# Bradley Merrill Thompson

## Member of the Firm

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**BRADLEY MERRILL THOMPSON** is a Member of the Firm at Epstein Becker & Green, P.C. There, he counsels medical device, drug, and combination product companies on a wide range of FDA regulatory, reimbursement, and clinical trial issues. At the firm, Mr. Thompson leads the Medical Device Regulatory Practice, the Clinical Trials Initiative, and the Connected Health Initiative, and he serves on the firm's National Health Care and Life Sciences Steering Committee.

Mr. Thompson regularly defends companies receiving FDA warning letters, on a wide gambit of subjects including good manufacturing practice compliance and off label promotion. He frequently counsels companies on premarket clearance and approval strategies and on marketing strategies. When medical device companies become concerned that perhaps their employees have not followed FDA requirements, they often engage Mr. Thompson to investigate. With a special focus on drug delivery companies, Mr. Thompson also advises such companies on the unique aspects of combination product development and manufacturing.

For trade associations, Mr. Thompson has served as counsel to AdvaMed for payment issues; as General Counsel to the Combination Products Coalition, the mHealth Regulatory Coalition, and the CDS Coalition (focusing on clinical decision support software); and for 17 years, as General Counsel and Secretary for the Indiana Medical Device Manufacturers Council (the "IMDMC").

For nearly 20 years, Mr. Thompson has focused on administrative law issues, particularly on the best ways for agencies and the public to work together in defining new regulatory policy and guidance. In the mid 1990s, on behalf of the IMDMC and about a dozen large trade associations representing virtually every industry the FDA regulates, Mr. Thompson advocated that FDA should improve its guidance development process to enhance the quality and reliability of guidance, as well as to better ensure public participation. Mr. Thompson's advocacy resulted in the so-called FDA Good Guidance Practices, now embraced by other federal agencies, as well. In the late 1990s, Mr. Thompson successfully advocated that what is now called the Centers for Medicare & Medicaid Services should conduct its coverage decision-making process more openly, and in particular should permit public attendance at its advisory committee meetings.

In legislative matters, Mr. Thompson has over the years actively worked to ensure

### PRACTICES

Health Care and Life Sciences
- Food and Drug Law
- Government and Commercial Reimbursement
- Product Marketing

### EDUCATION

J.D., *cum laude*, University of Michigan Law School, 1986
M.B.A., University of Illinois, 1983
B.A., *cum laude*, University of Illinois, 1982

### BAR ADMISSIONS

District of Columbia
Indiana

### COURT ADMISSIONS

Supreme Court of the United States

### MEMBERSHIPS

American Bar Association
American Bar Foundation, Fellow
American Health Lawyers Association
Food and Drug Law Institute
Regulatory Affairs Professional Society
Various positions in the Crossroads of America Council, Boy Scouts of America (1986-1995)

### BOARDS OF DIRECTORS

AquaMatic DISC, Inc. (1990-97)
AquaMatic, Inc. (1988-97)
HealthNet, Inc. (1990-94)
Indiana Health Industry Forum (Secretary and General Counsel, 1993-present)
Indiana Medical Device

that health care economic information can be appropriately shared without running afoul of FDA requirements, seeking to secure stakeholders a reasonable avenue of appeal when Medicare contractors deny claims. In both cases, Congress enacted responsive legislation.

He has taught Food and Drug Law as an Adjunct Professor at the Indiana University Law School and Columbia Law School. Mr. Thompson also serves as Co-Chair of the Food & Drug Law Committee of the Administrative Law Section of the American Bar Association, and of the Medical Device Committee of the Food & Drug Law Institute.

Mr. Thompson was included in 100 Notable People in the Medical Device Industry (*Medical Device & Diagnostics Industry*, June 2004), and has been listed in *Chambers USA: America's Leading Lawyers for Business* (2010, 2011, and 2012) and selected for inclusion in *Indiana Super Lawyers* (2004 to 2006).

**Diagnostics Practice**

For many years, *in vitro* diagnostic tests has been an area of substantial focus for Mr. Thompson. He has:

- Served for approximately 10 years as chief outside counsel to one of the world's largest IVD makers, handling essentially all FDA and Medicare reimbursement issues
- Represented, over time, four of the five largest IVD manufacturers, as well as many others
- Represented trade associations on special projects involving FDA and laboratory developed tests, as well as CLIA and Medicare reimbursement for IVDs
- Represented a coalition seeking the movement of regulatory responsibility for CLIA waiver determinations from CDC to FDA, and then seeking improvements in the way FDA administered the process
- Lectured on FDA's rules for ASRs and RUOs and the regulation of IVDs and LDTs
- Written a substantial number of diagnostics-related publications, including two book chapters, and has contributed regularly to *IVD Technology* magazine.

