**Mary Ellen Dronitsky, RN, MS, MBA, JD**

**Experience Highlights**

* Experience in Neurology, Oncology, Cardiovascular, Metabolism and Endocrine products including BOX WARNING, REMS and controlled substance products.
* 15+ years’ experience in Legal and Regulatory matters involving biopharma companies.
* Advanced Education with BS, MS, MBA, JD degrees.
* Drafting and negotiating commercial contracts including clinical trial, consulting, vendor, confidential disclosure, and supply agreements
* Review and providing advice promotional review materials, disease awareness, speakers programs, labeling, product liability, Federal anti-kickback, HIPPA and false claims
* Leading Promotional Review Committees (PRCs) and developing collaborative and compliant solutions:
  + - Successful Launches of new products for Multiple Sclerosis and new indications for Oncology products in soft tissue sarcoma and metastatic renal cell carcinoma.
    - Overseeing direct report successfully contribute to re-launch of acquired Oncology product for rare form of Thyroid Cancer.
    - Proactively working outside of PRC with marketing, medical and advertising agencies on new concepts and campaigns.
      * Developing Case Studies presentations to broaden patient population used in current campaigns in a manner that was not objected to by DDMAC in Advisory Comments.
      * Revamping brand strategy consistent with approved label with or without new data.
      * FADAMA 114 payer communications consistent with recent FDA Guidances.
    - Providing recommendations, FDA regulatory research and background to facilitate resolution of escalations to Executive Promotional Review Committees.
    - Presenting updates, analysis, risk assessment and mitigation recommendation to executive leadership.
* Providing Regulatory leadership to Medical Review Committee, Corporate Communications and Labeling Committee.
  + Policy and SOP development lead and contributor on multidiscipline teams.
  + Academic and Speaking Experience including;Adjunct Assistant Professor appointments at Temple and Northeastern Universities for MS Regulatory Affairs Programs teaching and developing courses; Regulation of Advertising and Promotion of Prescription Drugs; Food and Drug Law; Protection of Human Subjects in Research; Auditing and Validation of Clinical Trials.

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# Mary Ellen Dronitsky, RN, MS, MBA, JD

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# PROFESSIONAL EXPERIENCE

# Aegerion Pharmaceuticals, Cambridge, MA 2017 - Present

# *Senior Director, Regulatory Affairs - Advertising and Promotion*

# Head of Regulatory Advertising Promotion responsible overseeing process for reviewing promotional and sales training materials and collaborating with multidisciplinary team to find solutions to ensure materials are consistent with FDA regulations and approved product labeling for endocrine and cardiovascular products.

# Member of Compliance Committee to implement and oversee Corporate Integrity Agreement, REMS Consent Decree.

# Lead and oversee communications and submissions with FDA’s OPDP.

# Participate on Global Labeling Committee to review and recommend changes for product labeling including interfacing with pharmacovigilance to update labeling in response to safety and adverse event reports.

**Genzyme, Cambridge, MA**

***Director, Regulatory Advertising and Promotion*  2014 - 2017**

* Leadership role responsible for directing and mentoring direct reports and Pharm D fellows for review of promotional materials including patient materials, professional health care provider materials, sales training, press materials, corporate materials as well as materials for developmental products .
* Consulted with core Regulatory Team regarding US labeling updates and ensured changes were reflected in promotional materials.
* Provided regulatory advertising and promotion advice and strategic leadership to Multiple Sclerosis Brand Team in launch of new product and provide regulatory advertising guidance for rare disease products and biosimilar products.
* Participated on corporate steering committee for Regulatory Advertising and Promotional Excellence charged with developing regulatory standards and policies across Sanofi companies.
* Participated in pioneering team on the roll out a new electronic review system.
* Submission of materials to OPDP including 2253s, request for advisory comments, sub part e and h.

# GlaxoSmithKline, Philadelphia, PA 2011 - 2014

# *Director Regulatory Promotion and Policy*

* Provide strategic and operational leadership to Oncology and other Marketing Brand Teams, Legal, Medical Affairs and Clinical Research in the development of advertising and promotion for the US market in accordance with business goals and objectives, FDA regulation, ICH guidelines, PhRMA guidelines and company policy.
* Provide sound regulatory advice that minimizes the risk of regulatory and legal action, competitively positions assigned products and is consistent with applicable FDA regulations and GSK policies for advertising and promotion of prescription drug products and biologics.
* Effectively communicate with reviewers within US FDA Office of Prescription Product Promotion (OPDP, formerly DDMAC) to expedite resolution of issues.
* Participated on US labeling review teams for assigned marketed products.
* Participate in company, government and trade association working groups that focus on advertising and promotion standards and guidelines.

# Bristol-Myers Squibb, Princeton, NJ 2010 - 2011

# *Director, US PHARMA Law and Promotion Compliance*

* Lead Regulatory Promotion Compliance Group including direct reports for PLAVIX.
* Managed interactions and regulatory submissions with FDA/DDMAC.
* Collaborated with Medical and Commercial Organization to insure development of promotional programs that are compliant with state and federal law, regulatory guidelines and Company policy, while supporting achievement of business objectives.
* Provided expert regulatory review of branded and unbranded consumer pieces including television advertisements and websites; health care professional materials including speaker programs, e-detailing and FDAMA 114 items.
* Provide expert risk advice on federal and state law and FDA regulations governing the promotion and marketing of prescription pharmaceutical products.

