Mark S. Paxton

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PROFESSIONAL EXPERIENCE AND EMPLOYMENT

Brown Rudnick, LLP, Washington DCSeptember 2023 - Present

* Operating under an innovative arrangement with Brown Rudnick, provide comprehensive FDA regulatory and compliance counsel to the firm’s life science and BioAdvisory Services team. Regulatory and compliance advice covers FDA requirements for small molecules, biologicals (including HCT/Ps), medical devices and health tech (e.g., SaMD), and cosmetic and dietary ingredients and supplements.

**Defender Pharmaceuticals, LLC, St. Louis, MO January 2023 - March 2024**

**VP Regulatory Affairs and Quality Assurance/Consultant**

* Support the acquisition, development and implementation of a 21 CFR Part 11 compliant EDMS.
* Assist and provide leadership to the Quality team to ensure corporate wide support of QMS compliant processes and procedures for the management of the company’s lead drug/device combination product.
* Review, assess and report on GMP and GCP conformance issues to the General Counsel covering the development of early stage manufacturing processes/clinical programs through the final Phase III trial in anticipation of NDA submission (a lot of work!).
* Interact with C suite executives on adoption of necessary regulatory strategies and corrective action (CAPA) regulations.
* Upon request, address the Board on FDA regulatory matters.

*US Department of the Army, Fort Detrick, MD*

FDA Sponsor Representative for the Surgeon General of the Army, US Army Medical Research and

Development Command September 2018 - November 2022

* On behalf of the Surgeon General of the Army and the Chief Medical Officer of the Defense Health Agency (DHA), served as the final decision maker on all regulatory submissions to the US Food and Drug Administration.
* Primary Point of Contact for all FDA Centers on behalf of DoD sponsored investigational articles, approved products and other regulated products. In this capacity, I led or oversaw countless interactions with the Agency covering all regulated product types both at the review team and Center Director Office levels.
* Provided advice to MRDC sub-commands (e.g., Walter Reed Army Institute of Research, Institute of Surgical Research, etc.) on biologicals, including stem cells, regenerative medicine, and other HCT/Ps on proper regulatory pathways including CBER medical device jurisdiction and applicability of PHSA Sections 351 and 361.
* Oversaw every aspect of Army’s/DHA’s regulatory compliance function, including its internal Quality System, SOP development and approval, and established a compliant vendor qualification program.
* Provided regulatory leadership to a staff of approximately 70 Army civilian, military and contractors in support of advanced medical product development.
* Managed approximately 80 wide-ranging projects, with over 200 submissions per year, including NDA annual reports, INDs (CMC and Clinical Protocol development processes), DMFs, formal meeting requests to CDER, CBER and CDRH, and annual reports.
* Developed and implemented processes to integrate stand-alone Quality Agreements into DoD MSAs and supplier agreements as appendices to ensure proper conformance to regulatory agency expectations.
* Ensured conformance to local regulatory authority requirements for field (clinical) studies comprised of warfighters and allies deployed across the globe.

*Rx-360, Washington DC Metro Area*

**Chief Executive Officer November 2015 - November 2017**

Provided executive leadership to the organization as it transitioned all management, operational and administrative functions from its former Secretariat (a large, DC-based laws firm) while ensuring seamless integration with new systems with little or no disruption to existing operations.

Increased revenues by expanding Membership to stakeholders involved in the preparation, manufacturing, holding, propagating, dispensing and prescribing of drugs across the globe, and by creating greater awareness and demand of Rx-360’s unique joint audit program and other work product.

