 5/2001 – Present
***DIRECTOR (1/2010); ASSOCIATE ATTORNEY (5/2001-12/2009)***
- Provide legal and regulatory counsel to a wide variety of pharmaceutical clients (brand-name, generic; prescription and OTC) concerning patent and exclusivity issues, myriad drug development issues, pediatric testing issues, and orphan drugs.

**HYMAN, PHELPS & McNAMARA, P.C.** Washington, D.C. 6/1999 – 5/2001
***LAW CLERK***
- Review dietary supplement and cosmetic labeling to ensure statutory and regulatory compliance.
- Draft orphan drug designation and fast track designation requests.
- Work with medical device manufacturers to ensure appropriate regulatory treatment of single-use medical devices.
- Review and summarize data in clinical data for pharmaceutical development.

**HOFFMANN-LA ROCHE** Washington, D.C. 8/1996 – 6/1999
***SENIOR ASSISTANT/LOBBYIST***
- Develop and implement federal legislative strategic plans for animal Medicinal Feed Additives business on antibiotic resistance, *Animal Drug Availability Act* implementation, and specific company products.

- Create and advance federal legislative strategic plans for vitamin and dietary supplement businesses on *Dietary Supplement Health and Education Act* implementation, the Food Stamp program, California Proposition 65, and various other legislative initiatives.
- Act as federal government affairs liaison for patient confidentiality, diagnostics, international affairs, environment, animal health, and vitamins and dietary supplements issue management teams.
- Draft and garner Congressional support for myriad legislative proposals.
- Monitor state and federal legislative activities.

**BROYDRICK AND ASSOCIATES** Washington, D.C., 1995 and 1996
***INTERN*** Milwaukee, WI

- Drafted a fifty-state analysis of Medicaid and Medicare reimbursement methodologies for Milwaukee's Childrens' Hospital.
- Published a newsletter to update healthcare clientele on Medicare and Medicaid issues.
- Organized and executed a campaign strategy for the Milwaukee Metropolitan Sewerage District to raise customer awareness of possible cost increases due to a bill in the state legislature.

**HOFFMANN-LA ROCHE** Washington, D.C. Summer 1994
***INTERN***

- Drafted a bi-weekly company newsletter informing company executives and employees of federal legislation affecting the pharmaceutical industry.
- Attended and reported on Congressional hearings concerning health care issues.

**U.S. REPRESENTATIVE RICHARD DURBIN (D-IL)** Washington, D.C. Summer 1993
***INTERN***

- Drafted language for a bill that successfully passed the House of Representatives regarding the use of tobacco products.
- Responded to constituent requests regarding government procedure and the Congressman's position on various issues.

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## PUBLICATIONS

- Primary Author of the FDA Law Blog (www.fdalawblog.net) legal weblog (2007-2018).

- Kurt R. Karst, *Patents and Exclusivity* (Ch. 17), *Fundamentals of US Regulatory Affairs*, Regulatory Affairs Professionals Society, 10th Ed. (2017).

- Kurt R. Karst, John R. Fleder & Robert A. Dormer, How FDA Announces Drug Approval Decisions: A Broken FDA "System" That Must Be Fixed, Biotechnology & Pharmaceuticals 2017: EXPERT GUIDE, Corporate Live Wire (Jan. 2017).

- Jan Berger, MD, MJ; Jeffrey D. Dunn, PharmD, MBA, Margaret M. Johnson, BS, RPh; Kurt R. Karst, JD, and W. Chad Shear, JD, *How Drug Life-Cycle Management Patent Strategies May Impact Formulary Management*, Am J Manag Care. 2016;22:S487-S495.

- Kurt R. Karst, *FDA's Orange Book and ANDAs: Questioning the Policies and Precedents Surrounding RLD Patent Listings*, Respiratory Drug Delivery Europe 2015.

- Kurt R. Karst, *Jumping Legal Hurdles with the US FDA: The Generic Inhaler Challenge,* Respiratory Drug Delivery Asia 2014.

- Kurt R. Karst, *Letting the Devil Ride: Thirty Years of ANDA Suitability Petitions under the Hatch-Waxman Act*, 40 Wm. Mitchell L. Rev. 1260-1306 (2014).