**Connected Health Practice**

In the Connected Health Initiative at the firm, Mr. Thomspon focuses on the federal regulatory requirements—FDA, reimbursement, privacy, and others—that impact remote monitoring, mobile health, HIT, and device interoperability. The firm's Initiative brings together a multidisciplinary team of attorneys and consultants trained and experienced in Medicare and private insurance payment, FDA regulatory, scientific, IT, clinical, and security disciplines. Mr. Thompson serves as outside counsel to Continua Health Alliance, conducts educational

Manufacturers Council, Inc. (Secretary and General Counsel, 1991- 2006)
Indianapolis Ambassadors, Inc. (Secretary, 1988-89)

## BOARDS OF ADVISORS/ADVISORY COUNCILS

Medical Device Committee of FDLI
PharmaMedDevice Conference, Reed Exhibitions

## BOARDS OF EDITORS

BNA's Medical Device Law & Industry Report (2007 - present)
Food & Drug Law Journal (2007-present)
Medical Device & Diagnostic Industry, Santa Monica, CA (1993-present)
Regulatory Affairs Journal (China correspondent)
Regulatory Affairs, Rockville, MD (1991-1995)

programs on connected health regulation, and blogs for Mobihealthnews.com.

**Books/Chapters**

- *Off-Label Communications: A Guide to Sales and Marketing Compliance*, FDLI (2008, 2010, and 2012 - third edition) (Co-Authored One Chapter)
- Chapter 5, "*In Vitro* Diagnostic Devices," in *Medical Devices Law and Regulation Answer Book 2011-12* (PLI, Sept. 2011)
- *FDA Regulation of mHealth* (MobiHealthNews, June 2010)
- *In Vitro Diagnostics: The Complete Regulatory Guide* (Food and Drug Law Institute, April 2010) (Authored One Chapter, Chapter 5)
- *Guide to Medicare Coverage Decision-Making and Appeals* (ABA, 2002) (Authored Two Chapters)
- *FDA Regulation of Medical Devices* (Interpharm Press, 1995)

**Congressional Testimony**

Before a Joint Hearing of the Subcommittee on National Economic Growth, Natural Resources & Regulatory Affairs and the Subcommittee on Human Resources and Intergovernmental Relations, both of the House Committee on Government Reform and Oversight, September 14, 1995, on FDA's Use of Guidance Documents and Rulemaking.

## ANNOUNCEMENTS & PRESS RELEASES

| | |
|---|---|
| 6/12/2012 | Epstein Becker Green Recognized for Work in Health Care Industry; Receives 2012 *Chambers USA* Award for Excellence in Healthcare |
| 1/3/2012 | Epstein Becker Green Opens Indianapolis Office to Better Serve Its Client Base and Indiana Life Sciences Industry |
| 6/17/2010 | Epstein Becker Green Recognized Among Leading Law Firms by *Chambers USA* |
| 8/5/2009 | Bradley Thompson Elected to Fellows of the American Bar Foundation |

## ARTICLES

| | |
|---|---|
| 06/20/12 | How the FDA Regulates Pharmaceutical Apps, *in* MobiHealthNews |
| 03/14/12 | Comparing EU and US Approaches to Regulating Clinical Decision Support Software, *in* European Medical Device Technology |
| 12/28/11 | FDA's Approach to Clinical Decision Support Software: A Brief Summary, *as appeared in* FierceHealthIT |
| 10/17/11 | Mobile Medical Apps Guidance: What's Good for the US Is Good for the EU, *as appeared on* ScripRegulatoryAffairs.com |
| 09/19/11 | Is FDA's EHR Exemption Becoming Extinct? *in* MobiHealthNews |
| 08/31/11 | Chapter 5, "*In Vitro* Diagnostic Devices," in *Medical Devices Law and Regulation Answer Book 2011-12* (PLI) |

