# 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)**

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|---|---|---|
| **1. Your Name: Diane Johnson** | | |
| **2. Your Title: North American Policy and Intelligence, Medical Devices** | | |
| **3. The Entity(ies) You are Representing: Johnson & Johnson** | | |
| **4. Are you testifying on behalf of the Federal, or a State or local government entity?** | **Yes** | **No** X |
| **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, 2013. Only grants, contracts, or payments related to the subject matter of the hearing must be listed.**<br><br>**None to the best of my knowledge.** | | |
| **6. Please attach your curriculum vitae to your completed disclosure form.** | | |

**Signature:** [redacted] **Date: July 11, 2016**

# DIANE MACCULLOCH JOHNSON

[redacted]

## PROFESSIONAL EXPERIENCE

**JOHNSON & JOHNSON,** New Brunswick, New Jersey 2011 to present

**North America Regulatory Affairs, Policy and Intelligence, Medical Devices**
Provides key strategic direction related to Regulatory Affairs Policy and Intelligence for the United States and Canada. Develops regulatory goals to align with business goals as they pertain to new products, due diligence, license and acquisitions, risk management, development, product life cycle management, regulatory submissions and approvals. Collaborates with Regulatory colleagues on ideal regulatory pathways for growth, including planning and developing regulatory capabilities and strategies to support the growth of the businesses across the sector. Provides guidance to operating company regarding working with FDA and other regulatory agencies and notified bodies. Communicates and prepares the franchises for regulatory trends and changes, and where appropriate, influences and shapes the regulatory environment, as well as industry positions. Johnson & Johnson subject matter expert on digital health, combination products, and divestitures.

**BLACKSTONE MEDICAL,** Wayne, New Jersey (now part of Orthofix) 2004 to 2011

**Senior Vice President Regulatory Affairs/Quality Assurance/Clinical Affairs** 1/09 to 11/11
Advised on the consolidation of multiple regulatory, clinical, and quality facilities into a single national facility.

- Conducted post-market clinical studoes to support transition and sales growth of a 40 million dollar adult stem-cell allograft business. Conducted team meetings with the clinical departments in various locations, authored Trinity Evolution Cervical and Lumbar protocols, selected sites, obtained WIRB approvals.
- Developed initial plan for consolidating the Quality Assurance aspects of multiple facilities, ensuring continued compliance with applicable regulations.
- Implemented Risk Management/Clinical Evaluation process for spinal products.
- Wrote clinical reports as needed to support marketing initiatives (e.g., case studies, case series, and reimbursement papers).
- Continued monitoring Advent IDE study, including periodic Clinical Events Committee meetings and FDA reports. Negotiated ongoing follow up requirements.

**Senior Vice President Research/ Development, Regulatory/Quality/Clinical** 6/08 to 1/09
Managed all aspects of product realization, including design, testing, design transfer, conducting clinical studies, and obtaining approvals.

- Consolidated three separate engineering teams, leading to reduction in overall engineering expenses from 15% to 9%, and maintained this spending level in a time of declining sales.
- As a member of the executive team, helped implement a change in the distribution network/ customer base that represented 60% of sales within two years. Oversaw engineering pipeline to drive sales recovery.

**Group Vice President, Non-Fusion Technologies** 11/04 to 6/08
Directed the business unit that develops Class III spinal implants. Oversaw all aspects business including budgets, schedules, marketing, and product development pipeline.

- Implemented company-wide health-care compliance policy, minimizing impact to the company during a subsequent investigation by the Inspector General. Policy integrated charitable giving as well as research studies, allowing for the continued funding of multiple clinical programs including a 20 million dollar IDE study.
- Instituted an electronic data capture system for clinical data that reduced the need for clinical staff by 50% as compared to a paper based system.
- Managed the surgeon design team including the Principle Investigator and company Medical Director.

**Director, Clinical Affairs** 2/04 to 11/04

Responsible for designing and conducting clinical investigations on Class III spinal devices, including obtaining approval from the ethics committees and Competent Authorities in Europe, and the Institutional Review Boards and the Food and Drug Administration in the United States.

- Integrated off-site operations into company infrastructure. Received approval for the first company IDE in 28 days. Created all required clinical procedures and hired staff leading to study initiation in less than five months.
- Incorporated a Bayesian statistical analysis into IDE, which was expected to shorten the study by ten months.

Company was sold to Orthofix International in September of 2006.

