

PROGRAM

8:15 am	Registration
8:45 am	Program Introduction
9:00 am	<p>POTENTIAL CONSTITUTIONAL CONSTRAINTS ON GOVERNMENT REGULATION OF PRESCRIPTION DRUG MARKETING: TO WHAT EXTENT MAY GOVERNMENT LIMIT TRUTHFUL SPEECH ABOUT NEW DRUGS (INCLUDING PRESCRIBING DATA AND HEALTHCARE LITERATURE)?</p> <p><i>Ronald J. Krotoszynski, Jr., J.D., LL.M.</i> <i>John S. Stone Visiting Chair of Law, University of Alabama School of Law</i> <i>Professor of Law, Washington & Lee University School of Law</i></p>
10:00 am	<p>AN FDA PERSPECTIVE ON HEALTHCARE REGULATION</p> <p><i>Daniel E. Troy, J.D.</i> <i>Former Chief Counsel, U.S. Food and Drug Administration</i> <i>Partner, Sidley Austin LLP, Washington, D.C.</i></p>
11:00 – 11:15 am	Break
11:15 am	<p>RECENT DEVELOPMENTS IN FRAUD AND ABUSE LAW</p> <p><i>Nicole Huberfeld, J.D.</i> <i>Assistant Professor of Law</i> <i>University of Kentucky College of Law</i></p>
12:15 pm – 1:15 pm	Lunch
1:15 p.m.	<p>INDIANA PROFESSIONAL RESPONSIBILITY UPDATE</p> <p><i>María Pabón López, J.D.</i> <i>Associate Professor of Law</i> <i>Indiana University School of Law-Indianapolis</i></p>
2:15 – 2:30 pm	Break
2:30 pm	<p>EU DATA PROTECTION AND PHARMACEUTICAL RESEARCH: CURRENT ISSUES</p> <p><i>Daniel P. Cooper, J.D.</i> <i>Covington & Burling, LLP</i> <i>London, England</i></p>
3:30 – 4:30 pm	<p>IMPACT OF EUROPEAN UNION “REACH” REGULATIONS</p> <p><i>Eric Dannenmaier, J.D., LL.M.</i> <i>Associate Professor of Law</i> <i>Indiana University School of Law – Indianapolis</i></p>

SPEAKERS



RONALD J. KROTOSZYNSKI, JR., J.D., LL.M.

JOHN S. STONE VISITING CHAIR OF LAW, UNIVERSITY OF ALABAMA
PROFESSOR OF LAW, WASHINGTON & LEE UNIVERSITY SCHOOL OF LAW

Professor Krotoszynski joined the faculty of Washington & Lee University School of Law in 2000. After receiving his J.D. from Emory University he obtained an LL.M. from Duke University, where he was Articles Editor of the *Duke Law Journal* and Order of the Coif. He clerked for the Hon. Frank M. Johnson, Jr, U.S. Court of Appeals for the Eleventh Circuit. For three years after that he worked as an Associate with Covington & Burling in Washington D.C. He taught at Indiana University School of Law – Indianapolis from 1995-2000, and was a visiting scholar or professor at the University of Washington School of Law and at William and Mary Law School. Prof. Krotoszynski teaches administrative law, constitutional law, legal ethics, fourteenth amendment, and communications law.



DANIEL E. TROY, J.D.

FORMER CHIEF COUNSEL, US FOOD AND DRUG ADMINISTRATION
PARTNER, SIDLEY AUSTIN LLP, WASHINGTON, D.C.

Daniel Troy, a partner in Sidley Austin's Life Sciences Practice as well its Appellate Litigation group, is the former chief counsel of the Food and Drug Administration (FDA). In addition to providing strategic counseling on FDA-related matters, he practices administrative and constitutional law and litigation, with particular focus on the industries regulated by the FDA. During his tenure at the FDA, he played a key role in the drafting of the rule modifying the process by which generic drugs come to market, and successfully argued two Hatch-Waxman cases for the FDA. He oversaw the agency's warning and untitled letters, helped raise the agency's focus on First Amendment issues, and played a principal role in the FDA's generally successful assertion of preemption in selected product liability cases. Troy has testified before the Senate and House Judiciary Committees, the House Committee on Science, as well as before many state and local bodies. He has spoken on topics including Hatch-Waxman reform, preemption, a variety of First Amendment and other constitutional issues, telecommunications, the role of the courts, and administrative law. He has served on the Editorial Advisory Board of the *Food and Drug Law Journal*, and is currently on the Legal Policy Board of the Washington Legal Foundation, and the Editorial Advisory Board of the *FDA Enforcement Manual*. While in private practice, Troy was also an Associate Scholar at the American Enterprise Institute, for whom he published the book *Retroactive Legislation* (AEI 2000). He has also written 13 law review articles and book chapters. He currently heads the ABA's Section of Administrative Law and Regulatory Practice. Troy received his J.D. from Columbia University School of Law and is admitted to practice in the District of Columbia (including the D.C. Superior Court and D.C. Federal District Court), New York, the United States Supreme Court, and 10 different U.S. Court of Appeals circuits.



