JEFFREY K. SHAPIRO

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EXPERIENCE

May 2007 to Present	Director, Hyman, Phelps & McNamara, P.C., Washington, D.C. (focused on all aspects of FDA's medical device law and regulation), representing medical device companies on a wide range of FDA-related matters, including product clearances and approvals, clinical studies, combination product and jurisdictional issues, due diligence, 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. (focused on all aspects of FDA's medical device law and regulation)
1995 to 2000	Associate, Hogan & Hartson, Washington, D.C. (focused on all aspects of medical device law and regulation)
1994 to 1995	Associate, Buc & Beardsley (formerly Buc, Levitt & Beardsley), Washington, D.C. (focused on FDA law and regulation of drugs, food, medical devices)
1991 to 1994	Attorney Advisor, U.S. Department of Justice, Office of Legal Counsel, Washington, D.C.
1989 to 1991	Associate, litigation, Cleary, Gottlieb, Steen & Hamilton, Washington, D.C.
1986 to 1989	Associate, litigation, 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

DC Bar

Current Member, FDLI Medical Device Committee

Current Contributing Editor, *Medical Devices & Diagnostic Industry* magazine

Member, Regulatory Affairs Professional Society (RAPS)

Past Member, Editorial Advisory Board, Food and Drug Law Institute's (FDLI) Update magazine (2006-2008)

AWARDS & RECOGNITION

Life Science Star, LMG Life Sciences, 2012-2016

DC Super Lawyers, 2014-2016

The International Who's Who of Business Lawyers (Life Sciences), 2014-2016

TEACHING

Lecturer, George Washington University's Regulatory Law for Medical Devices course (2016)

Lecturer, University of Maryland's Regulatory Law for Medical Devices course (2014)

PUBLICATIONS

Articles

- Does FDA's Per Se Prohibition Against Off-Label Promotion Have a Future?, FDLI Update (Apr. 2016).
- FDA to Hold a Public Hearing for a Quartet of Draft HCT/P Guidances: A Scorecard, FDALawBlog.net (Nov. 2, 2015).
- A Long Overdue Revision to the Intended Use Regulation, FDALawBlog.net (Oct. 18, 2015).
- Combination Products Reform Bill Is A Good Start, But Its Provisions Need Strengthening, FDALAwBlog.net (Aug. 6, 2015).
- Enforcing The "Least Burdensome" Requirement for Premarket Review of Devices, FDALawBlog.net (June 22, 2015).
- Federal Courts Erroneously Continue to Claim that FDA Only Spends 20 Hours On Average Reviewing 510(k)s, FDALawBlog.net (June 9, 2015).
- At Last, FDA Issues (Draft) Guidance on 510(k) Transfers, FDALawBlog.net (Dec. 22, 2014).
- FDA's Hollow Medical Device Recall Guidance: Ending Not with A Bang But A Whimper, FDALawBlog.net (Oct. 23, 2014).
- What Legal Authority Does FDA Have to Regulate Medical Device Promotion on Internet Social Media Platforms?, FDALawBlog.net (Sept. 25, 2014).
- FDA's 510(k) Review is a Powerful Regulatory Tool, But a Better Public 510(k) Database is Needed to Improve the Predictability of Substantial Equivalence Review, FDALawBlog.net (Sept. 15, 2014).
- "Substantial Equivalence Premarket Review: the Right Approach for Most Medical Devices," 69 Food and Drug L.J 365 (2014)
- "FDA Issues New Draft Guidance for Custom Devices; Some Points Worth Highlighting," FDALawBlog.net (Jan. 27, 2014)
- "Free the FDAAA Hostage!" FDALawBlog.net (Oct. 7, 2013)
- "Draft Guidance on Medical Device Recalls: Improvements Are Needed," FDLI Update (July/August 2013).