- Donald O. Beers, Kurt R. Karst, *Generic and Innovator Drugs: A Guide to FDA Approval Requirements* (8th Edition; Legal Treatise), Aspen Publishers/Wolters Kluwer (May 2013) (Supplements in 2015 and 2016).

- Kurt R. Karst, *Orphan Drug Approval in the US (and Some EU Comparisons): Regulatory Mechanisms for Rare Pulmonary Disorders*, Respiratory Drug Delivery Europe 2013.

- H. Keeto Sabharwal, Dennies Varughese, Kurt R. Karst, *How Inter Partes Review Impacts Hatch-Waxman Exclusivity*, Law360 (Feb. 2013).

- Kurt R. Karst, *To 505(b)(2) or Not to 505(b)(2) – Jumping the Legal Hurdles for Inhaled Drug Products*, Respiratory Drug Delivery 2012.

- Kurt R. Karst, *Generic Drug Submissions* (Ch. 11) and *Patents and Exclusivity* (Ch. 12), *Fundamentals of US Regulatory Affairs*, Regulatory Affairs Professionals Society, 7th Ed. (2011).

- Kurt R. Karst, Contributor, *Pharmaceutical, Biotechnology and Chemical Inventions - World Protection and Exploitation*, Oxford Univ. Press (2011).

- Kurt R. Karst and Michelle L. Butler, *Dissecting the US FDA's new guidance on PDUFA user fee waivers, reductions and refunds*, Regulatory Affairs Pharma (Informa), Apr. 2011, 22-24.

- Kurt R. Karst, *Teva Pharmaceuticals USA v. Sebelius et al.* (Ch. 19), Food and Drug Law Institute, Top 20 Food and Drug Cases, 2009 & Cases To Watch, 263-81 (2010) (Edited by J. Reiss).

- Kurt R. Karst, *Forfeiture of Generic Exclusivity in the US: Who's to Blame?* Regulatory Affairs Journal Pharma (Informa) June 2010, 341-42.

- Kurt R. Karst, *A Lawyer's Perspective on the Approval and Legal Challenges for Topically Active Generic Inhalers*, Respiratory Drug Delivery 2010.

- Kurt R. Karst, *Teva Pharmaceuticals USA, Inc. v Sebelius* (Ch. 19), *Top 20 Food and Drug Cases 2009 & Cases to Watch 2010*, Food and Drug Law Institute (2010).

- Kurt R. Karst, *Generic Drug Submissions* (Ch. 14), *Fundamentals of US Regulatory Affairs*, Regulatory Affairs Professionals Society, 6th Ed. (2009).

- Kurt R. Karst, *FDA's RLD Choice and Change Prohibition: A New Tool in the Lifecycle Management Toolbox*, Genetic Engineering & Biotechnology News, Vol. 29 No. 12 (June 2009).

- Kurt R. Karst & Robert A. Dormer, *The Drug User Fee Catch-22*, Washington Legal Foundation Legal Backgrounder, Vol. 32 No. 17 (May 2009).

- Kurt R. Karst, *Marketed Unapproved Drugs –Past, Present and Future?*, RAPS Focus, Feb. 2007, 37-42.

- Kurt R. Karst & Jeffrey N. Wasserstein, *New Law Reins in "Authorized Generics" Despite Generic Industry Court Losses, But Leaves Several Ambiguities*, RAPS Focus, June 2006, 8-12.

- Kurt R. Karst, *FDA Issues Long-Awaited Prescription Drug Labeling Regulations*, RAPS Focus, Apr. 2006, 32-37.

- Kurt R. Karst, *FDA's Good Review Management Principles and Practices: The Essential FDA Guide to Drug Approval*, RAPS Focus, Oct. 2005, 32-33.

- Kurt R. Karst, *Exploratory INDS: A New Tool in the Drug Development Toolbox*, RAPS Focus, Sept. 2005, 36-37.

- Kurt R. Karst & Robert A. Dormer, *FDA's Unauthorized User Fee Money Grab*, Washington Legal Foundation Legal Backgrounder, Vol. 28 No. 30 (Aug. 2005).

- Kurt R. Karst, *Does the U.S. Constitution Preclude Generic Drug Companies from Seeking Patent Certainty Absent a Reasonable Apprehension of Imminent Infringement Litigation?*, Federal Bar Association Newsletter, June 2005.

- Kurt R. Karst, *Is the ANDA Suitability Petition Process Dead?*, RAPS Focus, May 2005, 35-6.

