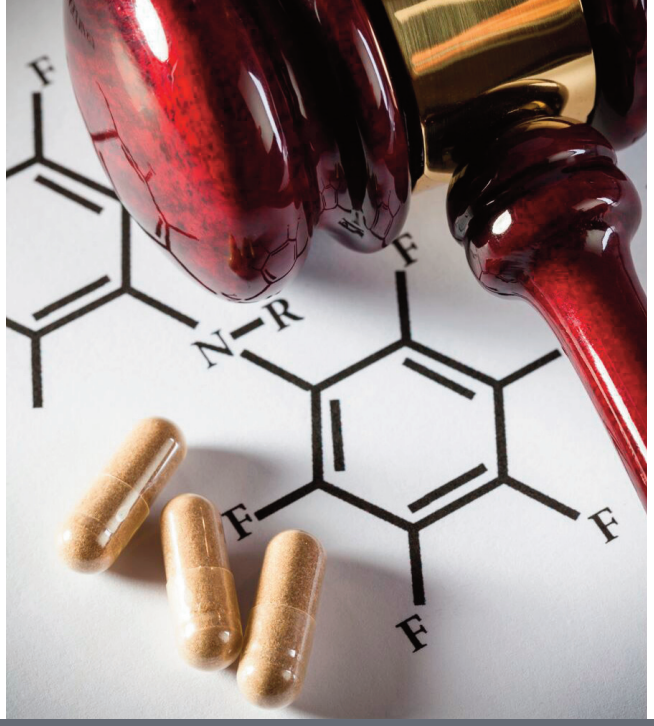
ACUMEN BIOPHARMA™

PHARMACEUTICAL ANTITRUST LITIGATION CONSULTING EXPERTS



Providing antitrust litigation attorneys with comprehensive consulting and expert testimony across the biotechnology, pharmaceutical, and medical device industries in matters that involve PIV ANDAs, authorized generics, pay-for-delay, Medicare Part B, drug price fixing, product launch readiness, loss of exclusivity strategies (LOE), and more.

OUR EXPERTS

Daisy Rivera-Muzzio
President & Founder
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With more than 30 years of global experience developing business in the pharmaceutical industry, Daisy Rivera-Muzzio, RPh, MBA, serves as president and co-founder partner of Acumen BioPharma. Rivera-Muzzio is an expert in positioning scientific arguments regarding intellectual property involving innovator and generic companies in the healthcare industry.

A past co-chair of the New Jersey Chapter of Licensing Executives Society (LES), she currently serves on its advisory board. LES is a professional organization for IP professionals, which facilitates global IP commerce through education, networking, standards development and certification. Rivera-Muzzio assists those seeking to develop innovative technologies in accelerating commercialization of intellectual property. Rivera-Muzzio is also Chief Operating Officer (COO) of Integra Continuous Manufacturing Systems (CMS), a wholly owned subsidiary of Acumen BioPharma. Integra CMS pioneers continuous manufacturing processes for the wider drug industry. Serving as COO, Rivera-Muzzio is responsible for all business operations and management of contractual alliances, drawing on her deep expertise in the evaluation and risk assessment of licensing generic formulations, and conducting cross-functional analyses for licensing and acquisition of several major platform technologies. Founded in 2015 by Dr. Fernando Muzzio, Integra CMS is supported by the wide resources of the C-SOPS network.

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Luis A. Molina

Antitrust Consultant

Luis A. Molina is a business executive with more than 20 years of experience managing projects and teams to build and optimize organizational processes, measurement systems, and infrastructure. He applies his extensive expertise in maximizing product launch results and in portfolio optimization for both branded and generic pharmaceutical products.

With a critical focus on strategic planning and improving the efficiency of commercial and manufacturing operations, such as inventory planning, Mr. Molina is an expert at managing the timely launch of multiple pharmaceutical products. He is also a strong cross-functional team manager with experience efficiently integrating required regulatory processes for commercial and manufacturing operations of new product launches.

