



Health Sciences Law Group LLC

Robyn S. Shapiro

Attorney and Founder

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My longstanding interest and experience in the health care and life sciences industries drive the manner in which I provide legal services to clients. My goal in working with health care providers and life sciences companies is to protect the innovative products and services they provide, to guide and help give expression to their passion to improve human health.

I provide legal counsel on health care compliance, research compliance, corporate compliance, bioethics, medical staff matters, health information privacy, and corporate and commercial issues faced by pharmaceutical and medical device manufacturers and health care providers.

I have been ranked by *Chambers USA* as a Leader in Life Sciences: Regulatory/Compliance (Nationwide) for the past three years. I was named one of 10 "Outstanding Hospital Lawyers" by *Nightingale's Healthcare News*. I was one of 12 selected as "Leaders in the Law" by the *Wisconsin Law Journal*. I have been listed in *Best Lawyers in America*, a number of Who's Who listings and *Wisconsin Super Lawyers*. I have been named a "Woman of Influence" by the *Milwaukee Business Journal*, and Milwaukee's Health Care Law "Lawyer of the Year" by *Best Lawyers*. My past position as Ursula von Der Ruhr Professor of Bioethics at the Medical College of Wisconsin and my 26-year leadership as Director of the Center for the Study of Bioethics at the Medical College of Wisconsin complement my wide-ranging experience in health care and life sciences law.

I have provided counsel to policymakers at the state and federal levels, including service as an appointed member of the NIH Recombinant DNA Advisory Committee, the FDA Drug Safety and Risk Management Advisory Committee, and the HHS Secretary's Advisory Committee on Xenotransplantation. I frequently present at national conferences on health care and life sciences issues, and I have authored more than 60 articles and book chapters on these and other topics.

My experience includes:

- Providing counsel on a wide variety of research compliance matters for a global medical device company, through a secondment arrangement.
- Assisting a large not-for-profit health care system with extensive drafting and revisions of policies and procedures to satisfy accreditation requirements of the Association for the Accreditation of Human Research Protection Programs.
- Assisting a global medical device company with the development of its Research Code of Conduct and human research compliance policies.
- Assisting a biotechnology company in developing a compliant genetic testing demonstration at a professional conference.
- Developing and presenting a compliance training module for global executive level-leadership of an international life sciences company.
- Advising a biotechnology corporation on policies and practices to assure privacy protection.
- Developing a bioethics consultation service for a large health care system, which is available 24/7 to respond to complex legal bioethics issues at the bedside.
- Assisting a community hospital system in its affiliation with a large academic medical center.
- Assisting a large university in its affiliation with a health system, addressing a wide range of research issues.
- Assisting a large university in development of privacy policies and practices.
- Assisting health care providers in a variety of services review activities, including corrective action counsel, fair hearings, and mediation of corrective action disputes.

Bar Admissions

State Bar of Wisconsin
U.S. Supreme Court
U.S. Court, District of Columbia Circuit
U.S. Court of Appeals, Seventh Circuit

Education

Harvard Law School, J.D.
University of Michigan, B.A.
summa cum laude, with highest distinction

Leadership Positions

Appointed Member, U.S. Department of Health and Human Services, National Institutes of Health Recombinant DNA Advisory Committee, 2005-2009

Appointed Member, U.S. Department of Health and Human Services, Secretary's Advisory Committee on Xenotransplantation, 2001-2004

Appointed Member, U.S. Food and Drug Administration, Drug Safety and Risk Management Advisory Committee, 2003-2007

Chair, American Bar Association, Coordinating Group on Bioethics and the Law, 1996-1998

Chair, American Bar Association, Section of Individual Rights & Responsibilities, 2007-2008

Delegate to House of Delegates, American Bar Association Health Law Section, 2015-present

Board Member, American Society for Bioethics and Humanities, 1997-2000

American Bar Association's Advisor to the National Conference of Commissioners on Uniform State Laws Committee on Misuse of Genetic Information, 2002-2010

Appointed Member, American Society of Health System Pharmacists-Commission on Goals, 2006-2009

Member, American Bar Association Commission on Law and Aging, 2013-present

Selected Publications

- "Ethics in Research" in ME Clark (ed.), *Pharmaceutical and Medical Device Law, Second Edition* (Bloomberg BNA, 2015)
- "Fraud and Abuse Issues Surrounding Clinical Trials" in LA Baumann (ed.), *Health Care Fraud and Abuse: Practical Perspectives* (BNA Books, 2015)
- "Recent Past is Prologue to Life Sciences Regulation," *Law360* (Life Sciences), January 2, 2013
- "Technology: The Ethical and Legal Challenges of Large-Scale Human Genome Sequencing," *Inside Counsel*, June 8, 2012
- "New FDA Informed Consent Requirements for Applicable Clinical Trials: Practical Approaches for Implementation," *Bloomberg BNA Medical Research Law & Policy Report*, Volume 11, April 4, 2012
- "CMS's Proposed 'Sunshine' Regulations: Implications for Research," *Bloomberg BNA Medical Research Law & Policy Report*, Volume 11, Number 5, March 7, 2012
- "Caring for Individuals with Alzheimer's Disease: Ethical Issues Along the Way," in T Kushner (ed.), *Surviving Health Care* (Cambridge University Press, 2010)
- "On the Horizon: Genetic Testing," in T Kushner (ed.), *Surviving Health Care* (Cambridge University Press 2010)
- "Medical Malpractice," in WB Poss, ME Rowin (eds.), *Current Concepts in Pediatric Critical Care* (Society of Critical Care Medicine 2009)
- "Integrating Bioethics into Clinical and Translational Sciences Research: A Roadmap," *Clinical and Translational Science* 2008; 1(1):67-70
- "Future Issues in Transplantation Ethics: Ethical and Legal Controversies in Xenotransplantation, Stem Cell and Cloning Research," *Transplantation Reviews* 2008; 22(3):210-214
- "Bioethics Issues Surrounding the Beginning of Life: Legal Aspects in the United States," in AS Iltis, SH Johnson, BA Hinze (eds.), *Legal Perspectives in Bioethics* (Rutledge, 2008)
- "The FDA and Drug Safety," *Archives of Internal Medicine* 2006; 166:1938-1942 (with Furberg, et al.)

American Bar Foundation Fellows, 2006-present

Co-Chair, American Bar Foundation Fellows Wisconsin Chapter, 2013-present

Member, Law360 Life Sciences Editorial Board, 2013-2016