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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.

Multidisciplinary Consulting

Mr. Thompson serves as Chairman of the Board of EBG Advisors, Inc. Affiliated with the law firm, EBG Advisors is a Washington, D.C., based consultancy that takes a multidisciplinary approach to helping health care and life sciences companies navigate the many obstacles that they face. EBG Advisors is a network of international attorneys, regulatory affairs professionals, reimbursement experts, engineers, clinicians, quality systems advisors, and other professionals who specialize in providing coordinated guidance and solutions across various segments of the health care industry. In his role with EBG Advisors, Mr. Thompson leads multidisciplinary teams delivering those integrated services.

Digital Health Practice

In the Digital Health Initiative at the firm, Mr. Thompson 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 served on a workgroup created by the U.S. Department of Health and Human Services (HHS) and the Federal Communications Commission (FCC), charged with identifying key considerations to improve patient safety and promote innovation in health information technology, including mobile medical applications. He co-chaired the workgroup's Regulations Subcommittee, which focused on identifying regulatory best practices for such technologies. Mr. Thompson regularly conducts educational programs on digital health regulation and blogs for Mobihealthnews.com.

Counseling, Investigations, and Defense

Mr. Thompson regularly defends companies receiving FDA warning letters, on a wide gamut 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.

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.

Policy and Industry Advocacy

For trade associations, Mr. Thompson has served as regulatory counsel for Continua Health Alliance; 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 over 30 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.

Mr. Thompson has also served 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.

Learn more about Mr. Thompson's Coalition Advocacy efforts.

Legislative Advocacy

In legislative matters, Mr. Thompson has over the years actively worked to ensure that health care economic information can be appropriately shared without running afoul of FDA requirements, and seeking to secure stakeholders a reasonable avenue of appeal when Medicare contractors deny claims. In both cases, Congress enacted responsive legislation.

Mr. Thompson has also testified before congressional subcommittees:

- Before the Subcommittee on Communications and Technology, House Committee on Energy and Commerce, March 19, 2013, on FDA regulation of mobile medical applications and devices under its medical device authority.
- 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.

Academia and Publishing

Mr. Thompson has taught food and drug law at Indiana University School of Law—Indianapolis and Columbia Law School, and has guest lectured at Cornell Tech, on clinical decision support software and algorithms.

Mr. Thompson's publications include:

- *FDA Regulation of mHealth (Second Edition)* (MobiHealthNews, November 2013)
- *Off-Label Communications:A Guide to Sales and Marketing Compliance*, FDLI (2008, 2010, 2012, and 2014 - fourth edition) (Co-Authored One Chapter)
- Chapter 5, "*In Vitro* Diagnostic Devices," in *Medical Devices Law and Regulation Answer Book 2011-12* (PLI, Sept. 2011)
- *In Vitro Diagnostics: The Complete Regulatory Guide* (FDLI, 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)

Honors

Mr. Thompson was elected by his peers as a Fellow of the American Bar Association, and he has received an "AV Preeminent" Peer Review Rating by Martindale-Hubbell, signifying the highest level of professional excellence. He 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 to 2017). He was selected by his peers for inclusion in *The Best Lawyers in America*® (2015 to 2020) in the field of FDA Law and included on the *Indiana Super Lawyers* list (2004 to 2006) and *Washington DC Super Lawyers* list (2013 to 2019) in the areas of Food and Drugs, Administrative Law, and Health Care. Additionally, Mr. Thompson was recommended in the Life Sciences category by *The Legal 500 United States* (2014).

Community Projects

Whenever Brad gets free time, he loves to meet and photograph people who serve others. Over the last few years, he has been focused on the "Gospel Justice Story Project," through which he collects and reports stories on what Christian legal aid attorneys do. He has also contributed to the Gospel Justice Initiative blog, "Do Likewise." Brad released his first multimedia film in July 2013, entitled "Gospel Justice: The Guardian," and wrote and photographed Christians at work serving others for a book called *Macedonia, Indiana.* Learn more about these projects.

Education

- University of Michigan Law School (J.D., cum laude, 1986)
- University of Illinois at Urbana-Champaign (M.B.A., 1983)
- University of Illinois at Urbana-Champaign (B.A., cum laude, 1982)

Court Admissions

- Supreme Court of the United States

Bar Admissions

- District of Columbia
- Indiana

Practice Areas

- Digital Health
- Food and Drug Law
- Government and Commercial Reimbursement
- Product Marketing

Industries

- Artificial Intelligence
- Health Care and Life Sciences Industry
- Medical Devices and Combination Products
- Pharmaceuticals
- Suppliers & Distributors
- Technology, Media & Telecommunications

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)