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|---|---|
| 05/15/11 | The Future Regulation of Mobile Healthcare, *as appeared in* Regulatory Affairs Medtech |
| 03/15/11 | FDA Regulatory Update: Top 10 Policy Development Issues for 2011 & What May Stand in the Way of Advancing Them, *as appeared in* Drug Development & Delivery |
| 12/29/10 | Three Key Questions for FDA mHealth Regulation, *in* Mobihealthnews |
| 06/30/10 | FDA Regulation on Mobile Health: MobiHealthNews 2010 Report |
| 04/08/10 | In Vitro Diagnostics: The Complete Regulatory Guide |
| 03/23/10 | Newly Proposed Good Manufacturing Practices, *as appeared in* Drug Delivery Technology Magazine |
| 02/26/10 | Washington Signals Possible FDA Regulation of mHealth, *as appeared in* MobiHealthNews |
| 01/14/10 | Should mHealth Companies Want FDA Regulation?, as appeared in MobiHealthNews |
| 12/01/09 | How to Get FDA to Clear a Mobile Health App, *as appeared in* MobiHealthNews |
| 10/02/09 | New Regulatory Developments *in the* Combination Product Area |
| 09/23/09 | FDA's New Draft Guidance on Technical Considerations for Pen, Jet & Related Injectors Intended for Use With Drups and Biological Products: Comments and Concerns, *as appeared in* Combination Update |
| 07/13/09 | FDA May Regulate Certain Mobile Phones, Accessories, *as appeared in* MobileHealthNews |
| 10/01/08 | Off-Label Communications: A Guide to Sales and Marketing Compliance |
| 08/01/08 | Regulating the Human Tissue Trade, *as appeared in* Health Lawyers Weekly |
| 03/31/08 | An Uncertain Path: A New Survey Indicates Industry's Desire for More Detailed Guidance for Developing and Commercialing Combination Products, *in* MX Magazine |
| 07/15/05 | Impact on Patient Care Must Be Factor When Assessing "Gainsharing" Arrangement, *as appeared in* Legal Backgrounder |
| 03/01/04 | The IVAT Solution, IVD Technology |
| 03/01/04 | Measuring Compliance |
| 11/01/02 | The FDA Approval and Medicare Coverage Processes, Part 2: Striving Toward Harmonization |
| 09/01/02 | The FDA Approval and Medicare Coverage Processes, Part 1: Current Interconnections |
| 01/01/02 | Book: Guide to Medicare Coverage Decision-Making and Appeals |
| 06/01/98 | Health Care Industry Working Group Develops Draft PE Guidance, FDA Advertising and Promotion Manual 4 |
| 05/01/98 | CLIA reform: Present and future, IVD Technology |
| 02/01/98 | Medical Devices in China, 6 The Regulatory Affairs Journal 25 |

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|---|---|
| 11/01/97 | The Product Development Protocol, Vol. 2, No. 11, RA Focus |
| 05/01/96 | The Demise of Rule Making and the Rise of Guidances, 18 Medical Device & Diagnostic Industry 99 |
| 01/01/95 | Book: *FDA Regulation of Medical Devices* (Interpharm Press) |
| 08/01/94 | 510(k)s for Sale, 16 Medical Device & Diagnostic Industry 34 |
| 01/01/94 | Keeping Track of Medical Devices, 11 Food, Drug, Cosmetic and Medical Device Law Digest 24 |
| 05/01/93 | FDA's Expanding Definition of Diagnostic Devices, 15 *Medical Device & Diagnostic Industry* 58 |
| 05/01/93 | Companies Should Police Themselves, Indiana Business Magazine 91 |
| 09/01/92 | FDA's New and Improved Approach to Device Tracking, 14 Medical Device & Diagnostic Industry 66 |
| 01/01/92 | FDA's New Rules for Investigational and Research IVDs, 4 Regulatory Affairs 305 |
| 01/01/91 | Resurrecting the Product Development Protocol for Medical Devices, 46 Food Drug Cosmetic Law Journal |
| 08/27/90 | Tax Savings for Small Exporters, Vol. 11, No. 20, Indianapolis Business Journal |
| 08/01/90 | Lifting the Burden of IDE Regulations Off Device Feasibility Studies, Medical Device & Diagnostic Industry |
| 09/11/89 | Some Tips for Protecting the Confidentiality of an Environmental Audit, Vol. 10, No. 22, Indianapolis Business Journal |
| 01/01/88 | Companies Must Weigh Competing Interests in Planning for FDA Inspection, Vol. 8, No. 52, Indianapolis Business Journal |
| 01/01/88 | FDA's Candid Camera, 43 Food Drug Cosmetic Law Journal 335 |
| 01/01/83 | Research and Development Strategies: Competitive Implications for American Firms, Outstanding Papers |

## CLIENT ALERTS

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|---|---|
| 5/8/2009 | New FDA Draft Guidance on Technical Considerations for Pen, Jet, and Related Injectors Intended for Use with Drugs and Biological Products |

## CLIENT NEWSLETTERS

| | |
|---|---|
| 2/9/2010 | Top Ten Connected Health Challenges in 2010 |
| 11/30/2009 | Top Ten Key Issues Concerning ‘Biosimilars' |
| 10/30/2009 | Top Ten Considerations for Industry Support of Investigator-Initiated Research |
| 9/30/2009 | Top Ten Issues In America's Healthy Future Act Of Interest To Pharmaceutical and Biological Manufacturers |
| 9/1/2009 | Top Ten Best Practices in Complying with Current Good Manufacturing Practice for Combination Products |
| 7/31/2009 | Top Ten Tips to Follow When Entering Into Financial Relationships With Health Care Professionals |