NICOLE HUBERFELD, J.D.

ASSISTANT PROFESSOR OF LAW
UNIVERSITY OF KENTUCKY COLLEGE OF LAW

Nicole Huberfeld is Assistant Professor of Law at the University of Kentucky College of Law and Bioethics Associate at the University of Kentucky College of Medicine. Professor Huberfeld teaches in the areas of health law and constitutional law. Her scholarship currently focuses on the juxtaposition of Spending Clause jurisprudence and federal healthcare programs as well as regulatory and transactional topics in health care. Her most recent article, *Clear Notice for Conditions on Spending, Unclear Implications for States in Federal Healthcare Programs*, is forthcoming in the Winter 2008 *North Carolina Law Review*. She is an active member of the American Society of Law, Medicine

& Ethics and the American Health Lawyers Association and is a member of the bars in New York and New Jersey. Previously, she was Health Law Faculty Fellow at Seton Hall Law School and taught Healthcare Fraud and Abuse as well as other health law courses in the Health Law and Policy Program. While at Seton Hall, she created and was Director of the Health Care Compliance Certification Program, which educates compliance officers of pharmaceutical and medical device companies in corporate and healthcare compliance and related regulatory law. Professor Huberfeld received her J.D., *cum laude*, from Seton Hall Law School and earned her B.A. in history from the University of Pennsylvania.



MARÍA PABÓN LÓPEZ, J.D.

ASSOCIATE PROFESSOR OF LAW
INDIANA UNIVERSITY SCHOOL OF LAW-INDIANAPOLIS

María Pabón López joined IU's faculty in the fall of 2002. Formerly a lecturer in advocacy and research at the University of Missouri-Columbia School of Law, she also served as a staff attorney and team leader for Legal Aid of Central Texas. She was an assistant U.S. Attorney, criminal division, for the U.S. Department of Justice, District of Puerto Rico. Professor López was formerly an assistant to the Puerto Rico Attorney General and an associate at Pepper, Hamilton & Scheetz (Philadelphia) and McConnell, Valdes (San Juan, Puerto Rico). A graduate of the University of Pennsylvania School of Law, she served as associate editor for the *University of Pennsylvania Law Review*. She received her B.A. from Princeton University.

Since June of 2003, Professor López has been an appointed member of the Indiana Supreme Court's Court Interpreter Certification Advisory Board. She is also a member of the Latino Affairs Committee of the Indiana State Bar. She was named a Dean's Fellow in recognition of scholarly excellence in 2005-2006 and 2006-2007, and in 2004 was the recipient of a special recognition award from the Chair of the Second National People of Color Legal Scholarship Conference, as well as the law school's Hispanic Law Society Award. In 2006, she was given the Trustees teaching award. She is a member of the bars of Pennsylvania, Puerto Rico and Texas. She teaches in the areas of professional responsibility, immigration law, family law, and trusts and estates.



DANIEL P. COOPER, J.D.

OF COUNSEL, COVINGTON & BURLING, LLP
LONDON, ENGLAND

Daniel Cooper is of counsel in Covington & Burling's London office whose practice area involves advising on European privacy and data protection matters, as well as contentious and non-contentious intellectual property work and e-commerce issues. Cooper heads up the firm's London privacy and security practice, and advises clients on compliance with UK and European data protection and privacy legislation, including the UK Data Protection Act, Regulation of Investigatory Powers Act, Human Rights Act, and related EU directives, such as the EU Data Protection Directive and EU Electronic Communications Data Protection Directive. He also has been involved in advising clients with respect to Internet-related liabilities under European laws and e-commerce-related matters, including European and UK legislation regulating distance sales, data retention, and e-commerce generally. Cooper received his J.D. degree from Harvard Law School (*cum laude*) and M.St. from University of Oxford. After graduation he clerked for the Honorable John Ferren, U.S. Court of Appeals, District of Columbia Circuit. He is admitted to practice law in the District of Columbia and by the Solicitor of the Supreme Court of England and Wales.