- Kurt R. Karst, *Authorized Generics –Historical Overview and Current Issues*, RAPS Focus, March 2005, 38-41.

- Kurt R. Karst, *Presages to the Coming War Over Generic Biologics*, JOURNAL OF GENERIC MEDICINES, Jan. 2004, 155-163.

- Kurt R. Karst & Frank J. Sasinowski, *Legal and Regulatory Factors,* in *Exploring the Pathway to Generic Biologics: Are Therapeutically Equivalent Biologics Feasible and Desirable?*, National Organization for Rare Disorders Conference Report, March 2003, 12-14.

- Carl C. Peck & Jill Wechsler, *Report of A Workshop on Confirmatory Evidence to Support a Single Clinical Trial as a Basis for New Drug Approval*, DRUG INFORMATION JOURNAL, Nov. 2002, 517-34 (Acknowledgement).

- Kurt R. Karst & Michelle L. Butler, *Orphan Drugs: Subsetting and Sameness*, Current Drug Discovery, Dec. 2001, 48-51.

- Kurt R. Karst & Frank J. Sasinowski, *Biologic Approvals for Small Businesses*, FDLI Update, 13-15, 35 (March/April 2001).

- Kurt R. Karst, Comment, *Going 90 in a 55 M.P.H. Speed Zone: Reprocessing of Used Single-Use Medical Devices and the Food and Drug Administration's Non-enforcement of the Food, Drug, and Cosmetic Act*, 56 FOOD & DRUG L. J. 57 (2001).

- Frank J. Sasinowski & Kurt R. Karst, FDLI DRUG AND BIOLOGIC APPROVALS: THE COMPLETE GUIDE FOR SMALL BUSINESSES — FDA FINANCIAL ASSISTANCE AND INCENTIVES (2000) (159 pages).

- Kurt R. Karst, Comment, *Pediatric Testing of Prescription Drugs: the Food and Drug Administration's Carrot and Stick for the Pharmaceutical Industry*, 49 AM. U. L. REV. 739 (2000).

- Kurt R. Karst, *Pediatric Testing of Prescription Drugs*, FDLI Update, 17 (Jan./Feb. 2000).

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## SPEECHES & PRESENTATIONS

- FDLI/American University Washington College of Law, FDA Past, Present, and Future, Oct. 2018.

- American Conference Institute, Paragraph IV Disputes, Oct. 2018.

- American Conference Institute, FDA Boot Camp, Sept. 2018.

- Association for Accessible Medicines, GRx+Biosims 2018, Sept. 2018.

- 12th Asian Biologics and Biosimilars Congress, Aug. 2018 (Tokyo, Japan).

- Coalition for Healthcare Communication, 2018 Rising Leaders Conference on Healthcare Policy, May 2018.

- Barclay's High Yield Bond & Syndicated Loan Conference, May 2018.
- 3rd International Convention on the Economy of Innovation, May 2018 (Tel Aviv, Israel).
- 11th European Biosimilars Congress. Apr. 2018 (Rome, Italy).
- American Conference Institute, Paragraph IV Disputes, Apr. 2018.
- American Conference Institute, FDA Boot Camp, Mar. 2018.
- University College London/Georgetown University Law Center, Clinical Innovation: Fair and Effective Incentives for New Uses of Established Drugs, Feb. 2018.
- Association for Accessible Medicines, Fall Tech Conference, Anatomy of an Expedited/Priority Review, Nov. 2017.
- Drug Information Association, Combination Products Conference, Generics for Combination Products: It's Complicated, Oct. 2017.
- National Organization for Rare Disorders, Rare Summit, Right to Try, Current Policy News & NORD's Policy Priorities, Oct. 2017.
- Barclays, Generic Pharmaceuticals and Biosimilars Symposium, Oct. 2017.
- American Conference Institute, Paragraph IV Disputes, Oct. 2017.
- American Conference Institute, FDA Boot Camp, Sept. 2017.
- Regulatory Affairs Professionals Society, Regulatory Convergence, Effective Orphan Drug Development in a Challenging Regulatory Environment, Sept. 2017.
- Regulatory Affairs Professionals Society, Regulatory Convergence, An Update on the First Reauthorization of GDUFA, Sept. 2017.
- Drug Information Association, Global Annual Meeting, Biosimilars and Generics: Access Versus Innovation, June 2017.
- National Organization for Rare Disorders, Corporate Council Meeting, The "Evergreening" Issue With Orphan Drugs, May 2017.
- American Conference Institute, Paragraph IV Disputes, Apr. 2017.
- American Conference Institute, FDA Boot Camp, Mar. 2017.
- American Society for Experimental Neurotherapeutics, 19th Annual Meeting, Mar. 2017
- Generic Pharmaceutical Association, Title XI of the 2003 Medicare Modernization Act: FDA's Final Regulations on ANDAs and 505(b)(2) Applications, Nov. 2016.
- International Conference and Expo on Generic Drug Market and Contract Manufacturing, Nov. 2016 (Barcelona, Spain).
- American Conference Institute, Paragraph IV Disputes, Sept. 2016.
- American Conference Institute, FDA Boot Camp, Sept. 2016.

