FTC ROUNDTABLE ON COMPETITON ISSUES INVOLVING FOLLOW-ON BIOLOGIC DRUGS
November 21, 2008

Participant Biographies

Alexis Ahlstrom, MPH

Alexis Ahlstrom is a Director at Avalere Health LLC, a strategic advisory firm in Washington D.C. She specializes in data analysis and creating financial models. She has developed an analytic framework for assessing the impact of biosimilars on public health care spending; she is currently researching the impact of different exclusivity periods for innovator products on predicted savings from biosimilars. Prior to joining Avalere Health, Alexis spent three years at the Congressional Budget Office estimating the budgetary impact of legislation on the Medicare program. Alexis holds an undergraduate degree and a Masters of Public Health from the University of Michigan.

Geoffrey Allan, PhD

Dr. Allan has been Chairman of the Board and has served as the President and Chief Executive Officer of Insmed Incorporated since its inception in November 1999. Dr. Allan has 28 years of experience in pharmaceutical drug development. Prior to joining Insmed Pharmaceuticals, Dr. Allan served as Vice President, Drug Development at Whitby Research, Inc., a pharmaceutical company. Before his association with Whitby Research, Dr. Allan was the Head of the Cardiovascular Section at Wellcome Research Laboratories. Dr. Allan received his Ph.D. in pharmacology from Cornell University Medical College.

Aaron Barkoff, JD, PhD

Dr. Aaron Barkoff is a partner at the intellectual property law firm of McDonnell Boehnen Hulbert & Berghoff LLP, in Chicago. Dr. Barkoff focuses on pharmaceutical and biotechnology patent litigation. He has extensive experience in pre-filing investigations, discovery, trial, and appeals. Dr. Barkoff is especially interested in issues at the intersection of patent law and food and drug law, such as ANDA litigation and FDA exclusivity. In May 2006, he founded Orange Book Blog, a website that reports on current developments in pharmaceutical patent law and food and drug law. Dr. Barkoff received his PhD in Biochemistry from the University of Wisconsin-Madison, and his JD from the University of Chicago Law School.

Rachel E. Behrman, MD, MPH

Rachel E. Behrman is the Associate Commissioner for Clinical Programs and Director of the Office of Critical Path Programs, U.S. Food and Drug Administration. In this capacity, she focuses on developing, coordinating and implementing policy and scientific programs aimed at innovating development and regulation of medical products. An internist with a subspecialty in infectious diseases who joined FDA in 1989, Dr. Behrman received her A.B in mathematics from Washington University, her M.D. from Mt. Sinai School of Medicine and her M.P.H. from The Johns Hopkins School of Hygiene and Public Health.

Elaine Blais, JD

Elaine Blais is a partner in the Litigation Department of Goodwin Proctor, which she joined in 2001. Her practice focuses on intellectual property litigation, particularly with respect to patent

1itigation. Ms. Blais has handled numerous patent infringement lawsuits in federal courts nationwide. She has advised clients and participated in all phases of patent litigation, from initial counseling up through trial and appeal. Ms. Blais has worked on patent cases involving diverse areas of healthcare technology, including pharmaceutical products (TEVA Pharmaceuticals), stem cell technology (ViaCel1, Inc.), software for reducing artifacts in MRI images, and spinal implants. She has also represented clients in cases involving copyrights, trademarks, trade secrets, unfair competition and patent-related antitrust issues. Ms. Blais also devotes a significant amount of her practice to counseling clients and advocating to Congress on behalf of clients regarding patent policy. In this capacity, she has worked on various pieces of legislation impacting the generic pharmaceutical industry. Ms. Blais has been involved in drafting proposed legislation and has made numerous presentations before Congressional members and staff. Prior to joining Goodwin Procter, Ms. Blais was an associate at Jones Day, where she concentrated her practice on patent, trademark and copyright litigation. She received her Juris Doctor, with honors, from The Ohio State University in 1995 and her BA from Allegheny College in 1991.

