PHILIP R. DESJARDINS, J.D.

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EXPERIENCE

Johnson & Johnson, Washington, DC **2015-Present**
Vice President, Global Regulatory Affairs Policy & Intelligence, Medical Devices

- Oversee global regulatory policy activities by creating a unified and consistent global policy voice across the J&J medical device (MD) segment including Ethicon, Cardiac and Specialty Surgery, DePuy Synthes, Diabetes Care, and Johnson & Johnson Vision.
- Serve as the global policy representative of the MD Regulatory Leadership Team and global MD representative to J&J's cross-sector Enterprise Policy Leadership Team.
- Manage a globally diverse team of regulatory policy professionals (comprised of attorneys, surgeons, & other RA professionals) in the U.S., Europe, China, Canada, and Latin America.
- Manage J&J MD organizational relationship with top tier global health authorities including FDA and European Notified Bodies.
- Lead global health authority policy outreach activities for MD businesses, with focus on harmonizing global requirements.
- Provide strategic regulatory advice to business and regulatory leaders, focusing on innovative products and innovative regulatory strategies.
- Oversee J&J's regulatory implementation activities, including preparing current and future portfolio for the new European Medical Device Regulation (MDR) requirements.
- Provide primary regulatory and policy support for J&J's evidence generation initiatives, including Real World Evidence and Patient Generated Health Data.
- Create and support third party coalitions and partnerships to drive global harmonization.
- Sponsor of and mentor for J&J's Regulatory Affairs Leadership Development Program, focused on transforming high potential mid-level RA talent into future leaders.
- Represent and present J&J positions at Industry meetings (e.g., AdvaMed and CIMDR annual meetings).

Advanced Medical Technology Association (AdvaMed), Washington, DC
Co-Chair, Technology and Regulation Committee **2017-Present**

- Serve as AdvaMed member company regulatory leadership for issues facing the medical device industry.
- Advise AdvaMed staff in efforts to improve the regulatory environment for regulated industry, including such efforts as 510(k) reform, postmarket surveillance and enforcement, and global harmonization.
- Serve as a negotiation member of industry coalition in reauthorization, implementation and execution of the Medical Device User Fee Act (MDUFA).

Food and Drug Administration, Washington, DC **2017-Present**
Industry Representative - Medical Devices Dispute Resolution Panel

- Provide advice to the CDRH Center Director on complex or contested scientific or regulatory issues between the FDA and medical device sponsors, applicants, or manufacturers relating to specific products, marketing applications, regulatory decisions and actions by FDA.

Arnold & Porter LLP, Washington, DC **2014-2015**
Counsel

- Advised clients in all aspects of pre- and post-market regulation of medical devices.
- Represented clients in regulatory interactions with US and international medical device regulators.
- Created regulatory policy interpretation documents for affected clients and the public.
- Created and modified policies and procedures for medical device companies in response to global regulatory and compliance standards.
- Provided strategic regulatory advice to corporate leaders in global medical device companies.
- Developed and maintained relationships with medical device trade associations.
- Reviewed and edited proposed legislation affecting the device and diagnostic industry.

Food and Drug Administration, Washington, DC
Center for Devices and Radiological Health (CDRH)
Office of the Center Director
Associate Director for Policy **2011- 2014**

- Developed or oversaw the development of all CDRH regulations, guidance documents, enforcement actions, legislation, reports, memoranda and other policy and analytical documents. Representative examples include:
    - Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
    - Center for Devices and Radiological Health Appeals Processes
    - Distinguishing Medical Device Recalls from Medical Device Enhancements
    - Unique Device Identification System; Final Rule
- Advised FDA and CDRH Center Director and senior management on policy and legal implications associated with potential compliance actions, pending litigation, and enforcing post-market regulatory requirements.
- Advised CDRH negotiation team during MDUFA III.
- Provided legal guidance to FDA and CDRH senior staff on emerging public health concerns and other sensitive issues including congressional inquiries.
- Advised FDA and CDRH post-market staff on compliance issues including strategic enforcement activities, recall policy and implementation, leading meetings with regulated industry to discuss resolution of regulatory compliance issues, and review of Warning Letters and other compliance correspondence.
- Advised FDA and CDRH premarket program staff by applying knowledge of the Federal Food Drug and Cosmetic Act and other pertinent laws and regulations in the review and evaluation of program operations including the review of Premarket Notifications (510(k)s), Premarket Approval Applications (PMAs), and Investigational Device Exemptions (IDEs).
- Served as a senior leader and advisor in adapting proposed policy (i.e., proposed rules and draft guidance) to comments and concerns of stakeholders including industry, congress, and patient advocates.
- Managed all aspects of CDRH guidance development, annually publishing 40+ policy and technical documents.
- Represented CDRH and FDA on internal and external medical device policy and legal matters including issues related to clinical trials, combination products, audits conducted by the Government Accountability Office and Office of the Inspector General.
- Grew and supervised staff of eight senior level Policy Advisors comprised of attorneys, Ph.D.s, & M.B.A.s.

