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EXPERIENCE

Jan. 1991 to present	Director, Hyman, Phelps & McNamara, P.C., Washington, D.C.
1986 to 1990	Partner, Mackler and Gibbs, P.C., Washington, D.C.
1984 to 1986	Associate, Hogan & Hartson, Washington, D.C.
1980 to 1984	Associate Chief Counsel for Enforcement, United States Food and Drug Administration, Rockville, Maryland.
Sep. 1982 to Apr. 1983	Special Assistant United States Attorney, District of Columbia.
1978 to 1980	Law Clerk, Honorable Frederick B. Lacey, United States District Court for the District of New Jersey.

EDUCATION

1975-1978	New York University School of Law, New York, New York. Awarded Juris Doctor; graduated cum laude. Order of the Coif. Projects Editor of Law Review.
1971-1975	Princeton University, Princeton, New Jersey Awarded Bachelor of Arts; graduated summa cum laude.

MEMBERSHIPS

<u>Bar:</u>	Member of the Bars of the State of New Jersey and the District of Columbia; the United States District Courts of New Jersey and the District of Columbia.
<u>Other:</u>	Member, George Mason University Human Subjects Research Board (2003- present); Member, Food and Drug Law Journal Editorial Advisory Board (1998- 2004); Member of Human Subject Research Board, George Mason University; Member of Editorial Advisory Board of In Vitro Diagnostic Technology; Member of Editorial Advisory Board of Guide to Good Clinical Practices; Chair of Food and Drug Law Journal Editorial Advisory Board (2003-04); Board of Trustees, Associates of Clinical Pharmacology (1993-95); United States Department of Agriculture Biotechnology Research Advisory Committee (1988-90).

AUTHORED PUBLICATIONS

Books:

Co-author: Biotechnology and the Environment: International Regulation (Macmillan 1987).

Articles:

“Exploring Other Options, Part 1: The trend toward alternative market pathways,” IVD Technology, Volume 11, Number 4, May 2005.

“FDA Must Reform its Arbitrary Drug Name Review Process,” Washington Legal Foundation, Vol. 20 No. 5, January 2005.

“Is Veterinary Compounding Illegal Under Federal Law?” International Journal of Pharmaceutical Compounding, Vol. 8 No. 6, November/December 2004.

“State Regulation of Pharmaceutical Clinical Trials,” Food and Drug Law Journal, Vol. 59 No. 2 (2004).

“The Past, Present, and Future of ASRs,” IVD Technology, November/December 2003.

“Compounding and the Courts,” International Journal of Pharmaceutical Compounding, July/August 2002.

“Compliance Auditing,” MX Magazine, Business Strategies for Medical Technology Executives, May/June 2002.

“FDA tightens the reigns, for better or for worse,” Biotechnology, Investors’ Forum, Worldwide Issue 1-2002.

“Informed Consent for IVD Studies: The Manufacturer’s Role,” IVD Technology, November/December 2001.

“Clinical Trials: What Executives Need to Know,” MX Magazine, Business Strategies for Medical Technology Executives, January/February 2001.

FDA’s Restitution “Authority” Relies Upon Flawed Court Ruling, Legal Opinion Letter, October 6, 2000.

Regulations and Standards. IVDs and the states: The other regulatory system, IVD Technology, September 2000.

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First Amendment Limits on Regulating Information: An Initial Reaction to the *Washington Legal Foundation* Case, Food and Drug Law Journal, Vol. 53 No. 4 (1998).

Regulations and Standards: Free-speech decision could advance off-label IVD promotion, IVD Technology, Vol. 4 No. 7, November/December 1998.

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FDA's RUO/IUO Policy: A Small Step Forward, IVD Technology NEWS, Vol. 4 No. 2, March/April 1998.

Industry-Supported Educational Programs: FDA's Final Policy, Regulatory Affairs Focus, Vol. 3 Issue 3, March 1998.

ASRs: FDA Issues Final Rule, IVD Technology, Vol. 4 No. 1, January/February 1998.

Avoiding the Liability Pitfalls of Internal Electronic Mail, Regulatory Affairs Focus, Vol. 2 Issue 8, August 1997 (co-authored with Alan M. Kirschenbaum).

When to Submit a New 510(k): FDA's Newest Guidance, Regulatory Affairs Focus, Vol. 2 Issue 5, May 1997.

Treatment IDEs: FDA Proposal Borrows from Treatment INDs, Regulatory Affairs Focus, Vol. 2 Issue 4, April 1997.

Banked Human Tissue: A Case Study in Agency Regulation, Regulatory Affairs Focus, Vol. 1, Issue 6, June 1996.

The Human Genome, FDA and Product Liability, RISK, Vol. 7 Issue 3, Summer 1996.

Legislation & Congressional Hearings Affecting The Outcome of FDA & Medical Manufacturers Reviewed, Biomedical Market Newsletter, October 1995.

FDA and Civil Money Penalties: New Regulations Change the Playing Field, RAPS News, October 1995.

FDA Enforcement: Its Impact on Civil Liability, RAPS News, September 1995.

FDA Certification: Signer Beware, RAPS News, June 1995.

FDA Inspections of Pharmacies: What Should You Do?, American Pharmacy, May 1995.

The WLF Case: A Challenge to FDA Regulation by Policy, RAPS News, May 1995.

FDA Financial Disclosure Proposal Should be Withdrawn, Legal Backgrounder, April 1995.

Commentary, IRB Approval for IVD Clinical Trials: An Unnecessary Burden, Medical Device & Diagnostic Industry, April 1995.

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Co-author:

Just Sign on the Dotted Line?, Legal Times, Vol. XXVIII, No. 25, Week of June 20, 2005 (co-authored with Anne Marie Murphy).

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Contributing author:

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