*FDA/Center for Drug Evaluation and Research, Compliance, Silver Spring MD*

**Regulatory Counsel September 2011-November 2015**

* Provided legal and regulatory counsel to the CDER Office of Compliance and Office of Drug Security, Integrity and Response on issues related to globalization and varying international requirements, including integration of DSCSA serialization standards.
* Served as Project Overseer and Chairperson, Oversight Committee on a major, multinational, private-public partnership in developing global strategies for ensuring medical product quality and supply chain security sponsored by the APEC (Asia Pacific Economic Cooperation) Secretariat in Singapore.
* Served as FDA representative to the Global Regulatory Curriculum Program for international capacity building.
* Provided leadership to FDA Office of Compliance in developing and implementing Risk Management Plans for enhancing global supply chain security.
* FDA Representative to World Health Organization’s Member State Mechanism.
* Principal Drafter of the Listing Request by FDA in response to EU’s Falsified Medicine’s Directive

*Pharmaceutical Research and Manufacturers of America (PhRMA), Washington, DC*

Associate Vice-President, Scientific and Regulatory Affairs January 2010-May 2011

Led PhRMA member company representatives on electronic and IT-related regulatory initiatives, including evaluation and recommendations for electronic pedigree systems, electronic labeling, and mitigating medication errors. Highlights include:

* Founder of a broad, multi-sector consortium comprised of manufacturers, wholesalers and pharmacies (also including their trade associations, e.g., HDMA, ASHP, NCPA, NACDS) to develop a technological pathway for serialization and e-pedigree implementation.
* Worked with industry leaders to support US FDA on implementing and validating electronic regulatory submissions covering submissions to CDER, DDMAC, and other offices within FDA, and to work with data standard setting organizations to ensure optimal integration with Electronic Health.

Associate Vice-President, International Regulatory Affairs July 2006-January 2010

Serve as the primary industry representative responsible for establishing global regulatory priorities. Work with executive level (VP and SVP) company regulatory leaders on a number of regulatory and technical committees to develop and implement global regulatory strategies.

* Established and led PhRMA’s Simultaneous Global Development (SGD) Committee which was comprised of Global Regulatory and Clinical Heads of PhRMA member companies.
* Led SGD in interactions with SFDA (China), TFDA (Taiwan), PMDA (Japan), and KFDA (Korea) resulting in several major collaborations covering pre-clinical, clinical, manufacturing/CMC and compliance (GLP, GCP, and cGMP) policy changes in the East Asia region.
	+ SGD advocacy directly led to the creation of the APEC Multi-Regional Clinical Trial (MRCT) framework, and resulted in review changes to supplemental NDAs at PMDA, forthcoming changes to China’s Drug Administration Law, and reduced IND/CTA review timelines in Korea.
* Established and led five (5) regional regulatory committees for SGD implementation.
* Serve as PhRMA’s international regulatory liaison to US Government Agencies and international organizations, including:
	+ HHS; US FDA (global and regional harmonization initiatives); Department of Commerce (Joint Commission on Commerce and Trade – China/US, MOSS dialog with Japan, TransAtlantic Administrative Simplification between EMA, FDA and the EU); US State Department (APEC, India, and China) ; US Trade Representatives Office (including the Life Science Innovation Forum of the Asia-Pacific Economic Cooperative, or “APEC LSIF”)
	+ Numerous international R&D based industry organizations including International Federation of Pharmaceutical Manufacturers Association (“IFPMA”); European Federation of Pharmaceutical Industries and Associations (“EFPIA”), Brussels, Belgium; and R&D-based Pharmaceutical Association Committee (“RDPAC”), Beijing, China.
	+ Primary regulatory liaison to PhRMA international business committees.

**Related Activities**

* **World Korean Medical Organization, Co-General Counsel 2014 - 2015**
* **APEC Harmonization Center (Seoul, Korea), Advisory Board Member 2011 - 2020**
* **Regulatory Affairs Professional Society, Annual Planning Committee Member (3 year term)**

**Private Practice/Consultant, Lexington, KY 2004**–**2006 Advisory Board Member and Regulatory Counsel, University of Kentucky College of Pharmacy**

**Murty Pharmaceuticals, Inc.,** **Lexington, Kentucky** **2001-2004**

**Director, Legal and Regulatory Affairs**

***United States Marine Corps, 1980 – 1984,*** **Sergeant (E-5), Enciphered Communications Analyst**

EDUCATION

***University of Dayton School of Law****,* ***Dayton, Ohio***

**Juris Doctor**, May 1998, Dean's Merit Scholar

***University of Kentucky, College of Business and Economics, Lexington, Kentucky***

M.S. Economics, August 1993

B.S. Business and Economics, Honors, August 1991

PAPERS and TRADE PRESS

Co-Contributor (Van Trieste, Martin), “Supply Chain SOS (Cover Story),” The Medicine Maker (both contributors named to the MM Top 100 influencers in industry by the MM Editorial Board), February, 2017.