Alex M. Brill

Alex M. Brill is a Research Fellow at the American Enterprise Institute as well as Economic Policy Advisor to Buchanan, Ingersoll & Rooney and Principal at Matrix Global Advisors, LLC. His current focus is on tax, health, pension and trade policy matters. From 2002 to early 2007, Alex served on the staff of the House Committee on Ways and Means where he served as Chief Economist and later Senior Advisor to the Chairman. In this capacity, Alex was the Committee's Policy Director and led staff negotiations on a number of important pieces of legislation including tax, pension, and health policy matters. In 2001, Alex worked for the White House Council of Economic Advisers on tax, budget and financial services issues. He has a B.A. in Economics from Tufts University and a M.A. in Mathematical Finance from Boston University. He is also a Term Member of the Council on Foreign Relations. A Boston native, Alex now lives with his wife and two children in Arlington, Virginia.

Steven B. Brugger, MBA

Mr. Brugger is currently the Chief Operating Officer at Momenta Pharmaceuticals, Inc, with more than 28 years of pharmaceutical R&D and commercial experience. He began his career in research pharmacology at Aventis (Hoechst) and clinical development at Ayerst (Wyeth) Pharmaceuticals. Mr. Brugger then spent 15 years at Novartis Pharmaceuticals, with his most recent position being Executive Director for the Transplant, Tissue Engineering, and Immunology Business Unit. Immediately prior to joining Momenta, Mr. Brugger was a Vice President at Millennium Pharmaceuticals, where his responsibilities included program, portfolio, and alliance management. Mr. Brugger earned his M.B.A from Rutgers University and his B.A. in Biology from Susquehanna University.

Ted Buckley, PhD

Edward (Ted) Buckley joined the Biotechnology Industry Organization (BIO) as the Director of Economic Policy in August 2006. In this role, Dr. Buckley is responsible for examining the economic impact of policy proposals on the biotechnology industry. In addition he conducts and commissions analyses that support the creation of an environment where innovation can thrive. Dr. Buckley previously worked as a consultant at McKinsey and Company where he advised a variety of companies including health insurance and pharmaceutical companies. Prior to joining McKinsey and Company, Dr. Buckley was the first National Center for Health Statistics (NCHS)/AcademyHealth fellow, where he completed his dissertation research. Before graduate school, Dr. Buckley worked in

a range of fields including IT consulting, operations and logistics management, and served as a live-in assistant for mentally handicapped adults in L'Arche communities in both Canada and Germany. Dr. Buckley received his B.A. in 1991 in Mathematics from the University of Pennsylvania, his M.A. in 2001 and his Ph.D. in 2004 in Applied Economics from the Wharton School of Business, University of Pennsylvania.

Kenneth J. Dow, JD

Kenneth J. Dow is Assistant Patent Counsel at Johnson & Johnson and Vice President, Patent Law at Centocor, Inc., a biotechnology company which is a wholly owned subsidiary of Johnson & Johnson. At Centocor, Mr. Dow is a member of the research management board and is responsible for overseeing all patent matters, including patent preparation and prosecution, infringement and validity opinions, and licensing matters. Prior to joining Centocor, Mr. Dow represented the pharmaceutical group within Johnson & Johnson, where he did work for Ortho-McNeil Pharmaceutical, Inc., Janssen Pharmaceuticals, and the R.W. Johnson Pharmaceutical Research Institute. Prior to joining Johnson & Johnson, Mr. Dow was employed as a patent attorney for American Cyanamid Company where he represented the Lederle Pharmaceuticals division, including the generic drug business of Lederle. He was also an associate attorney at the law firm of Morgan & Finnegan. Mr. Dow received his B.S. in Pharmacy from the State University of New York at Buffalo and his J.D. from St. John's University.

Suzanne Drennon, JD

Suzanne Drennon is Counsel for Intellectual Property in the Office of Policy and Coordination with the Bureau of Competition of the Federal Trade Commission and focuses on antitrust and intellectual property policy and enforcement. Suzanne speaks on Hatch-Waxman and follow-on biologics issues and publishes articles analyzing antitrust issues. Prior to joining the FTC, Suzanne was an antitrust and intellectual property litigator in Los Angeles. She received her A.B. in mathematics from Bryn Mawr College and her J.D. from the University of Minnesota Law School where she was a Managing Editor of the Minnesota Law Review.

