

BARBARA J. EVANS
Health Law & Policy Institute
University of Houston Law Center
100 Law Center
Houston, TX 77204-6060
(713) 743-2993 (office) • (713) 446-7576 (cell) • bjevans@central.uh.edu

LEGAL EDUCATION J.D., Yale Law School, 1994

LL.M. Health Law, University of Houston, 2003

OTHER EDUCATION Post-doctoral Fellow, Clinical Ethics, The University of Texas M.D. Anderson Cancer Center, 2003 – 2004

Ph.D., Earth Sciences, Stanford University, 1984

M.S., Applied Earth Sciences, Stanford University, 1982

B.S., Electrical Engineering, with Honors, The University of Texas at Austin, 1979

LAW LICENSES New York (since 1996); Texas (since 2000)

EMPLOYMENT AFTER LAW SCHOOL

2007 – present **University of Houston Law Center**, Houston, TX
Professor of Law (9/2011-present), Associate Professor (1/2007-8/2011); Co-director, Health Law & Policy Institute/Director, Center on Biotechnology & Law (9/2007-present)

2004 - 2007 **Indiana University**, Indianapolis, IN
Director, Program in Pharmacogenomics, Ethics, and Public Policy, Indiana University School of Medicine/Center for Bioethics (9/2004 - 5/2007, 50% commitment); Senior Scientist (9/2004 - 8/2006), then Research Professor of Medicine (9/2006 - 5/2007), Indiana University Department of Medicine/Division of Clinical Pharmacology; Adjunct Professor of Law (9/2004 - 8/2006), Visiting Professor of Law (8/2006 - 12/2006, 50% commitment to law school) Indiana University School of Law (Indianapolis)

Counsel, Medical Technology Practice Group, Baker & Daniels, L.L.P., Indianapolis (part-time commitment, 2004 – 2006, when our practice group moved to Epstein, Becker & Green); **Counsel, Health and Life Sciences Practice, Epstein, Becker & Green, P.C.**, Washington, D.C (part-time commitment, 1/2006 - 9/2006)

2003 – 2004 **The University of Texas M.D. Anderson Cancer Center**, Houston, TX
Post-doctoral Fellow in Clinical Ethics (9/2003 – 6/2004)

1996 – 2002 **LeBoeuf, Lamb, Greene & MacRae, L.L.P.**, New York, NY and Moscow, Russia
Associate (5/1996 – 5/1998); Partner (6/1998 – 7/2001); Of Counsel (8/2001- 2/2002)

1994 – 1996 **International Bank for Reconstruction and Development (The World Bank)**, Washington, D.C., *Senior Energy Economist, Region IV Europe and Central Asia, Infrastructure Division (9/1994 – 3/1996)*

GRANTS AND RESEARCH AWARDS **Greenwall Foundation Faculty Scholar in Bioethics, 2010 – 2013.** Research funding for three-year study entitled, “Governance Models to Enhance the Legitimacy and Public Acceptability of Decisions to Allow Nonconsensual Use of Data Held in Large Health Data Networks” (Barbara J. Evans, P.I.) (July 1, 2010 – June 30, 2013)

GRANTS, CONT'D

Mini-Sentinel Privacy Panel Project. Funding under subcontract between University of Houston (Barbara J. Evans, P.I.) and Harvard Pilgrim Health Care Institute as prime contractor under Department of Health & Human Services Contract No HHSF2232009100061, Richard Platt, MD, P.I.) (July 1, 2010 – Sept 30, 2010)

**RECENT
SERVICE
ACTIVITIES**

Member, Institute of Medicine Committee on the Public Health Effectiveness of the FDA 510(k) Clearance Process (2010 – 2011)

Member, Expert Panel for Canadian Institutes of Health Research-funded project to develop consensus guidelines for the ethical conduct and ethics review of cluster randomized controlled trials (Jeremy Grimshaw, Charles Weijer, Martin Eccles, and Monica Taljaard, P.I.s) (2011)

