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## Food and Drug Law Institute Announces New Board Member and Executive Committee Updates

Washington, DC – The Food and Drug Law Institute (FDLI) is pleased to announce the appointment of Anne K. Miller, Medtronic to its <u>Board of Directors</u>. She joins 15 other highly respected leaders in the food and drug law field in serving on the FDLI Board.

Anne K. Miller is a Senior Strategic Legal Counsel at Medtronic, where she focuses on FDA regulatory requirements for medical devices, and provides expert advice on quality system issues, FDA inspections, and responses to 483s and Warning Letters. She also specializes in post-market regulatory requirements, including complaint handling, Medical Device Reporting, risk assessments, and recall strategy and execution. Anne's expertise extends to post-market issues related to combination products, including GMP and post-market safety reporting. She also offers guidance on global quality system issues, such as Notified Body audits and the European Union Medical Device Regulation. Before joining Medtronic in 2007, Anne spent four years in the FDA's Office of the Chief Counsel, where she counseled FDA clients and handled enforcement matters and defensive litigation. She has served on the FDLI Enforcement, Litigation, and Compliance Conference Planning Committee and has been a speaker on several panels. Anne holds a BA in English from Gustavus Adolphus College and a JD from Mitchell Hamline School of Law.

In addition, FDLI announces the following Executive Committee changes: Vernessa T. Pollard, DLA Piper, has been named Chair and Freddy A. Jimenez, Celldex Therapeutics, Inc. has moved to Immediate Past Chair. Also serving on the Executive Committee are Secretary and General Counsel, Amy Norris; Treasurer, Melanie K. Gross, Genentech, Inc; and Christine M. Simmon, President and CEO, FDLI.

FDLI thanks outgoing Board of Directors member Sonali P. Gunawardhana, Assistant General Counsel, Regulatory Law, BD. Gunawardhana made invaluable contributions to FDLI and the broader food and drug law community through her Board service.

The Food and Drug Law Institute (FDLI) is a nonprofit membership organization that offers education, training, publications, and professional networking opportunities in the field of food and drug law. As a neutral convener, FDLI provides a venue for stakeholders to inform public policy, law, and regulation.