



NAMING PHARMACEUTICAL DRUG PRODUCTS: TRADEMARK LAW AND REGULATORY ASPECTS

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BIOGRAPHIES

David W. Opderbeck, *Professor of Law and Director, Gibbons Institute of Law, Science & Technology, Seton Hall University School of Law*

Professor Opderbeck's work focuses on the regulation of access to scientific and technological information. His published work has employed the tools of game theory, classical microeconomics, and statistical analysis to address issues such as settlements in Hatch-Waxman litigation, cybersecurity policy, intellectual property restrictions on essential medicines in developing countries, open source biotechnology, patent damages reform, and the interaction of law and social norms concerning music file sharing.

Professor Opderbeck's interest in cybersecurity law and policy included a multi-year grant-funded project sponsored by the Bergen County, New Jersey Prosecutor's Office, which included new courses, continuing legal education programs, and the creation of a governmental working group on cybersecurity and cybercrime. The governmental working group recently worked on a new online child pornography bill that was signed into law by Governor Christie. Professor Opderbeck frequently lectures to law enforcement agencies and other groups on cybercrime, cyberterrorism, and civil liberties.

In addition to his traditional legal scholarship, Professor Opderbeck is interested in the philosophical and moral foundations of information policy and other aspects of the law. He has written on ethical, philosophical and theological issues in law and jurisprudence, and currently is completing a doctorate in philosophical theology regarding the intersection of neuroscience and the law.

Professor Opderbeck maintains a website relating to his work at <http://www.davidopderbeck.com>.

Paolo Strino, *Director, Intellectual Property, Gibbons P.C.*

Drawing on almost 15 years of experience as in-house and outside counsel in both the United States and Europe, Mr. Strino concentrates his practice in domestic and international trademark clearance and prosecution, trademark portfolio management, anti-counterfeiting enforcement, and U.S. and multi-country litigation. He represents clients in a broad array of industries ranging from chemical and pharmaceuticals, fashion, food and wine, media, entertainment, finance, insurance, and tourism.

Mr. Strino is highly regarded in the field of opposition and cancellation proceedings before the Trademark Trial and Appeal Board, for all stages from discovery to trial. He has extensive experience in the area of geographic certification marks having prosecuted many applications to register and maintain world-renowned indications of origin including Prosecco Doc, Emilia, Asiago, and Pecorino Romano.

Mr. Strino is proficient in a number of related areas including copyright registration and enforcement, trade dress protection, licensing and distribution, trademark dilution, false advertising, internet and media law, domain name arbitration proceedings, technology transfer, and other vendor agreements.

He regularly advises clients on general corporate matters, with a special focus on international and cross-border transactions and is a frequent speaker at conferences and seminars in the United States and Europe.

Bob Przybylko, *Associate Director, Global Trademark Development, Merck & Co., Inc.*

Bob is part of the Global Trademark group at Merck & Co. Inc. He is currently responsible for facilitating the naming process for various compounds and devices in the Merck pipeline. Prior to that he headed up the Trademark Development group at Schering-Plough. In addition to his TM development experience, Bob also worked in the pharmaceutical industry for 12 years as a trademark paralegal.

Susan M. Proulx, *PharmD, President, Med-ERRS*

Over the course of her career in Medication Safety, Susan has become an expert in all aspects of product-related safety issues. In addition to being a leader in the industry in preventing medication errors due to trademark confusion, Susan also has overseen numerous projects related to improvement of packaging and labels to increase clarity and ease of reading. In recent years, Susan has lent her medication safety expertise to the field of Human Factors Engineering, collaborating on label safety and drug-device usability issues. Some of these projects have led to patents and publications. While not reading regulatory guidances, Susan enjoys traveling, gardening and her 3 adorable cats.

Kellie Taylor, *PharmD, MPH*

Dr. Taylor currently serves as the Deputy Director of the Office of Medication Error Prevention and Risk Management the Office of Surveillance and Epidemiology in FDA's Center for Drug Evaluation and Research's (CDER) where she is responsible for the Center's programs in risk management and medication error prevention. She is also the former director for the Division of Medication Error Prevention and Analysis (DMEPA), where she provided oversight, coordination, and technical expertise for the pre- and post-marketing activities involving medication error prevention and analysis regulated drug and drug/device products, including proposed proprietary names for human drug products.

Dr. Taylor has worked in DMEPA since 2006 and is involved with developing policy and procedures for FDA's name, labels and labelling evaluations for drug products. She is a pharmacist, and began her career as a clinical inpatient and outpatient pharmacist, before specializing in risk management and analysis. She was trained as a fellow specializing in medication error analysis and prevention at the Institute for Safe Medication Practices in Pennsylvania.

She is a Fellow of the Institute for Safe Medication Practices (ISMP), an expert advisory member to Health Canada's labelling and nomenclature working groups, and participates and leads many working groups within CDER on safety, labelling and nomenclature aspects that impact the safe use of drug products.