Christopher Garmon, PhD

Christopher Garmon is an economist with the Federal Trade Commission where he currently specializes in the economic analysis of hospital mergers. He is also an adjunct instructor at The Johns Hopkins University, teaching the course *Economics of Industry and Public Policy*. He received his Ph.D. from the University of Florida in 1997.

David Golding, R. Ph

David Golding is the Executive Vice President of Specialty Pharmacy Services for CVS/Caremark; he has been with the Company since 1987. Mr. Golding is a registered pharmacist and joined the Company as a clinical pharmacist in the Caremark home care division. In his present role, Mr. Golding has direct responsibility for the key business and functional areas that are largely unique to Caremark specialty business, directly managing Specialty Admissions and Enrollment, Pharmacy Operations, Sales, and Therapy Management functions. He is also responsible for coordinating efforts with the Company's shared services departments. In his previous role, Mr. Golding was the Vice President of Biotech Services, responsible for strategic planning and pharmacy operations for biotech drugs. Preceding that, he served as Vice President of Strategic Alliances and Specialty Services, providing strategic platforms to maximize the strengths and efficiencies of each entity within the Company. Mr. Golding also served as the Area Operations Director for Caremark with direct-line reporting of 10 branches in the Midwest and Northeast in addition to having responsibility for regulatory compliance, licensing and facility leases. Before joining Caremark, he worked as a clinical pharmacist at

both St. Anthony Hospital and Cook County Hospital in Chicago, Illinois. Mr. Golding earned his Bachelor of Science degree in pharmacy from the University of Illinois at Chicago, College of Pharmacy.

Ken Goldman, MS, JD

Ken Goldman is a Director, IP Strategy for Novartis Corporation. Ken has more than 20 years of IP experience, largely in the biotech area. Ken began his patent career at the Biotech specialty firm of Ciotti, Murashage, Irell and Manella, moving subsequently to Morrison & Foerster. He has 15 years of in-house patent counsel experience at biotechnology companies, including seven years at Chiron Corporation, and eight years as chief patent counsel at Cell Genesys, Inc. and Dynavax Technologies Corporation. Ken graduated from Harvard University, *summa cum laude*, with a dual-degree in Chemistry and Physics in 1981. He received a MS in Chemistry in 1985 from the University of California, Berkeley, and a JD from Berkeley's Boalt Hall School of Law in 1988.

Mark A. Goshko, MS

Mark A. Goshko began working for TEVA Pharmaceuticals in 1996. He has served as the Executive Director of Legal affairs for the past two years, responsible for managing all patent clearance activities for the North American market and coordinating legal and regulatory strategies for product registrations. Prior to that appointment, Mr. Goshko worked as TEVA's Senior Director of Legal Affairs from 2000-2006, and the Senior Director of Scientific Affairs from 1996-2000. Before joining TEVA, he worked in several capacities at the Lemmon Company (now TEVA-USA) over a ten period, including Director of Clinical Affairs, and Director of Scientific Affairs, Manager of Special Projects, Manager of Clinical Programs, and State Formulary Coordinator. His professional affiliations include Sigma Xi, The Scientific Research Society, Drug Information Association, and the American Association of Pharmaceutical Scientists. He received a Masters degree in Biological Science from Drexel University in 1980 and is a past member of the Delaware Medicaid Advisory Committee and the Georgia Formulary Advisory Committee.

Henry C. Grabowski, PhD, JD

Henry Grabowski has been at Duke University since 1972, where he is a professor of economics and the Director of the Program in Pharmaceuticals and Health Economics. He has also served on the faculty of Yale University and held visiting appointments at the Health Care Financing Administration in Washington, D.C., and the International Institute of Management in Berlin, Germany. Grabowski has published numerous studies on the pharmaceutical industry, with his principal research involving the economics of the innovation process, business regulation, and industrial organization. He has investigated the economics of pharmaceutical research and been an adviser and consultant to several organizations, including the National Academy of Sciences, the Institute of Medicine, the Federal Trade Commission, the General Accounting Office, and the Office of Technology Assessment.