Member, Expert Panel for study entitled “Protecting Privacy in Health Research,” funded by the National Institutes of Health (Proposal RC1 CA146501-01, Fred H. Cate, P.I.) (2009 – present)

Member, Privacy Panel, FDA Mini-Sentinel Project (2010 – 2011)

Member, Program Committee, First International Health Privacy Summit (Georgetown Law Center, June 13, 2011)

Adjunct Professor of Clinical Pharmacology, Indiana University School of Medicine (2007 – present) and Affiliated Investigator, IU Center for Bioethics (2009 – present)

Member, External Advisory Committee, Duke University Clinical and Translational Sciences Institute under NIH Clinical and Translational Sciences Award (Robert Califf, M.D., P.I.) (2008 – 2011)

Member, American Bar Association Special Committee on Bioethics and the Law (2006 - 2011); Liaison of ABA Administrative Law Section to the Special Committee on Bioethics and the Law (2005 – 2006)

Member, Program Committee for March 8, 2010 FDA Sentinel Initiative Meeting Series: Legal Issues in Active Medical Product Surveillance, convened by the Engelberg Center for Health Care Reform at the Brookings Institution under sponsorship of FDA

Member, Oversight Task Force of U.S. Department of Health & Human Services Secretary’s Advisory Committee on Genetics, Health, & Society (2007 – 2008)

Corresponding Member, Medical Technology Policy Committee, Institute of Electrical and Electronics Engineers (2006 – 2008). Senior Member, Institute of Electrical and Electronics Engineers (2006 – present)

Health Law Scholar, American Society of Law, Medicine, and Ethics/Saint Louis University Health Law Scholars Workshop (2007)

Member, Legal Working Group, Health Information Security and Privacy Collaboration (HISPC) (2006)

LAW ARTICLES

Barbara J. Evans, *Much Ado about Data Ownership*, 25 HARVARD JOURNAL OF LAW & TECHNOLOGY (forthcoming Fall, 2011)

Barbara J. Evans, *Seven Pillars of a New Evidentiary Paradigm: The Food, Drug, and Cosmetic Act Enters the Genomic Era*, 85 NOTRE DAME LAW REVIEW 519 – 624 (2010), reprint available at http://www.nd.edu/~ndlrev/archive_public/85ndlr2/Evans.pdf

**LAW ARTICLES
CONT'D.**

Barbara J. Evans, *Authority of the Food and Drug Administration to Require Data Access and Control Use Rights in the Sentinel Data Network*, 65 FOOD & DRUG LAW JOURNAL 67 – 112 (2010)

Barbara J. Evans, *Congress' New Infrastructural Model of Medical Privacy*, 84 NOTRE DAME LAW REVIEW 585 – 654 (2009), reprint available at http://www3.nd.edu/~ndlrev/archive_public/84ndlr2/Evans.pdf

Barbara J. Evans, *Judicial Scrutiny of Legislative Action that Presents Bioethical Dilemmas*, 16 VIRGINIA JOURNAL OF SOCIAL POLICY & LAW 179 – 257 (2008)

Barbara J. Evans, *What Will it Take to Reap the Clinical Benefits of Pharmacogenomics?*, 61 FOOD AND DRUG LAW JOURNAL 753 – 794 (2006)

Barbara J. Evans & David A. Flockhart, *The Unfinished Business of U.S. Drug Safety Regulation*, 61 FOOD AND DRUG LAW JOURNAL 45 – 63 (2006)

Barbara J. Evans & Eric M. Meslin, *Encouraging Translational Research Through Harmonization of FDA and Common Rule Informed Consent Requirements for Research with Banked Specimens*, 27 JOURNAL OF LEGAL MEDICINE 119 – 166 (2006)

**BOOK
CHAPTERS**

Barbara J. Evans, *Legal Trends Driving the Clinical Translation of Pharmacogenomics*, in Principles of Pharmacogenetics and Pharmacogenomics (Russ B. Altman, David A. Flockhart & David B. Goldstein, eds., Cambridge University Press, forthcoming 2011)