**SPINE NEXT**, Jacksonville, Florida 2003 to 2004

**Director, Regulatory Affairs**

Accepted this one year assignment to ensure adherence to a non-compete with a former employer. Managed the planning, budgeting, and execution of all regulatory activities required to obtain worldwide commercial clearances for products. Implemented and oversaw applicable Quality Systems. Served as primary corporate liaison with all regulatory agencies.

- Negotiated the IDE study design with the Surgeon Advisory Board and BOD. This management team was not familiar with FDA requirements, and there was no consensus on the potential impact of the study design on future reimbursement.
- Submitted the company's first six 510(k)s, communicating requirements and assembling data with a team of non-US based engineers.
- Implemented quality systems and clinical procedures in three months.

**SPINAL DYNAMICS CORPORATION,** Seattle, Washington 1997-2003

**Vice President, Regulatory Affairs/Quality Assurance** 2/98 to 2/03

Managed all regulatory activities required to obtain worldwide commercial clearances for products. Executed clinical trials. Served as primary corporate liaison with all regulatory agencies.

- Obtained the first IDE approval for a cervical disc implant. Negotiated with FDA on all aspects of pre-clinical testing (mechanical, *in vitro*, *in vivo*), while communicating with the BOD and participating in obtaining additional venture capital funding.
- Implemented human resources policies and managed for four years. Authored employee handbook and safety manual and implemented expanded employment benefits programs. Negotiated associated expenses with the BOD.
- Maintained company liability insurance program, obtaining quotes and selecting cost-effective coverage. Compiled all insurance applications, including the founding-Neurosurgeon's medical liability policy.
- Participated in developing reimbursement strategies for conducting clinical investigations in the United States, and prepared reimbursement dossiers for use during US clinical investigations and European market launch.

**Director, Regulatory Affairs** 9/97 to 2/98

Planned and budgeted for all regulatory and clinical activities.

- Implemented all required quality systems in six months, leading to certification to ISO certification to 13485 following initial inspection.

Company was sold to Medtronic Sofamor Danek.

**HEART TECHNOLOGY,** Seattle, Washington 1995 to 1997

**Manager, Regulatory Affairs**

Developed regulatory strategies and supervised the preparation of world-wide regulatory submissions to support domestic and international distribution of products, including supervising clinical staff.

- Conducted IDE studies supporting new indications that supported continued higher reimbursement.
- Responded to two warning letters received by the company prior to my employment. Resolved all GMP issues within 18 months, including implementing Design Controls. Negotiated continued distribution during this time with FDA.

Company was sold to Boston Scientific/Scimed.

**FOOD AND DRUG ADMINISTRATION,** Rockville, MD 1990 - 1995

**Senior Scientific Reviewer**

Reviewed marketing applications for cardiovascular devices, in particular IDEs and PMAs for heart valves, 510(k)s for annuloplasty rings, and IDEs for heart occluders. Reviewed fatigue studies on a variety of permanently implanted devices such as stents and endovascular grafts. Developed guidance documents for newly introduced devices, and appointed to ISO committee for cardiac valves (ISO 5840).

- Eliminated a backlog of PMA applications for pre-amendment heart valves which had existed for three years. Approved five original PMA applications in one fiscal year.
- Approved the first three IDEs for a new technology (stentless heart valves).
- Upgraded the FDA guidance for heart valves to include fracture mechanics, echodoppler requirements, and a revised statistical method for conducting the clinical trial.

**HERCULES**, Wilmington, Delaware 1989 to 1990

**Technical Service/ Development Engineer**

Developed applications utilizing a liquid molding resin. Resolved customer production issues to support sales. Supervised operators of the prototype molding facility. Product line was sold to a competitor.

**E.I. DuPONT,** Aiken, South Carolina 1988 to 1989

**Materials Consultant**

Conducted field-failure analysis in a nuclear facility. Projects primarily associated with the application and/or failure of polymeric materials and composites. Facility was sold to Westinghouse.

## EDUCATION

B.S. in Materials Engineering
M.S. in Materials Engineering
Drexel University, Philadelphia, Pennsylvania

## PUBLICATIONS

Grunkemeier, GL, Johnson, DM, and Naftel, NC, ”Sample Size Requirements for Evaluating Heart Valves with Constant Risk Events”, Journal of Heart Valve Disease, 1994; 3, 53-58

Johnson, DM, Chwirut DJ, Regnault, WF, "FDA's Requirements for In-Vitro Performance Data for Prosthetic Heart Valves", Journal of Heart Valve Disease, 1994; 3, 228-234

Johnson, DM, Sapirstein, W, "FDA's Requirements for In-Vivo Performance data for Prosthetic Heart Valves", Journal of Heart Valve Disease, 1994; 3, 350-355