Pamela Jones Harbour, JD

Pamela Jones Harbour, an independent, was sworn in as a Commissioner on the Federal Trade Commission August 4, 2003 to a term that expires in September 2009. Ms. Harbour joined the FTC from Kaye Scholer LLP where she served as a partner in the litigation department handling antitrust matters. She counseled clients on Internet privacy, e-commerce, consumer protection, and a variety of competition-related matters. Prior to joining Kaye Scholer, Ms. Harbour was New York State Deputy Attorney General and Chief of the Office's 150-attorney Public Advocacy Division. During her 11-year term in the Attorney General's office, she argued before the United States Supreme Court on behalf of 35 states in State Oil v. Khan, a landmark price-fixing case. She also successfully represented numerous states in New York v. Reebok, States v. Keds, and States v.

Mitsubishi, each resulting in multimillion-dollar national consumer settlements. Among her most notable antitrust cases were New York v. May Department Stores, a successful anti-merger challenge, and States v. Primestar Partners, a consent judgment culminating a four-year multistate investigation of the cable television industry. Ms. Harbour received her law degree in 1984 from Indiana University School of Law, and a B.M. in 1981 from Indiana University School of Music.

Paul Heldman

Paul Heldman is a Senior Health Policy Analyst with Potomac Research Group. Previously, he worked for Citigroup Research, a division of Citigroup Global Markets Inc. While with Citigroup, he was the primary author of the 2006 Biotechnology research study, *A Global "Generic Biologics" Guidebook.*

Linda Horton, JD

Linda R. Horton is a partner in the Washington, DC and Brussels offices of Hogan & Hartson LLP. She co-chairs the firm's European Life Sciences Practice for the firm's eight European offices and counsels clients on EU and U.S. requirements for pharmaceuticals and medical devices. Her areas of concentration include clinical trials, approval pathways, marketing practice compliance and relations with health professionals, and international harmonization. Linda joined Hogan's Washington office as a partner in 2002 and moved to its Brussels office for three years, returning to Washington in September 2007. Before joining the firm, Linda served the U.S. Food and Drug Administration (FDA) for 33 years in its legislative, legal and international policy offices. As Deputy Chief Counsel (1979-93), she was in charge of all legal services relating to regulations, counseling, and administrative procedure issues, including hearing litigation. As Director of International Policy (1993-01), she led FDA programs for international harmonization, agreements and trade. Linda is admitted to the bar in the District of Columbia, Maryland, and Brussels (Flemish section). She also is a member of the U.S. Supreme Court bar. Linda was an Adjunct Professor at both legal *alma maters*, the George Washington University Law School (JD, 1975) (where she taught FDA administrative law) and Georgetown University Law School (LLM, 1997) (where she taught international food, drug and medical device law). She served on the Boards of Directors of the American National Standards Institute (1995-2000) and of the Regulatory Affairs Professional Society (2000-06). She also was a member of the World Health Organization's legal expert group drafting model anti-counterfeiting legislation (2007). Linda was the first recipient of the Food and Drug Law Institute's Leadership and Meritorious Service Award (1999) and authored the international chapters in the FDLI-FDA book celebrating the centennial of the U.S. Food and Drugs Act (2006) as well as both editions of the leading FDLI treatise, Fundamentals of Law and Regulation (1997, 2008). She also authored the Regulatory Affairs Professional Society's book on EU Pharmaceutical Regulation (2005) and frequently speaks and writes on EU, U.S. and global regulatory topics.

Elizabeth A. Jex, JD

Elizabeth A. Jex has been an attorney in the Bureau of Competition at the Federal Trade Commission since 1990. Throughout her career, Ms Jex has worked on a variety of investigations and projects involving pharmaceutical, biotechnology, medical devices, health care issue and intellectual property cases. She has investigated dozens of biotechnology and pharmaceutical mergers, acquisitions, and licensing agreements and successfully litigated the *Olin/Alliant* case. Significant among her HSR investigations are *Roche/Genentech*, *Ciba-Geigy/Sandoz*, *Amgen/Immunex*, *Cephalon/Cima*, and *Fresenius/Daiich*i, all of which resulted in Consent Orders. While at the FTC, Ms. Jex also served as a Special Assistant United States Attorney in the Eastern District of Virginia where she prosecuted misdemeanor and felony criminal cases. Elizabeth is a

graduate of Williams College, and obtained her Juris Doctor from Georgetown University Law Center.