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| 6/30/2009 | Top Ten Key Regulatory Considerations in Combination Product Marketing |
| 4/30/2009 | Top Ten Best Practices for Effective Communication with FDA on Product Development Issues |
| 3/31/2009 | Top Ten Issues for Reimbursement of Remote Monitoring Devices In a Changing Health Care Environment |
| 2/28/2009 | Top Ten Tips For Operating An Effective Corporate Compliance Program |
| 1/31/2009 | Top Ten Ways Health Care Reform Benefits Packages Will Affect Innovation in the Life Sciences Sector |
| 12/4/2008 | Top Ten Ways For Sponsors To Manage Risk Better With CROs |

## EBG IN THE NEWS

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| 1/28/2013 | Bradley Merrill Thompson Quoted in Article "Industry Seeks More Clarity Following Combo Product GMP Final Rule" |
| 1/25/2013 | Bradley Merrill Thompson Quoted in Article "Modification Guide Could Up-Classify Devices in Combo Products, Lawyer Says" |
| 1/23/2013 | Bradley Merrill Thompson Quoted in Article "Off-Label Promotion, Enforcement, 510(k) Revisions Are Key Issues for Industry in 2013" |
| 1/23/2013 | Bradley Merrill Thompson Quoted in Article "FDA Issues Long-Awaited Combo Product GMPs, Industry Seeks Further Guidance" |
| 12/18/2012 | Bradley Merrill Thompson Quoted in Article "Combo Products May See Double ACA Tax Under IRS Rule, But Kits Exempt" |
| 10/19/2012 | Bradley Merrill Thompson Quoted in Article, "Attorney: Proposed mHealth Bill Will Do Little Without More FDA Funding" |
| 10/4/2012 | Bradley Merrill Thompson Quoted in Article, "Social Media Use Presents Challenges for Drug Manufacturers, Experts Say" |
| 10/1/2012 | Bradley Merrill Thompson Quoted in Article, "FDA Should Reassess Hacking Risk in Medical Devices, GAO Says" |
| 10/1/2012 | Bradley Merrill Thompson Quoted in Article, "Challenges Abound in Creating Regulatory Framework for Mobile Medical Apps, Health IT" |
| 10/1/2012 | Bradley Merrill Thompson Quoted in Article, "Federal Task Force Recommends Stepped up Role for FCC in mHealth Policy" |
| 10/1/2012 | Bradley Merrill Thompson Quoted in Article, "Panel Discusses How New User Fee Law Changes Interactions Between FDA, Industry" |
| 9/27/2012 | Bradley Merrill Thompson Quoted in Article, "FCC to Hire Health Director, Improve mHealth Collaborations with FDA" |
| 9/26/2012 | Bradley Merrill Thompson Quoted in Article, "Judge Vacates Finding That Prevor Skin Wash Is Drug, Not Device, Sends Case Back to FDA" |
| 9/18/2012 | Bradley Merrill Thompson Quoted in Article, "FDA Guidance on Mobile Medical Apps Could Come in Early Fall, Attorney Says" |
| 9/12/2012 | Bradley Merrill Thompson Quoted in Article, "The FDA Takes On Mobile Health Apps" |

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| 8/7/2012 | Bradley Merrill Thompson Quoted in Article "Attorney Says Clarification of FDA Mobile Health Application Guidelines Needed" |
| 8/1/2012 | Bradley Merrill Thompson Quoted in Article, "Voices of Frustration, Uncertainty in Medtech Election Perspective" |
| 7/26/2012 | Bradley Merrill Thompson Quoted in Article, "Medical App Regulations, Device Security Share the Spotlight at mHealth World Congress" |
| 7/25/2012 | Bradley Merrill Thompson Featured on Radio Segment Discussing mHealth and Telemedicine |
| 7/25/2012 | Bradley Merrill Thompson Quoted in Article, "mHealth Congress: Some Mobile Apps Unduly Burdened by Regulation" |
| 7/10/2012 | Bradley Merrill Thompson Featured in NPR Segment, "When Does an App Need FDA's Blessing?" |
| 6/26/2012 | Bradley Merrill Thompson Quoted in Article, "FDA Legislation Clears House, Moves Closer to Final Senate Approval" |
| 6/22/2012 | Bradley Merrill Thompson Quoted in Article, "Health-Care Apps for Smartphones Pit FDA Against Tech Industry" |
| 6/20/2012 | Bradley Merrill Thompson Quoted in Article, "Tweaked FDA Bill Removes Hurdle to Medical App Guidance" |
| 6/20/2012 | Bradley Merrill Thompson Quoted in Article, "Path Opens Up for FDA Regulation of Mobile Medical Apps" |
| 6/19/2012 | Bradley Merrill Thompson Quoted in Article, "FDA Can Go Ahead With Mobile App Guidance" |
| 6/18/2012 | Bradley Merrill Thompson Quoted in Article, "Combination Products Coalition Zeroes in on Autoinjectors and Personalized Medicine" |
| 6/1/2012 | Bradley Merrill Thompson Quoted in Article, "New Law Cuts Medicare Payments for Clinical Tests" |
| 5/28/2012 | Bradley Merrill Thompson Quoted in Article, "FDA Mobile Medical App Guidance Faces Delay to 2013" |
| 5/21/2012 | Bradley Merrill Thompson Quoted in Article, "Latest Senate FDA Reform Bill Would Delay Guidance on Mobile Health Apps" |
| 5/17/2012 | Bradley Merrill Thompson Quoted in Article, "FDA: Bill Has Indirect Moratorium on Apps" |
| 5/15/2012 | Bradley Merrill Thompson Quoted in Article, "Senator Seeks Halt to FDA Moves on Mobile Medical Apps" |
| 4/16/2012 | Bradley Merrill Thompson Quoted in Article, "FDA Tangles with Wireless Medical-App Makers" |
| 3/28/2012 | Bradley Merrill Thompson Quoted in Article, "Bill Proposes Modernizing IVD Regulations" |
| 2/23/2012 | David Matyas, Wendy Goldstein, Bradley Merrill Thompson Quoted in Article, "Regulatory Demands to Spur Health M&A in 2012: Report" |
| 1/30/2012 | Bradley Merrill Thompson Quoted in Article, "FDA Urged to Issue New Draft Guidance on Mobile Medical Apps" |

