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EXPERIENCE

May 2007 to Present Director, Hyman, Phelps & McNamara, P.C., Washington, D.C, representing medical device companies on a wide range of FDA-related matters, including product clearances and approvals, clinical studies, combination product and jurisdictional issues, labeling and advertising, compliance with adverse event reporting and other postmarket regulations, responding to Form 483s and warning letters, recalls, and other enforcement matters

2000 to 2007 Partner, Hogan & Hartson, L.L.P., Washington, D.C. (also focused on all aspects of medical device law and regulation)

1995 to 2000 Associate, Hogan & Hartson, Washington, D.C. (also focused on all aspects of medical device law and regulation)

1994 to 1995 Associate, Buc & Beardsley (formerly Buc, Levitt & Beardsley), Washington, D.C.

1991 to 1994 Attorney Advisor, U.S. Department of Justice, Office of Legal Counsel, Washington, D.C.

1989 to 1991 Associate, Cleary, Gottlieb, Steen & Hamilton, Washington, D.C.

1986 to 1989 Associate, Irell & Manella, Los Angeles, California

EDUCATION

1983-1986 Harvard Law School, Cambridge, Massachusetts
Awarded Juris Doctor; graduated cum laude.

1979-1983 Brown University, Providence, Rhode Island
Awarded Bachelor of Arts; graduated magna cum laude.

MEMBERSHIPS

Bar: Member of the Bars of the District of Columbia, the State of California (inactive), and the State of Pennsylvania (inactive).

Other: Past Member, Editorial Advisory Board, Food and Drug Law Institute's (FDLI) *Update* magazine (2006-2008); Current Contributing Editor, *Medical Devices & Diagnostic Industry* magazine; Member, Regulatory Affairs Professional Society (RAPS).

PUBLICATIONS

Books:

Co-author: Combination Products: How to Develop the Optimal Strategic Path for Approval (FDA News 2005).

Co-editor and contributing author: Promotion of Biomedical Products: Regulatory Considerations (Food and Drug Law Institute 2006).

Contributing author:

"Chapter 17: Combination Products and Jurisdictional Issues." *Food and Drug Law and Regulation* (David G. Adams et al. eds, FDLI 2008) pp. 557-70.

"Food and Drug Administration." *Emerging Spine Surgery Technologies: Evidence and Framework for Evaluating New Technology* (Terry P. Corbin et al. eds., Quality Medical Publishing, Inc. 2006) pp. 6-11 (overview of FDA law and regulation of medical devices).

Articles – Sole Author:

"The MDR Reporting System Badly Needs Reform: As A First Step, Malfunction MDRs Should Be Eliminated," *FDALawBlog.net* (March 2010)

"Preemption of State Law Tort Suits Against Medical Device and Drug Manufacturers," *FDALawBlog.net* (July 2008)

"The Pathway to Market for Your Medical Device: A Primer on Obtaining Information from FDA," *FDLI Update* (May/June 2008)

"Federal and State Requirements for HCT/Ps: An Overview," *Medical Device & Diagnostic Industry* (May 2005).

"Comparative Claims: Legally Permissible, But Proceed with Care," *Medical Device & Diagnostic Industry* (September 2004).

"When All Else Fails: The Medical Device Dispute Resolution Panel," *Medical Devices & Diagnostic Industry* (June 2003).

"Promoting Devices for Specific Indications Based Upon A General Clearance," *Regulatory Affairs Focus* (February 2003).

"Medical Device Reporting: A Risk Management Approach," *Medical Devices & Diagnostic Industry* (January 2003).

"FDA's Regulation of Internet Promotion and Advertising," *Medical Devices & Diagnostic Industry* (July 2001).

"The Washington Legal Foundation Litigation and Its Aftermath," *Regulatory Affairs Focus* (February 2001).

"How to Transfer Ownership of a 510(k) Clearance or PMA Approval," *Regulatory Affairs Focus* (April 2000).

"The Regulatory Implications of Labeling Errors on Medical Device Packaging," *Flexible Packaging* (August 1999).

"Taking Advantage of FDAMA's 'Least Burdensome' Requirements Provisions," *Association of Medical Diagnostics Manufacturers News* (March 1999).

"Next Steps for the Mutual Recognition Agreement," *Regulatory Affairs Focus* (January 1999).

"Who Pays to Fix Year 2000 Problems," *Medical Devices & Diagnostic Industry* (August 1998).

"Displaying Investigational and Unapproved Medical Devices According to FDA Policy," Medical Devices & Diagnostic Industry (October 1997).

Articles - Co-author:

"The Family Smoking Prevention and Control Act: An Overview," Food and Drug Law Journal (Vol. 64, No. 4, 2009)

"FDA's Regulatory Scheme for Human Tissue: A Brief Overview," FDLI Update (November/December 2007)

"Condition of Approval Studies: FDA Takes a New Look," Regulatory Affairs Focus (August 2005).

"The First Amendment and the Food and Drug Administration's Regulation of Labeling and Advertising: Three Proposed Reforms," Food and Drug Law Journal (Vol. 58, No. 3, 2003).

"A Sensible Approach to Biocompatibility Testing," Medical Devices & Diagnostic Industry (August 2003).

"FDA's Regulation of Analyte Specific Reagents," Medical Devices & Diagnostic Industry (February 2003).

"FDA in the Dock: The Supreme Court's Western States Decision," FDLI Update (September/October 2002).

"Cops Online: FDA's Regulation of Internet Promotion and Advertising," Regulatory Affairs Focus (October 2000).