Featured Interview, “Global Supply Chain Issues for Medical Products,” World Korea Medical Journal, Issue 12, December, 2016

APEC’s Roadmap to Promote Medical Product Integrity and Supply Chain Security,” Paxton, Mark, DIA Global Forum, Vol. 5, Issue 3, pp. 19-23, June, 2013.

“Current Challenges with Supply Chain Integrity and the Threat to the Quality of Marketed Products,” Paxton, Mark, ClinicalPharmcol Thera (*Nature*), Vol. 89, pp 316-319, Feb. 2011

“Industry Efforts on Simultaneous Global Development,” Saillot, JL, and Paxton, Mark S., DIA Journal, V II, May 2009

“Problems With Regionalization and Water Resource Development,” Kentucky League of Cities (July, 1999).

“Probabilistic Methods and the Law of Design Defects,” Society of Automotive Engineers (SAE) Technical Paper (October, 1998).

“A Model for Measuring Marginal Rates of Substitution of Prosecutors in Plea-Bargaining,” Dissertation essay (1995).

“The Myth of Market Externalities in Design Defect Law,” Dissertation essay (1995).

“An Application of Binomial Econometric Techniques: Measuring the Weights of Legal Factors Used in Design Defect Law to Predict the Probability of Success in Litigation,” Dissertation essay (1995).

**PRESENTATIONS**

Presenter, “International Regulatory Concerns with Globalization of the Biopharmaceutical Industry,” DHL Life Science Annual Meeting, Singapore, June 26-28, 2017

Keynote Speaker, “Common Carriers: Moving Medical Products and Raw Materials in International Commerce,” 2nd Annual FlyPharma Conference, Brussels, Belgium, June 6-7, 2017

Keynote Speaker, “Regulatory Concerns with the Quality of Medical Products and Raw Materials Moving in International Commerce”, Chinese Federation of Logistics and Procurement Annual Meeting, Hainan, China, November, 2016

Invited Subject Matter Expert and Presenter, Issues in Global Medical Product Quality, Canadian Institute of Health Research, Bucks for Brains, Feb. 20-21, 2016

Chairperson and Presenter, Bio Manufacturing World Summit, San Diego, Nov. 16-17, 2015

Presenter and Panelist, 3rd Annual Meeting of the World Korea Medical Organization, “Integrating Drug Safety Data into EMRs”, July 4-5, 2014 New York, NY

Presenter and Panelist, 2014 PDA/FDA Supply Chain Conference, “APEC Roadmap”, June 2-5, 2014, Washington, DC

Chairperson, “1st Stocktaking Meeting of Regulators and Experts to Review Implementation of the APEC RHSC Roadmap for Medical Product Quality and Supply Chain Integrity”, 2nd APEC Senior Officials Meeting, Qingdao, China May 5-9, 2014.

Presenter and Panelist, 2013 PDA/FDA Pharmaceutical Supply Chain Workshop, “Pharmaceutical Supply Chain Integrity: The New Horizon,” Bethesda, Maryland, June 3-5, 2013.

Honorary Speaker, “APEC Roadmap to Promote Medical Product Integrity and Supply Chain Security: Public Awareness and Establishing a Single Point of Contact,” Seoul, Korea, May 22-23, 2013.

Presenter, DIA Asian Regulatory Conference, “APEC Roadmap to Global Supply Chain Security,” Singapore, February 28-March 1, 2013.

Presenter, DIA Latin America Regulatory Conference, “FDAsia and Supply Chain Security,” Mexico City, Mexico, October 1-3, 2012

Presenter and Panelist, Intersecting Worlds of FDA and Brazil, Food and Drug Law Institute, Sao Paulo, Brazil, September 11-12, 2012

Speaker, American Association of Pharmaceutical Scientists (AAPS) Annual Meeting, Opportunities for Working with APEC Regulators (Washington, DC), Oct 24-27, 2011.