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| 1/27/2012 | Bradley Merrill Thompson Quoted in Article, "mHealth Coalition Presses FDA to Revamp Mobile App Guide, Seek More Input" |
| 1/26/2012 | Bradley Merrill Thompson Quoted in Article, "MRC Pushes for More Time on FDA's Mobile Medical App Guidance" |
| 1/11/2012 | Bradley Merrill Thompson Quoted in Article, "Industry Tax, Changes at FDA, ACOs Among Key Issues for Industry in 2012" |
| 1/4/2012 | Bradley Merrill Thompson Provided Commentary in Article, "Examining IVD-Related Election Year Issues" |
| 12/12/2011 | Bradley Merrill Thompson Quoted in Article, "iPad: 'Wild West' of Medical Apps Seeks Sheriff" |
| 12/5/2011 | Bradley Merrill Thompson Quoted in Article About Mobile Health |
| 12/2/2011 | Bradley Merrill Thompson Quoted in Article, "FDA Releases Guidance on Companion Diagnostics" |
| 11/29/2011 | Bradley Merrill Thompson Quoted in Article, "New Coalition Will Attempt to Unite Stakeholders on Clinical Software Regulation" |
| 11/14/2011 | Bradley Merrill Thompson Quoted in Article, "Next Up for Washington Attorney: Regulatory Clarity for Clinical Decision Support Tools" |
| 11/7/2011 | Bradley Merrill Thompson Quoted in Article, "Part I: If You Write an App, the FDA Will Come" |
| 11/7/2011 | Bradley Merrill Thompson Quoted in Article, "Part II: What Does the FDA Want?" |
| 11/6/2011 | Bradley Merrill Thompson Quoted in Article, "Hospitals, Vendors Team to Influence FDA, HHS on Decision Support" |
| 11/1/2011 | Mark Lutes Quoted in Article, "Payers Gain Influence Over the Delivery Side of Healthcare Through Acquisition Deals" |
| 10/24/2011 | Bradley Merrill Thompson Quoted in Article, "Would a Fixed-Term FDA Commissioner Help Industry? Maybe, Maybe Not" |
| 10/3/2011 | Bradley Merrill Thompson Quoted in Article, "mHealth Reg Coalition Creates Risk Assessment Tool for FDA" |
| 9/21/2011 | Bradley Merrill Thompson Quoted in Article, "FTC Settles Cases Alleging Unsubstantiated Claims by Developers of Apps to Cure Acne" |
| 9/15/2011 | Bradley Merrill Thompson Quoted in Article, "FDA's Deferral to FTC on mHealth Enforcement Raises Questions" |
| 9/15/2011 | Bradley Merrill Thompson Quoted in Article, "Mhealth Advocates Press FDA to Consider Risk in Assessing Apps" |
| 9/13/2011 | Bradley Merrill Thompson Quoted in Article, "FDA Forum Explores Regulation of Mobile Medical Apps" |
| 9/13/2011 | Bradley Merrill Thompson Quoted in Article, "FDA Mobile Apps Workshop: When Is a Car a Medical Device Accessory?" |
| 9/9/2011 | Bradley Merrill Thompson Quoted in Article, "US Regulators Remove Two Acne Medical Apps" |
| 9/2/2011 | Bradley Merrill Thompson Quoted in an Article About Hacking Mobile Devices |