His expertise includes work on: market access compliance; managed care brand products contracts; inventory management programs; Sarbanes-Oxley Act compliance for the Managed Care, Government and Guaranteed Pricing Contracts; market access contracts with Pharmaceutical Benefit Managers (PBMs) and Health Management Organizations (HMOs); procurement and inventory strategies to maintain optimum levels of products; strategies to minimize inventory obsolescence risks; optimization process for accurate forecasting volume and target market share for new product launches; strategic plans for loss of exclusivity process and optimization of product lifecycle management.

Mr. Molina holds an MBA from Capella University, Minneapolis, Minnesota and an Executive Certificate in International Management from the Thunderbird School of Global Management in Glendale, Arizona. Prior to this he earned a BS of Science in Business from S.U.N.Y, Excelsior College in Albany, New York with an Accounting Major from the School of Management at the S.U.N.Y Binghamton location in New York.

Susan Marchetti

Antitrust Consultant

Susan Marchetti has over 35 years of pharmaceutical business and operations experience. She has held high level positions at both branded and generic pharmaceutical companies with responsibility for General Management, Supply Chain Operations, Procurement, Internal and External (Contract) Manufacturing/Packaging, Demand Management (Forecasting) and Product Life Cycle Management.

She served as Director/Team Lead for US Supply Chain Operations at Pfizer where she was responsible for demand forecasting, supply assurance and inventory management of all products sold in the US market. This included both Pfizer branded and Greenstone Authorized Generic products. Susan led the Supply Chain and Demand Forecasting integration of Pharmacia and Pfizer which resulted in the development of a statistical forecasting system that significantly improved forecast accuracy. For this she received the 1993 WE Upjohn Award.While at Pfizer, Susan's team successfully led several Authorized Generic launches including Z-Pak (Azithromycin) and Zoloft (Sertraline). In her subsequent role at Pfizer, Susan was the Senior Director, Established Products Portfolio Management, responsible for Life Cycle Management of products which were approaching or had already reached patent expiration.

Susan became the Chief Operations Officer at West-Ward Pharmaceuticals in 2010. West-Ward was the US Generic division of Hikma Pharmaceutical and she was a member of the company's Executive Board. At West-Ward she was responsible for Manufacturing and Packaging Operations of oral solid dose products as well as Supply Chain, Procurement, and Information Technology. In her role as a director on the Executive Board, Susan was actively involved in business development and new product launch planning. Susan later became the Head of US External Supply Chain Management (Contract Manufacturing Operations) at Sandoz Pharmaceuticals, the generic division of Novartis.

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Ms. Marchetti holds a B.A. in Communications / Media, Western Connecticut State University, Danbury, CT. She retired from the pharmaceutical industry in 2015. She currently serves as a Senior Consultant for Acumen BioPharma in the Antitrust Litigation practice.

Jon Clark
Antitrust Consultant

Senior executive with 25+ years of experience in Pharmaceutical Regulatory. During his tenure at the Food and Drug Administration he served in the office of Generic Drugs (CDER), developed and published 25 FDA Guidance Documents, review hundreds of FDA market applications (CMC review), electronic submission expert, served as on-site consultant for 483's and was a founding member of ICH eCTD standard and medicinal go to market std. He also served at the United States Pharmacopeia (USP) as VP Chemical Medicines / VP Industry Standards Collaboration.

Prior to his service at the FDA and USP, Mr. Clark worked as a senior scientist at the Schering Plough Research institute, Chemical Process Research & Development where he was directly involved in the development and optimization of chemical manufacturing processes of new molecular entities (NME). He has authored several publications and patents.

Mr. Clark holds a BS in Chemistry from the University of Michigan and an MS in Chemistry from Rutgers University. He dedicates his extensive experience in pharmaceutical regulatory affairs as senior consultant for Acumen BioPharma in Antitrust and Intellectual Patent litigation cases.

