

ANNUAL CONTINUING LEGAL EDUCATION PROGRAM

CORPORATE INTEGRITY: MEETING CHALLENGES AND DOING THE RIGHT THING

TUESDAY, OCTOBER 13, 2009

6.0 hours of CLE credit, including 1.0 hour of ethics credit



INDIANA UNIVERSITY

SCHOOL OF LAW—INDIANAPOLIS
IUPUI

PROGRAM

- 8:15 am Registration
- 8:45 am Program Introduction
- 9:00 am – 12:15 pm CORPORATE INTEGRITY ISSUES
- Negotiation and Oversight Issues
“Negotiation of Corporate Integrity Agreements and Subsequent Monitoring: Lessons Learned from the Front Line”
Howard J. Young
Partner, Morgan, Lewis & Bockius, LLP
- Representing Companies Operating Under Agreements
“Living With a CIA: Day One and Beyond”
Thomas M. Gallagher
Partner, Pepper Hamilton LLP
- Monitoring
“The Critical Eye: A Monitor’s View on Corporate Integrity in the Health Care Industry”
Debra Wong Yang
Partner, Gibson, Dunn & Crutcher LLP
- 12:15 – 1:15 pm Lunch (*boxed lunch, no speaker*)
- 1:15 pm Indiana Ethics Update
Professor María Pabón López,
Indiana University School of Law - Indianapolis
- 2:15 pm Break
- 2:30 pm Panel Discussion
“Privacy and Ethics of Medical Information Governance”
Stan Crosley
Chief Privacy Officer, Eli Lilly and Company
Professor Fred Cate
Indiana University Maurer School of Law
Professor Eric Meslin
Director, Indiana University Center for Bioethics
- 3:30 pm- 4:30 pm Preemption Issues
“Preemption and Beyond: Legal Issues Changing the FDA”
Professor Ralph Hall
Distinguished Professor & Practitioner,
University of Minnesota School of Law



HOWARD J. YOUNG, J.D.

Partner, Morgan, Lewis & Bockius, LLP

Howard J. Young is a partner in Morgan Lewis's FDA/Healthcare Regulation Practice. He is based in the firm's Washington, D.C. office. He has more than 15 years of health law experience and is nationally recognized as a leader in fraud and abuse matters. Prior to joining Morgan Lewis, he was a partner at an international law firm, focusing on the healthcare industry. From 1997 to 2002, he served as a senior attorney and deputy branch chief with the Office of Counsel to the HHS Inspector General coordinating with the U.S. Department of Justice, state attorneys general, and CMS/HCFA on criminal and civil healthcare fraud matters. Mr. Young was involved in the negotiation and monitoring of hundreds of corporate integrity agreements (CIAs) and supervised the staff of attorneys and analysts who monitored CIA compliance. He also played a key role in many of the federal government's major healthcare enforcement and compliance initiatives at the time, including the largest corporate health fraud investigation to date. Mr. Young frequently writes and presents to client personnel and major healthcare trade and professional associations on fraud and abuse and healthcare regulatory issues. He received his J.D. from Duke University School of Law in 1993, where he worked with Duke University Medical Center's law department and served as an editor for the *Duke Environmental Law and Policy Forum*. He received his B.A., *magna cum laude*, in political science from Tufts University in 1989. He is admitted to practice in the District of Columbia and Maryland.



THOMAS M. GALLAGHER, J.D.

Partner, Pepper Hamilton LLP

Thomas M. Gallagher is Chair of the White Collar and Corporate Investigations Practice Group at Pepper Hamilton LLP. He is based in the firm's Philadelphia office. He represents corporate and individual clients in all white collar criminal matters, corporate investigations and complex civil litigation. Mr. Gallagher's practice is primarily focused in the health care industry. He represents pharmaceutical companies, medical device companies, hospitals, skilled nursing facilities, providers and individuals facing government scrutiny. Mr. Gallagher is a former prosecutor in the criminal division of the U.S. Attorney's Office in the Eastern District of Pennsylvania.

He has led the investigation and prosecution of numerous complex, multi-defendant white collar criminal matters including investigations of pharmaceutical companies and other health care entities. Mr. Gallagher received his undergraduate degree from the University of Pennsylvania in 1982, and his law degree, *cum laude*, from Villanova University School of Law in 1989, where he was editor-in-chief of the *Villanova Law Review*. Mr. Gallagher is a regular speaker on white collar crime, compliance, health care and trial advocacy.



DEBRA WONG YANG, J.D.