Esther M. Kepplinger

Esther Kepplinger is Wilson Sonsini Goodrich & Rosati's director of patent operations. She serves as a liaison with the PTO enhancing the firm's practice before the PTO and she provides client strategic patent counseling. Prior to joining the firm in 2005, Ms. Kepplinger served as the Deputy Commissioner for Patent Operations for five years at the USPTO. She holds a BS in biology from Indiana University of Pennsylvania and completed 2 years of graduate studies in biochemistry.

Jeffrey P. Kushan, JD

Jeffrey P. Kushan is a partner with Sidley Austin, LLP, in Washington, D.C., and heads the Firm's D.C. patent group. He specializes in Hatch-Waxman patent litigation, patent appeals, and complex patent administrative proceedings. He also represents clients on domestic and international patent policy matters. Before entering private practice, Mr. Kushan gained extensive experience in patent policy through positions he held in the Patent and Trademark Office and the Office of the U.S. Trade Representative. Mr. Kushan began his career as a patent examiner in 1987, where he was responsible for assessing the patentability of biotechnology therapeutics and diagnostic agents. Mr. Kushan is a graduate of the College of William and Mary, and obtained his JD from the George Washington University Law School and a MA in Chemistry from the University of North Carolina at Chapel Hill.

John A. Lane, MBA

John Lane is Vice President, Biologics, Global Pharmaceuticals for Hospira Inc., the world leader in generic injectable pharmaceuticals. During his tenure at Hospira, Lane has played a key role in establishing the company's biogenerics business. Among other initiatives, he led Hospira's efforts to establish an alliance with STADA for an erythropoietin (EPO) and to acquire the Australian biotech firm BresaGen. Prior to assuming his current position in early 2007, Lane was director, Global Business Development, for Hospira, a role he held since the company's spin-off from Abbott Laboratories in 2004. Lane held a variety of roles during his sixteen preceding years with Abbott. He spent eleven years within the company's finance organization. During the balance of his Abbott career, Lane worked in business development, including two years supporting the hospital products business. Lane earned a Bachelor's degree in finance from the University of Iowa, and a MBA from Northwestern University. He currently serves on the Board of Directors for Illinois Biotechnology Industry Organization

Bruce A. Leicher, JD

Mr. Leicher is Senior Vice President and General Counsel at Momenta Pharmaceuticals Inc., an innovative biotechnology company engaged in development of complex generic products and biogenerics, with 18 years legal experience in the biotechnology industry. Before joining Momenta, he served in senior legal positions at Altus Pharmaceuticals Inc., Antigenics Inc., Millennium Pharmaceuticals, Inc., Curis, Inc., Genetics Institute, Inc. and Wyeth. In private practice, he served as the Co-Chair of the Life Sciences Practice Group at Hill and Barlow, and was an attorney at Hale & Dorr and Butler & Binion after receiving his J.D. from Georgetown University Law Center and his B.A. from the University of Rochester.

David Manspeizer, JD

David A. Manspeizer is Vice President Intellectual Property and Associate General Counsel at Wyeth, one of the world's largest research-driven pharmaceutical companies. The Company discovers, develops, manufactures, and markets, vaccines, biotechnology products, and pharmaceuticals. Before joining Wyeth in 2002, David was a partner at Finnegan, Henderson, Farabow, Garrett & Dunner in Washington, D.C., where he focused on pharmaceutical and biotech patent litigation. David graduated from Rutgers University School of Law-Newark, in 1991, and from the University of Pennsylvania (B.A. Biology) in 1986.

Suzanne T. Michel, PhD, JD

Dr. Suzanne Michel is the Assistant Director for Policy in the Bureau of Competition at the Federal Trade Commission. In that capacity, she participates in all of the patent and patent/antitrust issues that arise in the FTC's enforcement and policy initiatives. She speaks frequently on those topics. Before joining the FTC nine years ago, Suzanne litigated patent infringement cases at the Department of Justice. Prior to that, she served as a law clerk to the Honorable Paul R. Michel (no relation) at the Court of Appeals for the Federal Circuit. She is a registered patent attorney. Suzanne received her Ph.D. in Chemistry from Yale University and her law degree from Boalt Hall School.