Policy Advisor **2009- 2011**

- Advised FDA and CDRH senior staff on guidance, policy, and regulatory decisions by applying relevant laws and regulations.
- Served as technical consultant and advisor to CDRH Deputy Center Director for Policy and staff in all areas of regulatory oversight including the development of regulations and guidance documents.
- Served as technical consultant and advisor to CDRH program staff in areas requiring enforcement action.
- Represented Office of the Center Director in meetings and discussions with internal and external stakeholders (i.e., Office of Commissioner, Office of Chief Counsel, trade associations).
- Drafted, reviewed, and edited medical device regulations, policies, guidance documents, and programs on behalf of the Office of the Center Director.

FDA Center for Tobacco Products (CTP),

Acting Regulatory Counsel **2009- 2010**

- Contributed to the establishment and development of the Center for Tobacco Products.
  - One of original 12 CTP development team members.
- Drafted, reviewed, and edited tobacco product regulations and guidance documents.
- Prioritized and monitored the progress of regulations and guidance documents under development.
- Collaborated with CTP and FDA senior staff in making regulatory decisions.
- CTP liaison with OMB.

Center for Devices and Radiological Health (CDRH),
Office of the Center Director

Regulatory Counsel **2005- 2009**

- Managed the CDRH annual development agenda for medical device regulations and guidance documents.
- Monitored the progress of regulations and guidance documents under development.
- Drafted, reviewed, and edited medical device regulations and guidance documents on behalf of the Office of the Center Director.
- Communicated regulation and guidance development processes with industry and trade associations.
- Collaborated with FDA and CDRH senior staff in making novel regulatory decisions.
- CDRH representative for audits conducted by the Government Accountability Office and Office of the Inspector General.

EDUCATION

The Catholic University of America, Columbus School of Law, Washington, DC
Juris Doctor **May 2006**

Cum Laude
Founder and Co-President, Health Law Society
Vice Chancellor, Moot Court Association
Member, National Telecommunications Moot Court Team
Recipient, Deans Award

Loyola College, Baltimore, MD
Bachelor of Science, Biology **May 2002**

MEMBERSHIPS

Maryland Bar **December 2006**
Washington DC **February 2015**
Food and Drug Law Institute, Washington, DC
Co-Chair Medical Devices and Diagnostics Committee **2010- 2014**

Publications

Articles

- "FDA Scrutinizes Networked Medical Device Security" Information Week, Dec 1, 2014.
- "Should FDA Assume Sole Enforcement Responsibility for Alleged Violations of the FDCA Lessons from Recent Medical Device Enforcement and Qui Tam Cases" FDLI's Food & Drug Policy Forum, Volume 4, Issue 11, Nov 2014.

Client Advisories

- "FDA Issues New Guidance, Classification Pathway on Medical Device Accessories" Jan 2015.
- "FDA Releases New Guidance Proposing Further Limitations on Regulatory Oversight of Low Risk Medical Devices" Jan 2015.
- "Update: FDA's Risk-Based Laboratory Developed Tests Proposal Formally Issued: Would Transform the Regulation of Diagnostic Testing in the U.S." Oct 2014.
- "FDA's Risk-Based Laboratory Developed Tests Proposal Would Transform the Regulation of Diagnostic Testing in the U.S." Aug 2014.