**Towers Watson, Philadelphia, PA 2009 - 2010**

***(Temporary) Senior Counsel, Commercial Contacts***

# Encorium Group, Inc., Wayne, PA 2006 - 2009

# *In-house Counsel and Director*

* Monitored changes in proposed FDA regulations and draft guidances to advise management interpretation, strategy and possible impact and implications.
* Reviewed press releases and promotional materials for regulatory compliance.
* Drafted and negotiated US and international commercial contracts with sponsors, customers, vendors and hospitals and complex agreements related to clinical and regulatory services with domestically and international sponsors for new drugs and devices including publication and termination provisions.
* Analytically assessed business and regulatory risk and advised senior management.
* Directed multi-disciplinary team to develop contracts for clinical trial services which included data management services, regulatory affairs, IVRS , central labs and other data capture devices.
* Developed procedures and contract templates for pharmaceutical company clients, vendors, and therapeutic expert consultants involving clinical trials and related services.

# Wyeth, Collegeville, PA 2002 - 2006

# *Associate Director, Regulatory Affairs*

* Member of US and Global Advertising and Labeling Review Team for Marketed Products that reviewed and revised promotional pieces for DDMAC submission and product labeling that were acceptable to both FDA and Wyeth’s marketing and legal departments.
* Lead liaison with FDA (CDER, CBER, DDMAC) for group of products.
* Responsible for directing and developing submissions to FDA on a group of products including NDAs, BLAs, labeling supplements, efficacy supplements, CMC reformulations and annual reports in accordance with 21 CFR that resulted in multiple approvals.
* Member of Task Force that developed templates and procedures for electronic submissions based on Common Technical Document.

# Versicor, Inc, King of Prussia, PA 2001 - 2002

# *Counsel, Sr. Manager, Contracts and Clinical Trials*

* Negotiated and drafted contracts and letters of agreement and indemnity with physicians,

Universities, hospitals, CROs (Clinical Research Organizations), laboratories and contract manufacturers.

* Negotiated settlements and resolved disputes over budgets and scope of work issues while preserving professional relationships between parties.
* Managed staff and oversight of administration grants and contracts for research projects.
* Provided advice on HIPPA privacy regulations and ICH guidelines and GCPs.
* Drafted patient consent forms in accordance with FDA regulations per 21 CFR and guidelines.

# Private Legal Practice 1994 - 2000

# *Attorney*

* Areas of Practice: FDA Regulatory and Compliance and Contracts, Product Liability, Medical Malpractice, Employment and Labor Law, Litigation, Discovery, Pleadings, Court Motions, Expert Witnesses, Trials and Settlement Negotiations

# Merck Research Laboratories, Blue Bell, PA 1987 - 1993

# *Clinical Research*

* Drafted IND reports, safety updates and sections of New Drug Applications.
* Designed and implemented a plan to audit clinical studies for adherence to FDA regulations and Good Clinical Practices.
* Developed a management audit reporting system for serious adverse experiences for a group of clinical studies as well as a corrective action plan.
* Contributed substantially to the drafting of a New Drug Application submitted to the FDA on schedule.
* Designed and implemented clinical studies to support advertising claims of marketed products. Initiated and monitored Phase I-IV clinical research projects for pharmaceutical agents in multiple therapeutic areas including OTC switches, pain and cardiovascular.
* Drafted study protocols, investigational drug brochures, and clinical study summaries.
* Coordinated with Legal, Marketing, Business Development, Pre-Clinical, Clinical and Regulatory Affairs Departments to facilitate product development**.** Managed research projects to completion on time and within budget.

# ACADEMIC, BAR ADMISSION AND LICENSING CREDENTIALS

**Northeastern University, Boston, MA 2015 - Present**

***Adjunct Teaching Professor***

* Teach online courses in Regulation of Clinical Trials, Protection of Human Subjects in Research and FDA Regulatory Advertising and Promotion of Drugs and Medical Devices for MS Regulatory Affairs Program in the College of Professional Studies.

**Temple University, Philadelphia, PA 2009 - Present**

***Adjunct Assistant Professor***

* Teach live and online courses in Food and Drug Law, FDA Regulation of Prescription Drug Promotion, for the Graduate RA/QA MS in the School of Pharmacy.
* Designed and developed new course and content for FDA Regulation of Advertising and Promotion.

**Admitted to Pennsylvania Bar and Federal District Court for Eastern Pennsylvania 1994**

**J.D., Temple University Law School, Philadelphia, PA 1994**

**MBA, St. Joseph’s University, Philadelphia, PA**

**M.S., Nursing, Adelphi University, Garden City, New York**

**B.S., Nursing, William Paterson University, Wayne, New Jersey Licensed Registered Nurse - Pennsylvania**