Steven B. Miller, MD, MBA

Dr. Steve Miller currently serves as the Senior Vice President and Chief Medical Officer of Express Scripts, Inc. He joined Express Scripts in 2005, bringing with him years of experience as a medical researcher, clinician, and administrator. He has been actively involved in the development of Express Script's clinical programs supporting the use of generic pharmaceuticals and specialty medications. Previously, Dr. Miller served as Vice President and Chief Medical Officer at Barnes-Jewish Hospital/Washington University School of Medicine in St. Louis with responsibility for Oncology Services, Radiation Oncology, Graduate Medical Education, International Health, Research Affairs, Patient Safety and Quality, Marketing and Communications, Pharmacy, Physician Services and Employed Physicians. Dr. Miller guided the hospital to significant improvement in both operations and financial performance. After receiving his medical degree from the University of Missouri, Kansas City, Dr. Miller trained as a Fellow in Pathology and Research at the University of Alabama, Birmingham, and as the William J. and Dorothy Fish Kerr Fellow in cardiology at the University of California, San Francisco. From 1983 through 1988, he was a house officer and faculty member at the University of Colorado Health Science Center in Denver. In 1988, he was appointed a Nephrology Fellow at Washington University, where he remains a faculty member. Dr. Miller also received his MBA at The Olin School of Business at Washington University in St. Louis. He is a frequent international speaker and has published over 80 scientific articles in the areas of acute and chronic renal failure, transplantation, hypertension and medical economics.

Douglas K. Norman, JD

Douglas K. Norman is Vice President and General Patent Counsel for Eli Lilly and Company in Indianapolis. He received his B.S. in Microbiology from Indiana University in 1981 and his J.D., *cum laude*, from the Indiana University School of Law – Indianapolis in 1988. Mr. Norman's practice has included all aspects of patent law, including procurement, licensing, and litigation. He is a member of the Board of Intellectual Property Owner's Association, where he serves as Treasurer, and where he served as Chair of the Amicus Committee from 2003 through 2005 and as Chair of the Annual Meeting in 2006. He is also a member of Interpat. Mr. Norman is currently Chair of the National Association of Manufacturer's subcommittee for Intellectual Property. He was the 2002 co-chair of the Intellectual Property and Anti-Trust Task Force for the United States Council for

International Business and served from 2002 through 2006 as the Chair of the Intellectual Property Task Force for PhRMA.

Naomi Pearce, LLB

Naomi Pearce is Hospira's IP Director & Counsel (Biologics), and has responsibility for all IP-related aspects of Hospira's global biopharmaceutical products. Naomi has 12 years experience in the pharmaceutical and biopharmaceutical industries, 6 years at Hospira (which acquired Mayne Pharma in 2007) and before that, 6 years at a large international law firm. Naomi has considerable experience in providing strategic IP advice and in managing litigation globally, including patent infringement and revocation proceedings in the United States, Canada, Europe, and Asia; global strategic advice on patent infringement risks and freedom to operate (FTO) strategies; and strategic management of patent portfolios. Naomi holds a Masters of Industrial Property; Graduate Diploma of Legal Practice; Bachelor of Laws (Honors) and a Bachelor of Science (Molecular Genetics).

Audrey Phillips, PhD

Audrey is an Executive Director of Biopharmaceutical Public Policy and Advocacy with more than 35 years of experience in the pharmaceutical sector at Johnson & Johnson. Her focus is to provide education with regard to health policies that affect patients and impact the innovation of biopharmaceutical medicine. Audrey moved up the ranks while completing her education and has held various leadership positions over the years throughout many areas of drug discovery, drug development, and strategic marketing. These positions include Discovery Team Leader, Reproductive Medicine Franchise Team Leader, various Global Product Leader positions, and head of Strategic Life Cycle Management. She was an Adjunct Associate Professor in the ObGyn Department at the University of Medicine & Dentistry of New Jersey, a recipient of the TWIN (NJ Tribute to Women in Industry) Award and has authored more than 60 publications.