Partner, Gibson, Dunn & Crutcher LLP

Debra Wong Yang is a partner in Gibson, Dunn & Crutcher's Los Angeles office. She is Co-Chair of the firm's Crisis Management Practice Group and the White Collar Defense and Investigations Practice Group, and is a member of the Media and Entertainment and Intellectual Property Practice Groups. Ms. Yang's practice specializes in corporate crime and compliance. She served as a DOJ-appointed Monitor over an orthopedic manufacturing company with health care compliance and regulatory issues. She has also represented a medical diagnostics company subject to DOJ and HHS inquiries. In her previous capacity, she oversaw a massive, multi-year investigation into a health care company. Ms. Yang previously served as the U.S. Attorney for the Central District of California. She was appointed in May 2002 and was the first Asian-American woman to serve as a U.S. Attorney. Ms. Yang was selected to serve on President Bush's Corporate Fraud Task Force and to chair the Attorney General's Advisory Committees on Cyber/Intellectual Property and Civil Rights. She was appointed by the Attorney General to sit on the Advisory Committee and on the Intellectual Property Task Force. She also served on the Ninth Circuit Jury Reform Committee. From 1997 to 2002, she sat on the Los Angeles Municipal Court, serving for a time as a Supervising Judge, and became a member of the Los Angeles Superior Court bench in 2000. She was appointed, sat and continues to serve on a number of judicial committees. Ms. Yang served as an Assistant U.S. Attorney for seven years prior to her judicial career, handling white-collar crimes, violent crimes, international money laundering, arson and computer crimes. As an Assistant U.S. Attorney, Ms. Yang has tried a number of cases, and argued many of those on appeal. Prior to government service, Ms. Yang was in private practice at law firms in Los Angeles and Chicago. Her practice focused primarily on commercial litigation and pharmaceutical defense.



PROFESSOR MARÍA PABÓN LÓPEZ, J.D.

Indiana University School of Law – Indianapolis

María Pabón López is a Professor of Law at the IU School of Law-Indianapolis. A graduate of Princeton University and the University of Pennsylvania Law School, she served as an associate editor for the *University of Pennsylvania Law Review*. Professor López has published numerous articles on immigration law and immigrants' rights. Her book, *Persistent Inequality*, a volume about the education of immigrant children, will be published during the fall of 2009 by Routledge Taylor and Francis. Her other research interests include professional responsibility, women in the legal profession, and race and the law. In 2007, Professor López was named to the Indiana State Board

of Law Examiners, the only academic on the 10-member board. She is a member of the Indiana Supreme Court's Court Interpreter Certification Advisory Board, and a member of the Latino Affairs Committee of the Indiana State Bar Association. She has been named a Dean's Fellow in recognition of scholarly excellence. In 2004, she was the recipient of a special recognition award from the Chair of the Second National People of Color Legal Scholarship Conference at The George Washington University School of Law. Professor López received the 2006 Trustees teaching award from IU, and was the 2007 recipient of the Indiana State Bar Association's Rabb Emison Award. In 2008, Professor Lopez received the Diversity in Practice Award from *The Indiana Lawyer*. She is a member of the bars of Indiana, Pennsylvania, Puerto Rico and Texas.



STAN CROSLEY, J.D.

Chief Privacy Officer and Assistant General Counsel, Eli Lilly and Company

Stan Crosley initiated Eli Lilly and Company's global privacy program in 1998. The program currently has more than 20 full-time employees and hundreds of global privacy stewards. Lilly's Privacy Program received the 2007 Innovation Award from the IAPP in 2008. Mr. Crosley sits on the IOM Medical Research and Privacy Committee, the State Alliance for eHealth privacy taskforce, and the board of the Indiana Health Informatics Corporation, as well as the board of the International Association of Privacy Professionals. He is a co-founder and Chair of the International Pharmaceutical Privacy Consortium (IPPC). Mr. Crosley is active in the Center for

Information Policy Leadership, the Consumer Privacy Legislative Forum, and the Conference Board's Chief Privacy Officers Council. Mr. Crosley earned his B.S. in Biology/Chemistry from Hillsdale College and his J.D. from Indiana University School of Law - Bloomington.



PROFESSOR FRED CATE, J.D.

Distinguished Professor and C. Ben Dutton Professor of Law, and Director, Center for Applied Cybersecurity Research
Indiana University Maurer School of Law

Fred Cate specializes in information privacy and security law issues. He speaks frequently about these issues before industry, professional, and government groups and testifies regularly before Congress. He is a member of Microsoft's Trustworthy Computing Academic Advisory Board, the National Academy of Sciences Committee on Technical and Privacy Dimensions of Information for Terrorism Prevention and Other National Goals, and the Research Steering Committee of the Center for Identity

Management and Information Protection. He also serves as reporter for the American Law Institute's project on Principles of the Law on Government Access to and Use of Personal Digital Information. Cate is the author of many books and articles, including *The Internet and the First Amendment*, *Privacy in the Information Age*, and *Privacy in Perspective*, and he appears frequently in the popular press.