**ERIC DANNENMAIER,
J.D., LL.M.**

ASSOCIATE PROFESSOR OF LAW
INDIANA UNIVERSITY SCHOOL
OF LAW – INDIANAPOLIS

Prior to joining IU's faculty in 2007 Prof. Dannenmaier was a Visiting Professor at Tulane Law School and

a Bretzfelder Fellow at Columbia Law School. He served as Director of Tulane Law School's Institute for Environmental Law and Policy from 2001 to 2005, and as a Legal Advisor for the Environment to the U.S. Agency for International Development from 1996 to 2000. He was the Visiting Chair of Natural Resources Law at the University of Calgary in Canada in 2001. He worked as a litigator in the Boston office of McDermott, Will and Emery and in the environmental practice group in the Washington, DC office of Bryan, Cave, LLP. He has served as an advisor to governments and international organizations in the reform of environment and natural resource laws and in the design of legal frameworks and processes for public participation in development decision-making. Prof. Dannenmaier has authored studies and policy papers on topics including the Implementation of Climate Change Commitments, Water Policy and Decentralization, Environmental Security, International Trade and the Environment, Human Rights and the Environment, and Environmental Democracy. His research focuses on citizen access to decision-making processes under both national and international law, in particular decisions affecting international development and the environment. He received his J.D. from Boston University and his LL.M. from Columbia University.

MODERATOR, SUSANAH M. MEAD, J.D.

PROFESSOR OF LAW
INDIANA UNIVERSITY SCHOOL OF LAW-INDIANAPOLIS

Susanah M. Mead became the first woman and the first graduate to lead the school when she served as Interim Dean from 2005 - 2007. She was the recipient of the 2007 Outstanding Alumna of the Year Award. Mead's previous experience in administration was as Associate Dean for Academic Affairs, from 1997 to 2004. A 1976 graduate of Indiana University School of Law - Indianapolis, she joined the faculty in 1978 as lecturer in the legal writing program and served as director of legal writing in 1980-81. Mead clerked for the Honorable Paul H. Buchanan Jr., chief judge of the Indiana Court of Appeals, from 1976 to 1978. Her articles examining issues in constitutional tort law and products liability law have appeared in national law journals.

**REGULATING THE
HEALTH CARE INDUSTRY
TUESDAY, OCTOBER 16, 2007**

REGISTRATION FORM

Please print or type clearly

Name _____

Firm _____

Address _____

Phone _____

E-mail _____

Attorney # _____

I will need a vegetarian meal.

*Return completed form, with a check for \$250 made payable to the IU School of Law-Indianapolis, to Shaun Ingram,
IU School of Law-Indianapolis, Lawrence W. Inlow Hall, 530 West New York Street, Indianapolis, IN 46202*

LOCATION

The conference will be held at the IU School of Law-Indianapolis, 530 West New York Street, Indianapolis, IN 46202.

PARKING

With your confirmation letter, you will receive a temporary campus parking permit. This should be displayed visibly in the windshield area. It will allow you to park in the surface lot immediately west of the law school building.

HOTEL RECOMMENDATIONS NEAR THE LAW SCHOOL

Courtyard Capitol (Marriott)

320 N. Senate Ave

Indianapolis, IN 46202.

Marriott reservation line at 800-321-2211

Direct number: (317) 684-7733

www.marriott.com

The University Place Conference Center

850 West Michigan Street

Indianapolis, IN 46202

(317) 269-9000 or Toll Free: 800-627-2700

upreserv@iupui.edu

www.universityplace.iupui.edu

DISABILITY

Individuals with disabilities who need special assistance, please call (317) 278-3400. Special arrangements can be made to accommodate most needs.

REGISTRATION

The registration fee of \$250 includes materials, refreshment breaks, parking and lunch. Please complete the attached registration form and mail with a check made payable to the IU School of Law-Indianapolis. The program will carry six hours of Indiana CLE credit (including 2.0 hours of ethics credit). **You must include your attorney number if you wish to receive that credit.** If you seek CLE credit in another state, contact that state's continuing legal education commission. Registrations should be mailed to Shaun Ingram, IU School of Law-Indianapolis, Lawrence W. Inlow Hall, 530 West York Street, Indianapolis, IN 46202. **Registrations must be received by Monday, October 8, 2007. Cancellations after Wednesday, October 10, 2007 will not be refunded. Questions? Call 317-278-4789.**

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**REGULATING THE
HEALTH CARE INDUSTRY
TUESDAY, OCTOBER 16, 2007**



INDIANA UNIVERSITY

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**ANNUAL CONTINUING
LEGAL EDUCATION
PROGRAM**



**REGULATING THE HEALTH CARE INDUSTRY
TUESDAY, OCTOBER 16, 2007**

6 hours of CLE credit (includes 2 hours of ethics credit)