Hans Sauer, MS, PhD, JD

Dr. Hans Sauer is Associate General Counsel for Intellectual Property for the Biotechnology Industry Organization. Dr. Sauer joined BIO in August of 2006 from MGI Pharma, Inc., in Bloomington, MN, where he was Chief Patent Counsel. Mr. Sauer began his industry career in 1995 as a postdoctoral fellow in the Department of Neuroscience of Genentech, Inc. He subsequently held various positions in the legal department of Guilford Pharmaceuticals Inc., where he was responsible for patent prosecution, clinical research health information privacy, and legal compliance in sales and marketing. Mr. Sauer is a registered patent attorney and adjunct professor of law at Georgetown University Law Center. He holds a Master's degree in biology from the University of Ulm in his native Germany, a Ph.D. in neuroscience from the University of Lund, Sweden, and a law degree from Georgetown University Law Center in Washington, D.C.

William B. Schultz, JD

William B. Schultz has been a partner in the Washington, D.C. law firm of Zuckerman Spaeder LLP since 2001, where he represents generic drug companies, states and municipalities, nonprofit organizations, and individuals. Previously, he served as Deputy Assistant Attorney General, Civil Division, U.S. Department of Justice (1999-2000), Deputy Commissioner for Policy, Food and Drug Administration (1994-98), Counsel to the Subcommittee on Health and the Environment, U.S. House of Representatives (1989-1994), and as a litigating attorney at Public Citizen Litigation Group (1976-89). Between 1983 and 1996, Mr. Schultz taught Civil Litigation and Food and Drug Law at Georgetown University Law Center. Prior to entering law practice, Mr. Schultz clerked for Judge William B. Bryant, U.S. District Court, Washington, D.C. (1974-75). He

received his J.D. from the University of Virginia Law School (1974) and his BA from Yale University (1970).

Rochelle Seide, JD

Dr. Rochelle Seide is currently Senior Counsel with Schwegman, Lundberg & Woessner. Her practice encompasses all facets of patent law, including litigation, written opinions, patent strategies and transactional matters, particularly in the life sciences. She has obtained patents in the areas of biotechnology, chemistry, and pharmaceuticals for a variety of clients. Rochelle also counsels clients on legal issues relating to biotechnology, chemical and pharmaceutical patents, including patent enforcement, validity and infringement, licensing and business development. She has broad experience in transactional matters for biotechnology and pharmaceutical clients. Rochelle also represents clients in patent litigations before the federal courts, as well as in patent interferences in the US Patent and Trademark Office, in biotechnology, pharmaceutical and medical device technologies. While attending law school, she was an instructor/assistant professor of medical genetics and microbiology at the Northeastern Ohio Universities College of Medicine and worked as a genetics counselor at the Akron Children's Medical Center.

Rochelle was a member of the National Academy of Sciences' Committee on Intellectual Property in Genomic and Protein Research and Innovation. She is a member of the Association of the Bar of the City of New York; the American Bar Association; the Biotechnology Industrial Organization Intellectual Property Counsel's Committee and the American Chemical Society. Rochelle is an active member of the American Intellectual Property Law Association (having served as chair of its Biotechnology Committee) and the New York Intellectual Property Law Association (where she is a past chair of the Public Information and Education Committee and the Legislative Oversight and Amicus Briefs Committee). She is a member of the advisory council to the University of Akron School of Law's Center for Intellectual Property Law. Rochelle is also a member of the board of directors of the National Inventors Hall of Fame and the Biojudiciary Project.

Recognized as an expert in her field, Rochelle is listed in the Chambers USA Guide, America's Leading Business Lawyers (2004-2008), Chambers Global, The World's Leading Lawyers (2004-2005) and The Best Lawyers in America (2005-2006). She has also been deemed a New York "Super Lawyer" in 2006- 2008. Rochelle has published and lectured extensively on biotechnology-related issues, including follow-on biologics. She has authored columns on biotechnology for the Licensing Journal, and an online column on patent law, Trendspotter, for GenomeWeb.com and twice, was Chair of the Preparing Patent Legal Opinions conference, Practicing Law Institute, New York, (September 2005 and September 2006). She co-chaired the Life Sciences IP Due Diligence conference, American Conference Institute, New York City, January and June 2006.