Panelist, The Burrill Pan-Asia Life Sciences Meeting (Washington, DC), June 26, 2011

Presenter, Korea Health Industry and Development Institute Columbus Project (Seoul, Korea), “Regulatory and Commercialization Strategies of Drugs and Devices in the US,” June 13-14, 2011

Presenter, VIBPharma Conference on Packaging and Labeling (Washington DC), “PhRMA Efforts on e-Labeling and Track-and-Trace Initiatives,” April, 2011.

Panelist, DIA Conference (Bethesda, MD) “Ensuring Quality and Balancing Risks for Multiregional Clinical Trials: Statistical, Clinical, Regulatory, and Ethical Factors”, October, 2010.

Presenter, The Conference Forum on Global Clinical Trials (Washington, DC), “Efforts to Resolve International Regulatory Barriers to Simultaneous Global Development,” September, 2010

Presenter, 46th DIA Annual Meeting (Washington, DC), “Drug Counterfeits: Industry Views and Actions,” June, 2010

Keynote Speaker and Presenter, APEC Pharmaceutical Supply Chain Workshop (Seoul, Korea), “EFPIA Supply Chain Pilot,” May, 2010

Planning Committee Member, Speaker and Session Chair, DIA 2nd Latin American Regulatory Conference (Mexico City, Mexico), “Simultaneous Global Development,” November, 2009

Presenter, 45th DIA Annual Meeting (San Diego, California), “Industry Efforts to Resolve International Regulatory Barriers to Simultaneous Global Development,” June, 2009

Planning Committee Member, Presenter, 2009 Inaugural Workshop of the APEC Harmonization Center, Multi-Regional Clinical Trials (Seoul, Korea), “Industry Efforts to Resolve International Regulatory Barriers to Simultaneous Global Development,” June, 2009

Keynote Speaker, International Workshop on Drug Clinical Trials (He Bei, China), June, 2009

Presenter, PhRMA Asia Managers Annual Conference (Singapore, Singapore), “Simultaneous Global Development in Asia,” January, 2009

Presenter, 2008 APEC Regulatory Science Symposium, LSIF (Taipei, Taiwan), “Industry Efforts to Resolve International Regulatory Barriers to Simultaneous Global Development,” November, 2008

Presenter, 2008 International Summit on New Drug R&D Policy and Practice (Shijazhuang, China), “New Drug Approval Requirements in the US),” October, 2008

Planning Committee Member, Speaker and Moderator, DIA 1st Latin American Regulatory Conference (Mexico City, Mexico), “Rational Use of the Certificate of Pharmaceutical Product,” May, 2008

Presenter and Moderator, IFPMA 5th Asian Regulatory Regulatory Conference (Kuala Lumpur, Malaysia), “The Attractiveness of the Asian Market,” March, 2008

Presenter, PhRMA European Local Area Working Group Annual Meeting (Berlin, Germany), “TransAtlantic Administrative Simplification,” February, 2008

Presenter, Interphex, API China (Shenzhen, China), “ Select Drug Approval Requirements of the US FDA Under Hatch-Waxman,” November, 2007

Moderator, APEC Life Science Innovation Forum (Seoul, Korea), “ICH Q8, Q9, and Q10,”

 September, 2007

Presenter, AFMC International Medicinal Chemistry Symposium (Istanbul, Turkey), “Intersection of Regulatory Requirements and Intellectual Property,” July, 2007

Presenter, Japan Pharma and Biotech Forum (London, England) “Intersection of Regulatory Requirements and Intellectual Property,” June, 2007

Presenter, BioResearch Monitoring Committee, PhRMA, “International Regulatory Affairs Update,” March, 2007

Presenter, Asia Managers Conference and Seminar (Hong Kong), “Asia-Pacific Regulatory Update,” December, 2006

Presenter, Clinical Trials Forum (Beijing, China), “Clinical Trial Requirements in the United States,” September, 2006

Speaker, KSTC/ICC Directors, “Good Clinical Practices and Drug Approval Requirements,” July, 2004.