PROFESSOR ERIC MESLIN, PH.D.

Director, Indiana University Center for Bioethics

Eric M. Meslin, Ph.D., is Director of the Indiana University Center for Bioethics; Associate Dean for Bioethics at the Indiana University School of Medicine; Professor of Medicine, Medical and Molecular Genetics and Philosophy; and co-director of the IUPUI Consortium on Health Policy, Law and Bioethics. The author of more than 100 publications, Meslin's research focuses on many ethical, legal and social issues in the life sciences. Prior his appointment at Indiana University, he was Executive Director of the U.S. National Bioethics Advisory Commission (NBAC) under President Bill Clinton, and was program director for bioethics research at the Ethical, Legal and Social Implications Research (ELSI) Program, at the National Human Genome Research Institute. Born in Canada, Dr. Meslin received his B.A. from York University in Toronto, and his M.A. and Ph.D. from Georgetown University. He has held academic positions at the University of Toronto and Oxford University and is currently Visiting Professor-at-Large at the University of Western Australia. He has advised UNESCO, the World Health Organization and the Canadian Institutes of Health Research and sits on several boards including the Indiana Organ Procurement Organization, Indiana Public Umbilical Cord Blood Bank and the Board of Directors of Genome Canada. In 2008 he was appointed a Chevalier de L'Order Nationale du Mérite (Knight of the National Order of Merit) by the President of France.



PROFESSOR RALPH HALL, J.D.

Distinguished Professor & Practitioner, University of Minnesota School of Law

Ralph F. Hall is also Counsel to the Indianapolis, Indiana law firm of Baker & Daniels where he counsels clients in the area of drug and medical device regulation and corporate compliance. He also serves as CEO of MR3 Medical LLC, a start-up medical device company. Previously, Professor Hall served in various capacities with Guidant Corporation including Senior Vice President and Deputy General Counsel—Litigation and Compliance and General Counsel of the Cardiac Rhythm Management group. He also served as Special Counsel to the Guidant Board of Directors Compliance Committee and as Counsel to the Guidant Chief Compliance Officer. Prior to joining Guidant, he was with Eli Lilly and Company, including serving as the head of Lilly's worldwide environmental law group. Professor Hall received his B.A. from Indiana University in 1974 and his J.D., *cum laude*, from the University of Michigan where he was a Weymouth Kirkland Scholar. Professor Hall's interests include FDA regulation, corporate compliance, negotiations and ADR, intellectual asset management, the interface between corporate practice and the academic world, and nanotechnology.

MODERATOR, ANDREW R. KLEIN, J.D.

Paul E. Beam Professor of Law, IU School of Law – Indianapolis

Andrew R. Klein joined the law school in 2000, after eight years on the faculty at Samford University's Cumberland School of Law. Before entering the academy, Professor Klein practiced law with the Chicago firm of Sidley & Austin, specializing in products liability litigation involving pharmaceutical products. He earned his B.A. with distinction in journalism and economics from the University of Wisconsin and a J.D. with distinction from Emory University School of Law, where he studied as a Robert W. Woodruff Fellow in Law and was editor-in-chief of the *Emory Law Journal*. Following law school, Professor Klein served as a law clerk to Judge Joseph W. Hatchett of the U. S. Court of Appeals for the Eleventh Circuit. A member of the Illinois bar and the American Law Institute, Professor Klein also serves as Reporter for the U.S. Court of Appeals for the Seventh Circuit Civil Jury Instructions Committee. He is co-author of a casebook, *Torts: Cases, Problems and Exercises* (Lexis/Nexis 2nd ed. 2005). In addition to being an active scholar, Professor Klein is a dedicated classroom teacher who has won eight student teaching awards during his career. Professor Klein also is a national lecturer on tort law for BarBri Bar Review.



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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 1.0 hour 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 5, 2009. Cancellations after Wednesday, October 7, 2009 will not be refunded. Questions? Call 317-278-4789.**

Online registration available at:
http://indylaw.indiana.edu/CLE/annualcle_reg.htm

REGISTRATION FORM

Please print or type clearly

Name _____

Firm _____

Address _____

City _____

State _____

Zip _____

Phone _____

E-mail (required) _____

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.



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Indiana University School of Law-Indianapolis
Lawrence W. Inlow Hall
530 West New York Street
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