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| 8/31/2011 | Bradley Merrill Thompson and Jason Brooke Coauthor Chapter on *In Vitro* Diagnostic Devices, in Medical Devices Answer Book |
| 8/10/2011 | Bradley Merrill Thompson Quoted in Article About FDA's Mobile Health Care Application Guidelines |
| 8/1/2011 | Bradley Merrill Thompson Quoted in Article About FDA Mobile Medical Apps |
| 7/26/2011 | Bradley Merrill Thompson Quoted in Article About FDA's Mobile Apps Guidance |
| 7/25/2011 | Bradley Merrill Thompson Quoted in Article About FDA Mobile Medical Apps |
| 7/25/2011 | Bradley Merrill Thomson Quoted in Blog About FDA Draft Guidance |
| 7/21/2011 | Bradley Merrill Thompson Quoted in Article About Proposed Rule for Mobile Apps |
| 7/21/2011 | Bradley Merrill Thompson Quoted in Article About FDA's Mobile App Guidance |
| 7/20/2011 | Bradley Merrill Thompson Comments on Device Apps Guidance |
| 7/20/2011 | Bradley Merrill Thompson Quoted in an Article About FDA's Proposed Guidance for Certain Mobile Medical Apps |
| 7/19/2011 | Bradley Merrill Thompson Featured in Article About Mobile Medical Apps |
| 7/19/2011 | Bradley Merrill Thompson Appeared in Article About FDA's Mobile Apps Guidance |
| 7/7/2011 | Bradley Merrill Thompson Quoted in Article About mHealth Software Apps |
| 7/7/2011 | Bradley Merrill Thompson Featured in Article About Classification for mHealth Devices |
| 6/15/2011 | Bradley Merrill Thompson Featured in Article About FDA Draft Guidance on "Research Use Only" for Diagnostic Devices |
| 6/6/2011 | Bradley Merrill Thompson Quoted in Article About Research-Only Test |
| 5/22/2011 | Bradley Merrill Thompson Quoted in Article About Regulatory Issues Health IT Firms Face |
| 5/19/2011 | Bradley Merrill Thompson Quoted in Article About Proposing That FDA Regulate mHealth Accessory Products |
| 5/15/2011 | Bradley Merrill Thompson Quoted in Article About In-Vehicle Mobile Health Concept |
| 5/9/2011 | Bradley Merrill Thompson Quoted in Article About FDA Guidance on Research-Use Tests |
| 5/9/2011 | Bradley Merrill Thompson Quoted in Article About Mobile Health App Guidance |
| 4/25/2011 | Bradley Merrill Thompson Quoted in Article About FDA Rules for Combination Products |
| 4/21/2011 | Bradley Merrill Thompson Quoted in Article About Device Data Systems |

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| 3/15/2011 | Bradley Merrill Thompson, Leah Kendall: Article on Top Ten FDA Development Issues for 2011 |
| 3/15/2011 | Bradley Merrill Thompson Quoted in Report About New Medical Devices |
| 2/24/2011 | Bradley Merrill Thompson Quoted in Article About FDA Final Rule for Reclassification of Medical Devices |
| 2/18/2011 | Bradley Merrill Thompson Comments on Article About FDA Rule of Mobile Health |
| 2/15/2011 | Bradley Merrill Thompson Writes on Understanding the FDA's New MDDS Rule |
| 2/10/2011 | Bradley Merrill Thompson Quoted in Article About Clearance of First Diagnostic Radiology App |
| 2/9/2011 | Bradley Merrill Thompson Quoted in Article About Radiology Mobile Apps |
| 2/1/2011 | Bradley Merrill Thompson Quoted in Article About FDA Processes |
| 1/14/2011 | Bradley Merrill Thompson Comments on Mobile Health Regulatory Plan |
| 1/2/2011 | Bradley Merrill Thompson Quoted on mHealth Issues |
| 12/22/2010 | Bradley Merrill Thompson Comments on Impact of Midterm Elections on the IVD Industry |
| 10/20/2010 | Thompson Comments on FDA Probe on Recalled Devices |
| 10/15/2010 | Thompson Quoted in E-book About mHealth |
| 9/14/2010 | Thompson Comments on m-Health Regulation |
| 9/13/2010 | Thompson Quoted on FDA Guidance on Mobile Health Technology |
| 9/8/2010 | Thompson Comments on How FDA Is Evaluating Medical Smartphone Apps |
| 8/31/2010 | Thompson Quoted in Article About FDA Surveillance of App Stores |
| 8/31/2010 | Thompson Interviewed on App Store Monitoring by the FDA |
| 8/25/2010 | Thompson Featured in Article About FDA Regulation of Mobile Health Products |
| 7/14/2010 | Thompson Comments on Formation of mHealth Regulatory Coalition |
| 6/17/2010 | Thompson Quoted in Article About Medical Smartphone Apps Industry |
| 6/15/2010 | Thompson Comments on Formation of Mobile Health Coalition |
| 6/1/2010 | Thompson Quoted in Article About Radiological Devices |
| 5/17/2010 | Thompson Quoted in Article About Mobile Medical Devices |
| 4/9/2010 | Thompson Quoted On Expected Regulation Of Mobile Health Devices |
| 3/26/2010 | Thompson Interviewed On FDA and FCC Approvals For Smart Phones |
| 2/26/2010 | Thompson Quoted On Possible FDA Oversight Of Health Information Technology |
| 2/15/2010 | Thompson Quoted On Benefits For Health IT Software Developers |