Barbara J. Evans, *Ethical and Privacy Issues in Pharmacogenomic Research*, in Pharmacogenomics: Applications to Patient Care, Second Edition 313 – 338 (Howard L. McLeod et al., eds., American College of Clinical Pharmacy, 2009)

**OTHER
WRITING**

Deven McGraw, Kristen Rosati & Barbara Evans, *A Model for Advancing Public Health and Protecting Privacy*, *Pharmacoepidemiology & Drug Safety* (forthcoming, 2011)

Member of Committee for preparation of report: INSTITUTE OF MEDICINE, COMMITTEE ON THE PUBLIC HEALTH EFFECTIVENESS OF THE FDA 510(K) CLEARANCE PROCESS, MEDICAL DEVICES AND THE PUBLIC'S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS

Amy L. McGuire, Barbara J. Evans, Timothy Caulfield & Wylie Burke, *Regulating Direct-to-Consumer Personal Genome Testing*, 330 SCIENCE 181 – 82 (8 Oct. 2010)

Kristen Rosati, Barbara Evans & Deven McGraw, HIPAA and Common Rule Compliance in the Mini-Sentinel Pilot (Mini-Sentinel Coordinating Center, 2010), http://mini-sentinel.org/work_products/About_Us/HIPAA_and_CommonRuleCompliance_in_the_Mini-SentinelPilot.pdf

Barbara J. Evans, *Establishing Clinical Utility of Pharmacogenetic Tests in the Post-FDAAA Era*, 88 CLINICAL PHARMACOLOGY & THERAPEUTICS 749 – 751 (2010) (solicited work)

Barbara J. Evans, RIN 0991-AB57: Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under the Health Information Technology for Economic and Clinical Health Act (Docket No. HHS-OCR-2010-0016, Sept. 10, 2010), <http://www.regulations.gov/#!documentDetail;D=HHS-OCR-2010-0016-0086.1> (commenting on constitutional constraints affecting implementation of the cost-based fee for preparation and transmittal of data under section 13405(d) of the HITECH Act)

**OTHER WRITING
CONT'D.**

Member of Committee for preparation of report: INSTITUTE OF MEDICINE, COMMITTEE ON THE PUBLIC HEALTH EFFECTIVENESS OF THE FDA 510(K) CLEARANCE PROCESS, MEASURING POSTMARKET PERFORMANCE AND OTHER SELECT TOPICS (Theresa Wizemann, *ed.*, 2010)

Member of Committee for preparation of workshop report: INSTITUTE OF MEDICINE, COMMITTEE ON THE PUBLIC HEALTH EFFECTIVENESS OF THE FDA 510(K) CLEARANCE PROCESS, BALANCING PATIENT SAFETY AND INNOVATION (Theresa Wizemann, *ed.*, 2010)

Barbara J. Evans, *Issue Brief: Appropriate Human-Subject Protections for Research Use of Sentinel System Data*, in FDA SENTINEL INITIATIVE MEETING SERIES: LEGAL ISSUES IN ACTIVE MEDICAL PRODUCT SURVEILLANCE (Engelberg Center for Health Care Reform at the Brookings Institution, 2010),
http://www.brookings.edu/~media/Files/events/2010/0308_FDA_legal_issues/Panel%20Issue%20Brief.pdf

Member of Oversight Task Force and contributing author, U.S. SYSTEM OF OVERSIGHT OF GENETIC TESTING: A RESPONSE TO THE CHARGE OF THE SECRETARY OF HEALTH AND HUMAN SERVICES, REPORT OF THE SECRETARY'S ADVISORY COMMITTEE ON GENETICS, HEALTH, AND SOCIETY (April, 2008)

Barbara J. Evans, *Finding a Liability-Free Space in which Personalized Medicine Can Bloom*, 82 CLINICAL PHARMACOLOGY & THERAPEUTICS 461 – 67 (2007)

Barbara J. Evans, *Distinguishing Product and Practice Regulation in Personalized Medicine*, 81 CLINICAL PHARMACOLOGY & THERAPEUTICS 288 – 293 (2007) (solicited work)