- American Conference Institute, FDA Boot Camp, Mar. 2016.
- Camargo 505(b)(2) Forum; Product Development Using the NDA 505(b)(2) Pathway, Nov. 2015.
- American Conference Institute, FDA Boot Camp, Sept./Oct. 2015 (Co-Chair).
- MedCity News, Converge, Sept. 2015.
- Food & Drug Law Institute, Introduction to Drug Law and Regulation: The Legal Framework for Drug Regulation, Aug. 2015.
- American Conference Institute, FDA Boot Camp, July 2015 (Co-Chair).
- DIA 51st Annual Meeting, Implications of the Generic Drug Labeling Rule, June 2015.
- Respiratory Drug Delivery Europe, May 2015 (Nice, France).
- American Conference Institute, Paragraph IV Disputes, Apr. 2015.
- American Conference Institute, Summit on U.S. Biosimilars, Apr. 2015 (Munich, Germany) (Co-Chair).
- American Conference Institute, FDA Boot Camp, Mar. 2015.
- Respiratory Drug Delivery Asia, Nov. 2015 (Goa, India).
- American Conference Institute, Paragraph IV Disputes Master Symposium, Sept./Oct. 2014.
- American Conference Institute, FDA Boot Camp, Sept. 2014 (Co-Chair).
- 4th Biosimilars Conference 2014, Understanding the Competitive Biosimilars Landscape in the U.S. – 15 Questions & Answers, June 2014 (London, England).
- American Conference Institute, Hatch-Waxman Boot Camp, June 2014.
- American Conference Institute, Paragraph IV Disputes, Apr. 2014.
- American Conference Institute, Pharmaceutical and Biotechnology Patent Life Cycles and Portfolio Strategies, Feb. 2014.
- BIT 1st Annual World Congress of Biosimilars and Biobetters, November 2013 (Haikou, China).
- American Conference Institute, Paragraph IV Disputes Master Symposium, Oct. 2013.
- Momentum Event Group, International Conference on Paragraph IV Litigation, Sept. 2013.
- American Conference Institute, Legal and Regulatory Summit on Generic Drugs, July 2013.
- American Conference Institute, Advanced forum on Biosimilars, June 2013.
- American Conference Institute, Paragraph IV Disputes, May 2013.
- Respiratory Drug Delivery Europe, May 2013 (Berlin, Germany).
- American Conference Institute, FDA Boot Camp, Mar. 2013.