Christine J. Siwik, JD

Christine J. Siwik is a partner with Rakoczy Molino Mazzochi Siwik LLP, an intellectual property firm assisting clients in the pharmaceutical, biotechnology, and chemical industries. Ms. Siwik's practice focuses primarily on pharmaceutical regulatory counseling and litigation, pharmaceutical patent litigation, and federal legislative issues involving the pharmaceutical industry. She assists clients in developing long-term legal and business strategies for developing, obtaining regulatory approval for, securing patent clearance for, and launching a wide range of pharmaceutical products. Christine obtained her Juris Doctor from Loyola University Chicago School of Law, magna cum laude.

Mateja Urlep RPh

Mateja Urlep is a pharmacist with 17 years experience in the field and has held management positions in several areas, including development, production, marketing and sales, and academia. As the head of Global Marketing and Medical team at Sandoz (Novartis), she is responsible for establishing and guiding all marketing activities of biosimilar biopharmaceutical products. She also coordinates specific country operations for marketing, launch plans, and commercialization strategies for the company's overall biosimilar biopharmaceuticals portfolio. As the leader, she ensures that the pipeline and portfolio are aligned with market strategies and requirements. Prior to taking on this position, Mateja was the Head of the Centre of Excellence in Mengeš, where she led biopharmaceutical development and production from 2001 to 2007. During this time, she served for two years as Sandoz's Head Biopharmaceutical Franchise CEE, responsible for regional activities of the business in development, production, marketing, and sales.

Michael Wroblewski, JD, MPA

Michael Wroblewski returned to the FTC in June 2008 as an attorney in the FTC's Bureau of Competition. From 1998-2006, Mr. Wroblewski served in several capacities at the FTC, including Assistant General Counsel for Policy Studies in the Office of the General Counsel, and as an attorney advisor to Commissioner Leary. During this time, he directed many of the Commission's efforts to study competition issues in the pharmaceutical and electric power industries. He oversaw the Commission's efforts to examine whether a conflict of interest exists when a pharmacy benefit manager (PBM) owns a mail-order pharmacy and to examine the competition issues raised by the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, which govern the approval of generic drug products. He is the primary author of the 2005 FTC Report *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies*, and of the 2002 FTC study *Generic Drug Entry Prior to Patent Expiration*. He is the primary author of two reports (2000 and 2001) that examined competition and consumer protection issues in the electric power industry. In 2007 and 2008, Mr. Wroblewski worked at Consumers Union, the non-profit publisher of *ConsumerReports*, in which he led a team to research and develop CU health care service provider ratings (doctors, hospitals, nursing homes, insurance providers). Prior to joining the FTC in 1998, he was a telecommunications attorney in the Washington, D.C. offices of Latham & Watkins and of Verner, Liipfert, Bernhard McPherson & Hand. He attended Loyola College, receiving his B.S., B.B.A. *Magna Cum Laude* in Finance and Computer Science. In 1992, Mr. Wroblewski received his J.D. from the University of Texas School of Law, and a Masters in Public Affairs from the Lyndon Baines Johnson School of Public Affairs.

Bryan C. Zielinski, MS, JD

Bryan C. Zielinski has been with Pfizer since 1994. Currently, he is responsible for the La Jolla Bioinnovation and Biotherapeutics Center at St. Louis patent groups. Since 2002, he has worked as the La Jolla Patent Department Site Head. He is the Chair of the Industry Issues Team, focusing on U.S. legislative and amicus issues. From 1994 to 2002, he was a member of Pfizer's New York patent department, where he handled matters in the areas of oncology and antibacterial therapeutics. Prior to joining Pfizer, he worked in private practice on various intellectual property matters at the New York law firm Davis Hoxie Faithfull & Hapgood from 1989-1994. Mr. Zielinski received BS and MS degrees in Chemistry from Davidson College and a Juris Doctor from the University of Florida. His admissions include the New York State Bar and the U.S. Patent and Trademark Office.