Barbara J. Evans, David A. Flockhart & Eric M. Meslin, *Creating Incentives for Genomics Research to Improve Targeting of Therapies*, 10 NATURE MEDICINE 1289 – 91 (2004)

Barbara J. Evans, *Inconsistent Regulatory Protection Under the U.S. Common Rule*, 13 CAMBRIDGE QUARTERLY OF HEALTH CARE ETHICS 366 – 79 (2004)

Evans, Barbara J., *Investing in Russian Power*, in Power in Eastern Europe, a Special Report of THE FINANCIAL TIMES, Issue 59, 16-18 (11 June 2001).

**LEGAL
WRITING
AWARD**

Second Prize, Sixth Annual Student Health Law Writing Competition (2004) sponsored by Epstein, Becker & Green P.C., for LL.M. student paper, *The Six Enigmas of Bioethical Jurisprudence: Why Bioethics Fails to Produce Constitutional Rights*

**THESES AND
DISSERTATIONS**

Thesis for the Degree of LL.M. in Health Law, The University of Houston Law Center (2002) (revised and published under the title *Inconsistent Regulatory Protection Under the U.S. Common Rule*, cited above)

Mine Capacity Utilization During Recessionary Periods: Operating Strategy for the U.S. Copper Industry. Dissertation for the Degree of Doctor of Philosophy in Earth Sciences with specialization in Mineral Economics, Stanford University (1984)

Statistical Techniques for Subsurface Reservoir Management. Thesis for the Degree of Master of Science in Applied Earth Science with specialization in Applied Hydrogeology, Stanford University (1982)

PRESENTATIONS

Proposed Changes to the Common Rule, Texas Medical Center Council of Research Directors Meeting (August 24, 2011)

Panelist, *Control of Patient Data—Health Information Exchanges*, First International Summit on the Future of Health Privacy, Georgetown Law Center (June 13, 2011)

Public Use of Private Health Data, ASLME Health Law Professors' Conference (June 10 – 11, 2011)

Panelist, *Legal & Ethical Obligations*, Clinical Translation of Pharmacogenomics: Management of Incidental Findings and Related Issues, Duke Institute for Genome Sciences & Policy (June 8 – 9, 2011)

Work in Progress Presentation, *Data Ownership*, Greenwall Foundation Annual Meeting (May 23, 2011)

Panelist, *Planning Meeting for Summit on the Future of Health Privacy* sponsored by the LBJ School of Public Affairs and Patient Privacy Rights with support of the U.S. Army Telemedicine and Advanced Technology Research Center (November 19-20, 2010)

New Scholars Presentation, Greenwall Faculty Scholars Meeting (November 17 – 19, 2010)

Panelist, *Overview of the Legal & Regulatory Environment*, National Institutes of Health-funded Critical Issues Workshop, Protecting Privacy in Health Research (August 10, 2010)

Panelist, *Alternatives or Supplements to Consent: Existing Regulatory Models*, National Institutes of Health-funded Critical Issues Workshop, Protecting Privacy in Health Research (August 10, 2010)

Panelist, *Ethical Considerations*, National Institutes of Health-funded Critical Issues Workshop, Protecting Privacy in Health Research (August 10, 2010)

Ethical and Legal Issues in Pharmacogenetic Research and Application, Duke Clinical Research Institute Think Tank: Pharmacogenomics in Cardiovascular Disease: Balancing Scientific Promise with Clinical Reality (August 2, 2010)

Medical Device Legislation and FDA's Regulatory Authority: Legal Authorities to Develop Evidence and Manage Risks in the Postmarket Period for Drugs, 510(k) and PMA Devices, Institute of Medicine Committee on the Public Health Effectiveness of the FDA 510(k) Clearance Process (Closed Session, June 27, 2010)

Moving Pharmacogenomics into the Clinic, AARP Board of Directors/Management Retreat, Special Session on Personalized Medicine (June 10, 2010)