- Consumer Health Products Association, Annual Executive Conference, Mar. 2013.
- Global IP Convention 2013, Jan. 2013 (Bangalore, India).
- American Conference Institute, Paragraph IV Disputes, Dec. 2012.
- American Conference Institute, Over the Counter Drugs, Oct. 2012.
- American Conference Institute, Maximizing Pharmaceutical Patent Life Cycles, Oct. 2012.
- C5 Forum on EU Pharma Regulatory Law, Sept. 2012 (Brussels, Belgium).
- Practicing Law Institute Audioconference, Are You Ready to Enter the U.S. Biosimilars Pathway?, Aug. 2012.
- American Conference Institute, Hatch-Waxman Boot Camp, June 2012.
- Respiratory Drug Delivery, May 2012.
- American Conference Institute, FDA Boot Camp, Mar. 2012.
- International Conference on Drug Development, Mar. 2012.
- Thompson Audioconference, Navigating the Orphan Drug Designation Process & the Benefits of Obtaining Designation, Nov. 2011.
- FDA News Audioconference, Marketed Unapproved Drugs: FDA to Take Immediate Enforcement Action at Any Time, Without Prior Notice, Oct. 2011.
- Regulatory Affairs Professionals Society, Annual Meeting, Generic Drugs in the U.S.: A regulatory Primer on Filings and Recent Actions, Oct. 2011.
- Informa Life Sciences, Inhalation Drug Development, Oct. 2011 (London, England).
- American Conference Institute, Maximizing Pharmaceutical Patent Life Cycles, Oct. 2011.
- Informa Life Sciences, Global Generic Strategy Summit, Sept. 2011 (Berlin, Germany).
- American Conference Institute, Paragraph IV Disputes, May 2011.
- World Orphan Drug Conference, Apr. 2011.
- Generic Pharmaceutical Association Annual Meeting, February 2011.
- American Conference Institute, Patent Term Adjustment and Patent term Extensions, Jan. 2011.
- Center for Business Intelligence, Paragraph IV Disputes, Oct. 2010.
- American Conference Institute, FDA Boot Camp, Sept. 2010.
- Respiratory Drug Delivery 2010, May 2010.
- American Intellectual Property Law Association, Spring Meeting, May 2010.
- C5, Maximising Pharma Patent Lifecycles, June 2010 (London, England)

- American Conference Institute, Paragraph IV Disputes, Apr. 2010.
- Center for Business Intelligence, Early Access Programs, Mar. 2010.
- IBC, Biotech & Pharmaceutical Patenting, Feb. 2010 (Munich, Germany).
- Center for Business Intelligence, Forum on Pre-Approval Expanded Access Programmes, Nov. 2009.
- American Conference Institute, Maximizing Pharmaceutical Patent Life Cycles, Oct. 2009.
- Center for Business Intelligence, Paragraph IV Disputes and Settlements, Oct. 2009.
- Center for Business Intelligence, Annual Congress on Early Access Programs, Oct. 2009 (London, England).
- Thompson Audioconference, *FDA Unapproved Drugs Initiative – Determine, Prove and Ensure Compliance*, July 30, 2009.
- Center for Business Intelligence, Summit on Biosimilars and Follow-On Biologics, Mar. 2009.
- Indian Pharmaceutical Association, To and Thru the Skin, Feb. 2009 (Mumbai, India).
- Thompson Audioconference, *New Drug Exclusivity Provisions: How They'll Impact Your Product Lifecycle Management*, Jan. 13, 2009.
- Center for Business Intelligence, Intellectual Asset Management Strategies, Jan. 2009.
- BNA Legal & Business Edge, *Pharmaceutical Patent Laws: A prescription for Success in Challenging Times*, Nov. 2008.
- Center for Business Intelligence, Pharmaceutical Congress on Paragraph IV Disputes, Oct. 2008.
- Thompson Audioconference, *FDA Amendments Act – New DTC User Fees and Potential Penalties*, Dec. 12, 2007.
- Thompson Audioconference, FDA "Revitalization" Legislation – Essential Changes You Must Know, Oct. 24, 2007.
- FDA News, FDA Cracks Down on Marketed Unapproved Drugs – Prepare for Increased Enforcement, Oct. 23, 2007
- American Conference Institute, Maximizing Pharmaceutical Patent Life Cycles, June 2007.
- Washington Information Source, FDA's Final Compliance Policy Guide for Marketed Unapproved Drugs ─ Is Agency Enforcement at a Crossroads, or Stuck in a Traffic Circle, Aug. 2007
- BIOMEDEX 2006, *Clinical Strategy: Understanding Phase 0*, May 2006 (Montreal, Canada)
- Henry Stewart Conference Studies, Latest Thinking on Attacking & Defending Patents in the U.S. Pharmaceutical Market, Apr. & Sept. 2003.
- Drug Information Association, 39th Annual Conference, *The Development and Implementation of the Food and Drug Administration's Animal Rule,* June 2003.
- Food & Drug Law Institute, *Interactive Audioconference: Need a Drug or Biologic Approved? FDA Wants to Help . . . Believe It!*, Nov. 2000.

- Food and Drug Administration/Food and Drug Law Institute, *Center for Drug Evaluation and Research In-House training: Introduction to Drug Law & Regulation*, annually from 1999-2012.

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