David J. Engels, RPh, MBA
Antitrust Consultant

David J. Engels, RPh, MBA, brings to Acumen more than 35 years of executive experience in marketing, sales, and operations management, most recently with the global pharmaceutical manufacturer, Pfizer, Inc. For Pfizer, Engels served as VP of Portfolio Maximization and had direct responsibility for managing Pfizer's oral solid and injectable products. Engels holds a BS in Pharmacy from the University of Wisconsin-Madison and an MBA from Northwestern University, Kellogg Graduate School of Management.

Dave's many accomplishments with Pfizer include co-forming Global Established Products with revenues of $13.9 billion. This portfolio consisted of more than 600 products, medical devices, and biologics. In addition to developing and in-licensing multiple products and line extensions, he established departments for biosimilars, orphan and neglected diseases. Dave also successfully brought the diversified product concept to Pfizer, maximizing value in segmenting a creative marketing mix with high ROI. His in-depth clinical and commercial experience brought unique value in both generic and brand marketing, payer/ market access, contracting and pricing, and gross-to-net sales management.

Engels routinely represented Pfizer as a 30(b)(6) corporate witness in various IP, marketing promotion, and product depositions. He has courtroom testimony experience around ANDA and IP litigations, and in separate judge-directed negotiations. Not only has Pfizer Legal called on Dave for input into anti-trust areas, he has also been requested by the FTC for anti-trust and ANDA discussions unrelated to his work with Pfizer.

Mr. Engels has an extensive pan-therapeutic knowledge in hospital, outpatient, and alternate care channels with pre-launch market prep through LOE life-cycle management for both brand and generic product portfolios. His success, in part, is due to his strategic, operating, and brand planning as well as his tactical execution.

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Sandra Cartwright
Antitrust Consultant

Sandra "Sandy" Cartwright comes to Acumen with nearly 20 years experience establishing and expanding markets for regional pharmacy, managed care, and infusion therapies. With a degree in biological and environmental engineering, Cartwright is an award-winning senior level sales manager responsible for developing business through leveraging healthcare analytics and cross-selling opportunities for national organizations that include CVS/Caremark and Walgreens Specialty.

Ms. Cartwright's fields of specialty include biologics, immune globulin (IVIG) & infusion, dermatology, allergy/immunology, pain management, addiction, neurology (pain, CNS, and neuromuscular), and rheumatology. She has demonstrated advanced skill in product and territory launch, developing market expansion strategies, trade relations, formulary negotiations, clinical program development, and building and managing sales teams. Her acumen with territory expansion is evident in her long list of career achievements that often include driving revenue growth substantially over planned projections.

Ms. Cartwright applies her extensive knowledge and insights to antitrust litigation by analyzing marketing, supply contracts, sales data, and regulatory compliance.

Ms. Cartwright is currently the Owner, President and Consultant, PalsPharma Specialty Pharmacy Services and Consulting, as well as a pharmacy business consultant with Realo Specialty Care, a nationwide Specialty and Home Infusion Pharmacy specializing in IVIG and Sub Q IG. She previously served as Regional Manager of IVIG/Infusion and Pain Management Sales and Program Development for Avella Specialty Pharmacy, Regional Vice President for CHS, Inc., and Regional Sales Manager for Bio Products Laboratory.

ACUMEN BIOPHARMA, LLC, is a privately held biopharmaceutical consultancy in Oceanport, New Jersey. Acumen serves intellectual property (IP) attorneys in need of scientific expert witnesses and/or laboratory testing to support patent litigation, those in need of testimony from hands-on industry experts in antitrust cases, and scientists seeking help solving a formulation or manufacturing problem affecting product quality. Acumen routinely collaborates with NDA Partners, LLC and other organizations to provide regulatory consulting services for litigation across the biotechnology, pharmaceutical, and medical device industries.

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