Committee on Energy and Commerce
U.S. House of Representatives
Witness Disclosure Requirement - "Truth in Testimony"
Required by House Rule XI, Clause 2(g)(5)

1. Your Name: Patricia Brown Shrader		
2. Your Title: Vice President, Global Regulatory Affairs, Medtronic		
3. The Entity(ies) You are Representing: AdvaMed		
4. Are you testifying on behalf of the Federal, or a State or local government entity?	**Yes**	**No** XX
5. Please list any Federal grants or contracts, or contracts or payments originating with a foreign government, that you or the entity(ies) you represent have received on or after January 1, 2015. Only grants, contracts, or payments related to the subject matter of the hearing must be listed. None.		
6. Please attach your curriculum vitae to your completed disclosure form.		

Signature: [redacted] **Date:** 29 April 17

PATRICIA B. SHRADER
Vice President, Global Regulatory Affairs
Medtronic plc

Pat assumed the role of Vice President, Global Regulatory Affairs for Medtronic, the world's largest stand-alone medical device company, in April 2011. In this new role, Pat has responsibility for developing the vision and strategy for the global regulatory organization for Medtronic and assuring best practices in the regulatory arena. In 2015, Medtronic acquired Covidien plc, broadening the Medtronic portfolio.

Immediately prior to joining Medtronic, Pat was Senior Vice-President, Regulatory and External Affairs at Becton Dickinson and Company. She reported to the CEO of BD and was a member of the BD Office of the CEO, the BD Operating Committee, and the BD Leadership Team. She was an officer of the corporation and participated in company strategy development and high-level operational decisions. Her regulatory responsibilities included establishing vision, direction, and policy for company-wide global programs in Regulatory Affairs and Compliance, as well as working directly with worldwide businesses as needed. A corporate staff reporting to Pat covered BD's premarket regulatory affairs, and postmarket regulatory compliance program, including regulatory audits. Business and regional heads of regulatory and compliance reported either directly or dotted line to this position. Pat was responsible for all negotiations with FDA and participated directly in all non-routine interactions with the agency.

In the external affairs role, Pat had worldwide responsibility for public policy and government relations, reimbursement, communications and public relations, and social investing. Key roles included development of public policy strategies, public policy positions consistent with BD business strategies, interactions with government officials worldwide, either directly or through an established BD network of professionals, messaging related to public policy positions and company reputation, and alignment of social investing with overall business strategies. Pat established the Washington, D.C. office of BD in 2005; the office now houses federal and state public policy and government relations associates, reimbursement staff, and market development staff.

Pat also served in an interim role leading the Corporate and Global Quality Organization for BD, from February 2009 until October 2010. During that time, she established mission, vision, and strategic objectives for BD global

Quality and reorganized the corporate Quality function, enabling more efficient and effective support of businesses and regions.

Prior to joining the corporate staff at BD, Pat served as Director, Regulatory Affairs for BD's Diagnostic Systems (BDDS) business unit, where she supervised and developed regulatory staff and regulatory capabilities for the site, including providing training and mentoring for RA, R & D, Medical, and Marketing staff, enabling efficient submissions processes for BD products worldwide. From September 1997-December 1998, she also was responsible for BDDS Quality Assurance and Quality Control organizations. This involved setting policy and providing re-direction for the quality organization, along with overall responsibility for compliance with FDA Quality Systems regulation and ISO 9001 and 13485. In this role, her key accomplishments included the following: making key staffing and organizational decisions for both the regulatory and quality functions, managing an $8 million budget and a staff of 100. She was responsible for re-establishing productive and harmonious relationships with FDA in the areas of compliance and device evaluation. Her trade association work resulted in the release of FDA guidance documents on PMA supplements, 510(k)s for changes to devices, research use and investigational use in vitro diagnostic assays, use of symbols in labeling for in vitro diagnostics devices. She also helped with the shifting of CLIA complexity categorization decisions from CDC to FDA.

Before joining BD, Pat was an attorney with the Washington, DC. firm Hogan & Hartson (now Hogan Lovells), from 1988-1995, as a member of the FDA Practice Group.

Hogan & Hartson's medical device practice group represented several hundred medical device companies in the U.S. and internationally. Attorneys functioned as legal advisers and regulatory consultants to clients ranging from small start-up companies to large multinational corporations on all issues involving FDA regulation of medical devices and related products.

In this role, Pat's responsibilities included conducting quality audits for a large variety of medical device companies, manufacturing in vitro diagnostic reagents and instruments, cardiovascular, orthopedic, radiological, ob/gyn, surgical, general hospital, infection control, ophthalmic, and dental devices. She also directed the development and implementation of quality systems designed to meet GMP and ISO requirements for several client companies and drafted policies and procedures covering all areas of GMP. Pat assisted companies in preparing for FDA inspections, responding to inspectional observations, managing Warning Letters and other enforcement and legal actions related to GMP deficiencies and other regulatory issues.

As project leader for product submission teams, Pat coordinated the activities of attorneys, regulatory specialists, and company personnel in developing strategies and documentation for investigational device exemption applications, premarket approval applications, and premarket notifications and interacted with key personnel at FDA on a regular basis, to discuss regulatory strategies and assist with issues in the premarketing clearance process.

Pat started her career in the medical device and diagnostics industry with Whittaker Bioproducts, Inc. (now part of Lonza Corporation). There she served in a variety of roles, including quality control technician, quality assurance supervisor, and Director of Regulatory and Quality Assurance. In this capacity, she established regulatory and quality policies and procedures for the company and served as inspection coordinator for all regulatory inspections, including FDA and USDA.

Among Pat's professional activities are participation in the Advanced Medical Technologies Association (AdvaMed), as co-chair of the Technology and Regulatory group and Special Representative to the T & R Board Committee. Pat also chairs the Postmarket Policy Group at AdvaMed, which is currently focused on the development of NEST, the National Evaluation System for Technology. She also serves as a member of numerous working groups at AdvaMed.. From 2014-2016, Pat also served on the Planning Board, chartered by FDA and facilitated by the Brookings Institute and later, the Duke Margolis Center. This group developed the vision and initial strategy for NEST.

Pat is a member of the Food and Drug Law Institute, where she previously served on the Board of Directors and chaired the Finance Committee, and the Regulatory Affairs Professionals Society (RAPS). She was a member of the industry team for MDUFA I through IV, the medical device user fee program, a regular speaker at various trade and professional meetings and has published on regulatory issues

Pat is a 1988 graduate of Georgetown University Law Center and is a member of the bars of Pennsylvania, Maryland, and the District of Columbia. She holds an M.A. from Hood College and a B.A. from McDaniel College.