Ethical and Privacy Issues in Large Pharmacoepidemiological Data Networks, American Society of Law, Medicine & Ethics Health Law Professors' Conference (June 5, 2010)

Recent Developments in Genetic Screening and Medical Privacy, Annual Convention of TxCOEM, the Texas Chapter of the American College of Occupational and Environmental Medicine (May 21, 2010)

Panelist, *Public Policy Session*, American Society of Clinical Pharmacology and Therapeutics Annual Convention (March 19, 2010)

Pathways for Clinical Translation of Pharmacogenomics after FDAAA, Personalized Medicine in the Clinic, sponsored by Arizona State University/Mayo Clinic/AAAS/Food & Drug Law Institute (March 9, 2010)

Appropriate Human Subject Protections for Research Use of Sentinel System Data, Legal Issues in Active Medical Product Surveillance, convened by the Engelberg Center for Health Care Reform at the Brookings Institution with sponsorship of FDA (March 8, 2010)

Keynote Address: Health Technology, Privacy, and Process, Center for Applied Cybersecurity Research Workshop: A Research Agenda for Privacy and Security of Healthcare Technologies (October 26-27, 2009)

Building Capacity Within Post-FDAAA Data Network Infrastructure, Institute of Medicine Forum on Drug Discovery, Development, and Translation, Community Update: Improving the Science of Drug Safety (September 2, 2009)

Update on Privacy and Governance Issues with FDA's 100-million-person Sentinel Data Network, American Society of Law, Medicine & Ethics Health Law Professors' Conference (June 5, 2009)

Ethical Framework for Pharmacogenomics Implementation (Including Economics), Mayo Clinic Pharmacogenetics Research Network Analysis Workshop and Scientific and Steering Committee Meetings (April 17, 2009)

Panelist, ABA Special Committee on Bioethics and the Law Roundtable on Hot Topics in Bioethics and Law, ABA Midyear Convention (February 14, 2009)

Panelist on Data Network Privacy Issues, FDA Public Workshop (Docket No. FDA-2008-N-0612) Sentinel Initiative: Structure, Function, and Scope (December 16, 2008)

Legal and Ethical Issues in Personalized Medicine: Making Therapies Safe for the Individual Patient Rather than the Average Patient, Houston Bar Association Health Law Section (September 10, 2008)

FDA's Sentinel System for Drug-safety Surveillance, Personalized Therapeutics Seminars, Indiana University School of Medicine (August 5, 2008)

Legal and Regulatory Issues Affecting Clinical Use of Personalized Medicine, American Association for Cancer Research, Translational Medicine 2008 Conference (July 21, 2008)

Pharma-provider Interactions and Ethical Guidelines, University of Houston Continuing Legal Education, Health Care Law (July 10, 2008)

FDA's Sentinel Initiative and Regulation of Medical Products with Predictive and Preventive Uses, American Society of Law, Medicine, and Ethics Annual Health Law Professors' Conference (June 7, 2008)

Ethical and Legal Challenges in Bioengineering, Rice University Lecture Series: New Developments in Bioengineering Technology (March 20, 2008)

Making Personalized Medicine Work: The Legal and Regulatory Paradigm Shift, New York Academy of Sciences, Predictive Toxicology Discussion Group Meeting on Toxicogenomics and Personalized Medicine (February 4, 2008)

Cornerstones of Postmarket Considerations in Personalized Medicine: Label Updates, Surveillance, Clinical Practice, and Legal Liability (panelist), FDA/DIA 4th Annual Pharmacogenomics Workshop (December 11, 2007)

HIPAA Privacy Rule Reform Alternatives for Research Use of Human Biological Materials and Health Data, Roundtable on Personalized Medicine, Privacy, and Ethics (November 7, 2007)

Why Bioethics Fails to Produce Constitutional Rights, American Society of Law, Medicine, & Ethics/Saint Louis University Health Law Scholars Workshop (September 7, 2007)

