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PROFESSIONAL EXPERIENCE

April 2018 – Present JOHNSON & JOHNSON (Ethicon, Inc.):

Worldwide Vice President, Regulatory Affairs and Franchise Global Leadership Team Member: Drive the advancement of the Ethicon Franchise innovation portfolio by devising and carrying out effective regulatory strategies; supporting the growth of the Ethicon franchise by supporting and maintaining global market access. Support the growth of Research & Development talent within Ethicon and across the Johnson & Johnson Medical Devices Companies (JJMDC). Serve on both the Ethicon, Inc. Leadership Team and the JJMDC Regulatory Affairs Leadership Team to advance the development of the Johnson & Johnson enterprise position in the medical devices sector.

- **Ethicon Franchise Leadership Team:** Perform all functional leadership and office level-duties associated with J&J's General Surgery Franchise Global Management Board.
- **Portfolio Leadership:** Develop and execute global regulatory strategies to enable J&J's Robotics/Digital Surgery, Wound Closure and Repair, Biologics, Energy, Endo-Mechanical, and Ablation Portfolio including development, acquisition and deployment.

Feb 2015 – April 218 JOHNSON & JOHNSON (Johnson & Johnson Consumer Health):

Senior Director, Regulatory Affairs and Global Management Board Member: Lead Regulatory Affairs strategy for the Johnson & Johnson Consumer Inc. (JJCI) OTC global portfolio including broad Regulatory classifications (Drugs, Medical Devices, Dietary Supplements, Combination products, etc.).

- **Rx-to-OTC Switch:** Rhinocort/Budesonide US; Rhinocort/Budesonide global license.
- **Lead Regulatory Reform:** Influenced how 1.6 billion people purchase OTC medications (US OTC Industry Monograph reform team) and China Regulatory Reform (Global OTC Industry Team Lead CHPA).
- **Lead Industry Adoption:** Co-Lead US Industry Proprietary Naming/Umbrella Branding Task force and new proposed guidance document; Industry aligned safety measures for pediatric safety (US Only - Single concentration solid dose acetaminophen; Volumetric/mL only dosage cup).
- **Innovation:** Enabled and drove innovation pipeline through strategic regulatory submissions, successful health authority negotiations; Business development evaluations (Acetaminophen/Ibuprofen, Extended release Ibuprofen, Medical Devices, Naproxen, etc.).

2012 – Feb 2015 JOHNSON & JOHNSON (Operating Company - Ethicon Biosurgery):

Director, Regulatory Affairs - Base Business and Globalization: Shape the global Regulatory environment to create predictable pathways for Biologic, Medical Device and Combination product expansion through direct reports in multiple regions. Enhance global regulatory affairs capabilities.

- **Secured over thirty global approvals** and managed post-market challenges through successful negotiation with established and evolving Regulatory Authorities.
- **Lead the creation of the Global Biosurgery Prioritization Team** that evaluates J&J affiliate ability (infrastructure, value analysis; etc.) to be granted resources and franchise commit to submit for Biologic license approval to the respective health authority. Strategy focused on “Effective Efficiency” and resulted in a streamlined more focused global portfolio.
- **Enhanced the business** through membership in critical teams including the Biosurgery Commercial Leadership Team, Global Commercial Team, EMEA Leadership Team, Corporate CAPA Review Board, Risk Management Board, and Global Copy Approval Leadership Team.

2007 – 2012 **JOHNSON & JOHNSON (Operating Company - Ethicon Endo-Surgery):**
Product Director, Global Marketing, Energy (2010-2012)
Senior Manager, Regulatory Affairs, Sedation Systems (2007-2010)

Product Director, Global Strategic Marketing - Energy: Innovation/Ideation for Advanced Energy portfolio's product and non-product solutions.

- **Innovation/Ideation Team Lead:** Developed business unit strategy through leadership of cross-functional team. Gained Business Unit Leadership Team alignment to Ideation process and Strategic plan.
- **Pipeline Clarity:** Defined global and regional strategic framework for business-critical procedures and specialties that lead to pipeline delineation, therapeutic area focus and M&A decisions (Gastrointestinal; Head/Neck; Next Gen. Harmonic Focus®).
- **Global Strategic Marketing Lead:** Owned regional strategy (NA/LATAM) and supported key regional initiatives to deliver global business Strategic plan commitments.

Senior Manager, Regulatory Affairs - Sedation Systems: Gain regulatory approval to market for the SEDASYS System, the first-of-a-kind Computer-Assisted Personalized Sedation system.

- **FDA Advisory Panel Preparation Program Leader:** Established and led internal & external team that delivered an 8-2 approval recommendation from FDA's Anesthesiology and Respiratory Therapy Devices Advisory Panel. **FDA Approvable Letter Issued February 29, 2012.**
- **Exceptional Partnering/Cross-Operating Company Collaboration:** Leveraged FDA Panel experience to support DePuy Pinnacle® CoMplete™ Acetabular Hip System win Unanimous FDA Advisory Panel approval recommendation (time, resources, etc.).