- "The Medical Device Amendments of 1976: The Statute That Went Awry," FDALawBlog.net (June 3, 2013)
- "CDRH Issues Final Appeals Guidance, Q&A About FDASIA Appeals Process," FDALawBlog.net (May 20, 2013)
- "Substantial Equivalence Review of Medical Devices," Paper Presented at Harvard Law School Petrie-Flom Annual Conference (May 4, 2013)
- "CDRH Working to Update Appeals Guidance for Consistency with FDASIA," FDALawBlog.net (Apr. 17, 2013)
- "Keeping up with events: The US FDA and its draft guidance on medical device appeals," Scrips Regulatory Affairs (Apr. 2013).
- "Cytori Case Decision Upholds FDA's Not Substantially Equivalent Determination," FDALawBlog.net (Mar. 24, 2013)
- "Medical Device Recall or Product Enhancement? FDA's New Draft Guidance Should Be Recalled for Significant Repairs" (Feb. 28, 2013)
- "First Fruits of FDASIA's New Device Reclassification Procedure" (Feb. 17, 2013).
- "FDA Ramps Up Focus on Advertising of Restricted Devices to Consumers" (Jan 7, 2013).
- "A Difference of Opinion: CDRH's SOP for Internal Supervisory Appeals" (Oct. 8, 2012).
- "FDA's Voluntary ISO Audit Submission Program," FDALawBlog.net (Sept. 30, 2012).
- "FDA Should Be Required To Provide 510(k) Decision Summaries," FDALawBlog.net (June 2012).
- "FDA's Brief in Par: The Gift that Keeps on Giving," FDALawBlog.net (Mar. 2012).
- "MDR Reporting – FDA Appears to Disavow The Two Year Presumption," FDALawBlog.net (Feb. 2012).
- "FDA Issues Draft Guidance on Medical Device Appeals Processes," FDALawBlog.net (Jan. 2012).
- "FDA is Sued Over Product Designation Determination; Lawsuit Seeks Device Declaration and to Vacate FDA's Drug Findings," FDALawBlog.net (June 2011).
- "Examination of MDR Reporting Criteria Warranted in Light of Recent Warning Letter," FDALawBlog.net (Nov. 2011).
- "Appealing Premarket Disputes in the Device Center: Reform Is Needed," FDALawBlog.net (Oct. 2011).
- "Nothing New: FDA Announces its Innovation Pathway Program for Breakthrough Technologies," FDALawBlog.net (Feb. 2011).
- "FDA Releases Plan Intended to Improve the 510(k) Program; Plan Contains 25 Action Items to Implement During 2011," FDALawBlog.net (Jan. 2011).
- "More Members of Congress Concerned About 510(k) Reform," FDALawBlog.net (Jan. 2011).

- "What Happens to Medical Device Reports Once They Reach FDA?", Medical Device & Diagnostic Industry (Dec. 2010).
- "The Family Smoking Prevention and Control Act: An Overview," Food and Drug Law Journal (Vol. 64, No. 4, 2009)
- "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)
- "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 (Aug. 2005).
- "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 (Sept. 2004).
- "A Sensible Approach to Biocompatibility Testing," Medical Devices & Diagnostic Industry (Aug. 2003).
- "When All Else Fails: The Medical Device Dispute Resolution Panel," Medical Devices Diagnostic Industry (June 2003).
- "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).
- "FDA's Regulation of Analyte Specific Reagents," Medical Devices & Diagnostic Industry (Feb. 2003).
- "Promoting Devices for Specific Indications Based Upon A General Clearance," Regulatory Affairs Focus (Feb. 2003).
- "Medical Device Reporting: A Risk Management Approach," Medical Devices & Diagnostic Industry (Jan. 2003).
- "FDA in the Dock: The Supreme Court's Western States Decision," FDLI Update (Sep. /Oct. 2002).
- "Cops Online: FDA's Regulation of Internet Promotion and Advertising," Regulatory Affairs Focus (Oct. 2000).
- "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 (Feb. 2001).
- "How to Transfer Ownership of a 510(k) Clearance or PMA Approval," Regulatory Affairs Focus (Apr. 2000).

- "The Regulatory Implications of Labeling Errors on Medical Device Packaging," Flexible Packaging (Aug. 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 (Jan. 1999).

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

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

Books & Chapters

- "Chapter 3: Device Premarket Submissions." *Medical Device Law and Regulation Answer Book 2014* (Onel & Becker eds., Practicing Law Institute) (3rd Edition, 2014).

- "Chapter 17: Combination Products and Jurisdictional Issues." *Food and Drug Law and Regulation* (David G. Adams et al. eds, !st & 2d editions, FDLI 2008 & 2011).

- "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).

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

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