Interactions Between Medical Product Manufacturers and Health-care Providers (Including Ethical Guidelines), University of Houston Continuing Legal Education, Health Care Law (Dallas, July 12, 2007 and Houston, July 19, 2007)

Use of Genetic Information to Guide Treatment Decisions, American Society of Law, Medicine, and Ethics 30th Annual Health Law Professors' Conference (June 1, 2007)

Individualized Medicine: Ethical Principles and Considerations. Individualized Therapy Lectures, Indiana University School of Medicine (April 13, 2007)

Protecting Patients from Invalid and Excessive Claims in Personalized Medicine, Personalized Medicine and Molecular Diagnostics: Legal, Regulatory, and Ethical Perspectives, Arizona State University (March 2, 2007)

Access to Human Biological Materials and Data in Cancer Research. American Society of Clinical Oncology HIPAA Workshop (February 23, 2007)

Regulatory Barriers to Clinical Introduction of Targeted Cancer Therapies, National Institute of General Medical Sciences, Pharmacogenetics Research Network—Consortium on Breast Cancer Pharmacogenomics Biannual Meeting (November 2, 2006)

Regulatory Barriers to Clinical Introduction of Genetically Targeted Drug Therapies, GenomeCanada International Conference, 2020 Vision: Variation and Function in the Genome (October 25, 2006)

Ethical and Regulatory Issues in New Product Development, Purdue University BIOMEDSHIP Program on Entrepreneurship in Biotechnology (April 20, 2006)

Genetic Studies in Hematological Malignancy: Ethical and Legal Considerations, Horizons in Diagnostics and Therapeutics: Developing Patient-Targeted Therapy, CME Corporate Friday Symposium at 47th American Society of Hematology Annual Meeting (December 9, 2005)

Intellectual Property and Regulatory Issues Affecting Targeted Therapies, Indiana University Department of Medicine, Presentation to Clinical Pharmacology Researchers (May 31, 2005)

Pharmacogenomics and its Implications for the Future of the Health Care Industry, Indiana University Medical Humanities Rounds (April 5, 2005)

Creating Incentives for Genomics Research to Improve Targeting of Therapies, Presentation to Eli Lilly Clinical Research Managerial Personnel (November 23, 2004)

Cultural and Economic Factors in Clinical Ethics, Presentation to Delegation of Japanese Oncologists, The University of Texas M.D. Anderson Cancer Center (May 19, 2004)

Should Prenatal Identification of Inherited Cancer Syndromes be Offered? Multidisciplinary Conference on Parenthood After Cancer: Today's Options and Tomorrow's Hopes, Sponsored by the National Cancer Institute (NCI), National Institute of Child Health and Development, Office of Women's Health at NCI, Office of Women's Health at the Department of Health and

Human Services, and the Lance Armstrong Foundation, held at The University of Texas M.D. Anderson Cancer Center (March 7, 2004)

Ethical Considerations of Genetic Testing and Screening for Cancer, Institutional Grand Rounds, The University of Texas M.D. Anderson Cancer Center (February, 2004)

Part II: Therapeutic Misconception and the Ethics of Phase I Clinical Trials, Clinical Ethics Didactic Presentation for M.D. Anderson Personnel (May 11, 2004) (with co-presenter Valerie Olson of Rice University Department of Anthropology)

Part I: Therapeutic Misconception and the Ethics of Phase I Clinical Trials, Clinical Ethics Didactic Presentation for M.D. Anderson Personnel (March 17, 2004) (with co-presenter Valerie Olson)

Emerging Issues in Clinical Application of Genetic Testing, Clinical Ethics Didactic Presentation for M.D. Anderson Personnel (January 16, 2004)

Professional Independence and the Ethics of Clinical Ethics Practice, Clinical Ethics Didactic Presentation for M.D. Anderson Personnel (December 9, 2003)

Patients' Decision-making Styles and Desire for Information When Making End-of-Life Decisions: Insights from Recent Empirical Studies, Clinical Ethics Didactic Presentation for M.D. Anderson Personnel (October 17, 2003)