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| | of FDA Oversight |
| 2/8/2010 | Thompson Quoted On Need For Regulatory Clarity In Mobile Health Devices Field |
| 2/1/2010 | Thompson Quoted On FDA's Proposed Adverse Event Reporting Requirements |
| 1/28/2010 | Thompson Quoted On FDA's ‘Streamlined Approach' To Combination Products |
| 11/25/2009 | Thompson Quoted On Need To Expedite OIVD Review Process |
| 11/19/2009 | Thompson Discusses How FDA May Regulate Mobile Health Technology |
| 10/2/2009 | Thompson Quoted On FDA's Proposed Rule on Postmarket Safety Reporting Requirements For Combination Products |
| 9/24/2009 | Thompson Quoted On New FDA Framework for Combination Products |
| 9/23/2009 | Thompson Quoted On FDA Rule On Good Manufacturing Practices For Combo Products |
| 9/18/2009 | Thompson Quoted On FDA Rules To Be Issued For Comments |
| 9/11/2009 | Thompson Quoted On Planned FDA, Industry Meeting |
| 9/7/2009 | Bradley Thompson Quoted On FDA Good Guidance Practices |
| 8/26/2009 | Bradley Thompson Quoted On FDA Regulation of Mobile Phones |
| 8/1/2009 | Bradley Thompson Quoted on Rise of Adverse Events Reported for Medical Devices |
| 7/1/2009 | Bradley Thompson Quoted on Regulatory Issues for Convergent Technologies |
| 6/17/2009 | Bradley Thompson Quoted On Move Toward Transparency At FDA |
| 6/5/2009 | Bradley Thompson Quoted On Priorities Of Combination Product Industry |
| 6/1/2009 | Bradley Thompson Quoted On FDA Regulation of Laboratory Developed Tests |
| 2/16/2009 | Bradley Thompson Quoted on FDA Review Process for High-Risk Medical Devices |
| 11/20/2008 | Thompson Quoted on Gunvalson Case and Drug Companies |
| 10/10/2008 | Bradley Thompson Quoted on Impact of Gunvalson Case on Medical Trials |
| 9/4/2008 | Brad Thompson Quoted on ‘Unique' Case Over Access to Experimental Drug |
| 5/5/2008 | Bradley Thompson Quoted On Labs' Compliance With FDA Guidelines |
| 2/25/2008 | Bradley Thompson quoted on Drug Companies' Hopes for Combination Product Policy Development |
| 10/16/2007 | Thompson Interviewed on Medical Technology Regulation |
| 6/15/2007 | Bradley M. Thompson Named as Co-Chair of ABA’s Food and Drug Law Committee |
| 5/2/2007 | Epstein Becker & Green Announces Launch of EBG ClinTrials Law |

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| | Initiative |
| 5/2/2007 | *HealthLaw360* Profiles EBG ClinTrials Law Initiative |

## EVENTS

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| 01/24/13 | Medical Devices and the FDA - Tips for Researchers: Medical Device Apps |
| 11/09/12 | Diabetes Technology Meeting: Overcoming Regulatory Hurdles to Make Wireless Diabetes Real |
| 11/07/12 | DIA Workshop: Regulatory Considerations for Drug/Device Combinations and Companion Diagnostics |
| 10/27/12 | 2012 RAPS Annual Conference: Combination Product Regulation for the US Market |
| 10/16/12 | 2012 CEA Industry Forum: Health and Fitness Tech - the Consumer, the Product, and Regulation |
| 10/10/12 | Med Tech Webcast Series: Calculating the Medical Device Tax |
| 10/02/12 | FDLI's Advertising and Promotion Conference: Social Media in Medical Product Companies: Using Emerging Technology to Communicate About Products |
| 09/19/12 | Med Tech Webcast Series: Medical Device Investigations |
| 07/25/12 | The 4th Annual mHealth World Congress: Keynote Panel Discussion: Mobile Medical Regulation in the U.S. and Worldwide |
| 06/18/12 | Medical Device Regulation and Litigation Conference: Case Study on Medical Device Recalls and Post-Market Reporting |
| 06/13/12 | Continua Summer Summit 2012: Update on US and EU Connected Health and Software Law |
| 05/16/12 | iMedicine & Mobile Life Sciences World Summit: FDA's Regulation of mHealth and Decision Support Software: Past, Present and Future |
| 04/28/12 | ATA Annual Meeting "Making mHealth Work" Education Seminar |
| 04/25/12 | FDLI Annual Conference: Social Media & New Technology: FDA Guidance, Mobile Apps & Digitization |
| 03/13/12 | FDLI Introduction to Medical Device Law and Regulation: Promotion and Advertising |
| 03/07/12 | Continua Spring Summit 2012: FDA and Regulatory Sessions |
| 12/06/11 | 2011 mHealth Summit: The mHealth Regulatory Coalition Presents and Reviews Its Final Mobile Medical Apps Guidance Recommendations to FDA |
| 05/23/11 | 2011 ILSI BioMed Conference: FDA's Evolving Regulation of Mobile Health |
| 05/18/11 | TechAmerica Conference: Future Regulation of mHealth Technologies |
| 05/01/11 | ATA Annual Meeting: Future Regulatory Pathways for mHealth |
| 04/28/11 | 2011 AMDM Conference: Reagent Marketing Compliance: Controlling Your Intended Use |
| 04/04/11 | FDLI Annual Meeting: Analyzing Hypothetical Cases Involving FDA Regulation of mHealth |