2000 – 2007 **PROCTER & GAMBLE (Personal Health/Over-the-Counter [OTC] Division):**
R&D Global GI Lead (2004-2007)
Global Regulatory Manager (2000-2004)

R&D Global GI Lead/Advertising Council Member – Prilosec OTC and Pepto-Bismol:

Product Development/R&D accountability for Prilosec OTC, the largest brand in P&G's Personal Health Sector; Pepto-Bismol; Global Fiber organization and the Calcium Citrate Malate platform.

- **Evidence Generation** – Led development of a new consumer research model that determined impact of Frequent Heartburn on the lives of OTC sufferers.
- **Technical External Relations & Convention Spokesperson:** National Heartburn Alliance, American Pharmacists Assoc., American College of Gastroenterologists, American Assoc. of Physician Assistants. Result: Designation of “#1 Pharmacist Reco. Heartburn Medicine” for Prilosec OTC (Pharmacy Times).
- **Licensing:** Led global R&D development of the external licensing strategy for the Calcium Citrate Malate technology platform. Created robust product claims portfolio, global regulatory portfolio, led proprietary formulation and package development. Result: **\$40 Million increase in portfolio value.**

Global Regulatory Manager, GI (Metamucil and Pepto-Bismol); Respiratory (Vicks): Lead global regulatory strategy and submissions (US) to enable successful product commercialization and claims.

- **Notable Launches:** **Gastrointestinal:** Metamucil Plus Calcium® (US and Canada) -The 1st Dietary Supplement only product in P&G Personal Health); Align®, the organization's 2nd Dietary Supplement and 3) Children's Pepto® (US). **Respiratory:** Vicks First Defense® (Germany)
- **Crisis Management Leader & Author:** Established Product Safety and Regulatory Affairs Crisis Management organization. Resulted in an internal company Interactive Electronic Training Module and a published article in RAPS “Focus” (The Regulatory Affairs Industry Magazine).
- **Rx-to-OTC Switch Lead:** P&G's Health Care Rx-to-OTC Switch Team. Led effort to identify key respiratory sector switch candidates and technologies that present compelling acquisition opportunities. Enriched P&G respiratory pipeline 3 to 5-year horizon strategy.
- **FDA Approval:** Multiple submissions working with the OTC industry trade association (Consumer Healthcare Products Association). Led industry effort that resulted in approval for the “Treatment of Travelers' Diarrhea” indication for Bismuth-Subsalicylate containing products (e.g., Pepto-Bismol).

EDUCATIONAL BACKGROUND

Ph.D., University of North Carolina at Chapel Hill School of Public Health; Environmental Sciences and Engineering Department (Developmental Toxicology)

M.S., Biology, North Carolina Central University, Durham, NC

B.S., Biology, North Carolina Central University, Durham, NC

KEY AWARDS/RECOGNITION:

2017 **J&J Accelerate Enterprise Leadership Program**

2009, 2014, 2017

2018 and 2019 **J&J Leadership Awards:** Exceptional Leadership and business results

2013 - Present **Member, Board of Directors:** North Carolina Central University College of Arts and Sciences.

2010 - 2019 **Member, Board of Directors:** University of North Carolina at Chapel Hill Public Health Foundation (Gillings School of Global Public Health).

2008 **Ethicon Endo-Surgery/J&J Trailblazer:** Community Impact Award

2008 **Industry Leadership:** Featured in Carolina Public Health magazine's inaugural Leadership Issue (May '08). Recognized for sustained Leadership in Global Public Health and developing & inspiring leaders in the healthcare sector.

2005 **"Rising Leader" Award:** Outstanding leadership & business results (Product Development/R&D) - Procter & Gamble Co. Global R&D – Cincinnati, OH

1999 **Marie W. Taubeneck Award:** The Teratology Society.

Diversity and Inclusion:

2018 – Present Executive Sponsor J&J/Ethicon Diversity and Inclusion Council

2015 - Present J&J Diversity and Inclusion **Executive Sponsor** (McNeil Consumer Healthcare)

2010 - 2012 **Chair**, Ethicon Endo-Surgery African American Leadership Council.

2011 - 2013 Member, Ethicon Endo-Surgery Diversity & Inclusion Workforce Pillar.

Relevant RA Publication:

2003 (February) FOCUS Magazine Article: Recognized for excellence in Crisis Management organization leadership: "Crisis Management and the Regulatory Affairs Professional"

Honor Society:

Inducted 2001 **Delta Omega, the Public Health National Honor Society, Inductee** (Sustained contributions to Global Public Health).

Selected Community/Other:

2019 – Present **Board Member** Central New Jersey United Way.

2013 – 2014 **Advisory Council** PURE Youth Organization

2007 - 2011 **Board Member** Greater Cincinnati Hospice (Summer Time Classic).

2007 & 2008 **National Philanthropy Award Honoree** Greater Cincinnati.

2005 - 2006 **Co-Founder/Chair** "Smiles Through Toys for Girls and Boys". Partner institution: Cincinnati Children's Medical Hospital, Cincinnati, OH.

Published Scientific

Articles/References: Furnished upon request.