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| 02/18/11 | FDLI Introduction to Medical Device Law and Regulation Conference: Device Labeling and Promotion |
| 11/08/10 | 2010 mHealth Summit |
| 10/24/10 | RAPS Annual Conference: Shedding Light on New Rules for Adverse Event Reporting |
| 09/23/10 | Combination Products Regulatory & Compliance Summit |
| 09/23/10 | Disruptive Women in Healthcare 2010 Breakfast Series: Wired Women: Connected Health Care Decision Makers |
| 09/08/10 | 2nd International mHealth Networking Conference |
| 02/10/10 | Continua Winter Summit 2010 |
| 02/03/10 | mHealth Networking Conference |
| 01/21/10 | RAPS Webcast: Postmarket Safety Reporting for Combination Products: Understanding and Exploring the Proposed Rule |
| 01/12/10 | RAPS: CGMPs for Combination Products - An Interactive Analysis with Industry and FDA |
| 10/29/09 | CommNexus: Regulatory Issues for Wireless Health Companies |
| 10/16/09 | AHLA Life Sciences Institute: Combination Products Update |
| 10/14/09 | FDLI Enforcement and Litigation Conference |
| 10/14/09 | AHLA Life Sciences Law Institute |
| 10/07/09 | Continua Fall Summit 2009 |
| 09/14/09 | 2009 RAPS Annual Conference & Exhibition |
| 06/23/09 | Continua Summer 2009 Summit |
| 06/22/09 | Sixth Annual Healthcare Unbound Conference & Exhibition |
| 06/04/09 | Thompson Publishing: Managing Communication Before Device Approval |
| 06/02/09 | CHI Conf: Update on Regulatory Requirements for Combination Products |
| 04/14/09 | BNA: Sponsor-CRO Relationships: Managing Risk |
| 02/26/09 | FDLI: Introduction to Medical Device Law and Regulation: A Program on Understanding How the Government Regulates the Medical Device Industry |
| 10/31/08 | Continua Health Alliance Fall Summit |
| 09/30/08 | IMDMC: "Sponsor-CRO Relationships: Managing Risk" |
| 09/15/08 | Combination Products: Cross Labeling and Single Entity Labeling |
| 05/12/08 | RAPS: Managing Communication Before Device Approval |
| 04/24/08 | AMDA: Analyte Specific Reagents (ASRs) Frequently Asked Questions |
| 03/26/08 | Third Annual Medical Device Regulatory, Reimbursement and Compliance Congress at Harvard |
| 02/26/08 | ACI-CRO Relationships: Managing Risk |
| 02/11/08 | FDLI: Managing and Complying with Clinical Trial Quality Obligations for Sponsors |
| 12/20/07 | hcPro web cast "Medical Device Promotion: Avoid Off-label Pitfalls |

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| 12/06/07 | Adva Med: Working With FDA to Develop Policy |
| 08/07/07 | American Medical Association: "Advanced Issues in Labeling and Promotion |
| 07/17/07 | ACI: Managing and Complying with Clinical Quality Obligations |
| 04/27/07 | RAPS: The Future of Combination Products |
| 04/25/07 | PharmaMedDevice 2007: Cross Labeling Combination Products and User Fees |
| 01/25/07 | FDLI's Introduction to Medical Device Law and Regulation Workshop: Understanding How FDA Regulates the Medical Device Industry |
| 08/28/06 | NACDS: Medicare Competitive Bidding for DMEPOS: Stakeholder Perspectives |
| 06/21/06 | CBI: Off Label Promotion of Medical Devices |