Touro College of Pharmacy Presents:

Advances in Generic Pharma and Biosimilars

A Research Symposium*

Tuesday, March 29, 2016

P2 Lecture Hall, 4th Floor

*symposium is a complementary event

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Welcome

Welcome to the Advances in Pharmaceutical Generics and Biosimilars Symposium*

Touro College of Pharmacy is excited to host this symposium focused on, “Advances in Generic Pharmaceuticals and Biosimilars.” The symposium will be held at the Manhattan Campus of the Touro College of Pharmacy located at 231 West 124th Street on March 29, 2016. Leading scientists in the pharmaceutical and biotechnology industry as well as in academia will present seminars addressing advances in the development, manufacturing, marketing and regulatory pathways of generics and biosimilars. The symposium is being sponsored by OMICS International Conference Series.

Touro College of Pharmacy, a member of the Touro College and University System, is committed to providing an outstanding education to its students, service to the profession of pharmacy and advancing the field of pharmacy through research and scholarship.

We thank OMICS International for supporting the Symposium and the administration of the Touro College and University System for their vision, support and dedication. As an academic community, we are dedicated to our quest to advance the pharmaceutical sciences, biomedical sciences and pharmacy practice.

Henry Cohen, PharmD, MSc  
Dean and Professor

Mariana Babayeva, MD, PhD  
Associate Professor

Zvi Loewy, PhD  
Professor, Chair  
Immediate Past Dean

* Non-CE Program
Agenda

March 29, 2016

10:00 am - 10:30 am  Arrival
10:30 am - 10:40 am  Welcoming Remarks  
   Dr. Henry Cohen, Dean  
   Dr. Zvi Loewy, Professor and Chair Pharmaceutical and Biomedical Sciences
10:40 am - 11:10 am  Generic Drugs - Dr. Mariana Babayeva
11:15 am - 11:45 am  Generic Drugs in Transdermal Dosage Forms - Dr. Fotios Plakogiannis
11:50 am - 12:25 pm  Product Selection and Launch Optimization in the Generic Pharmaceutical Industry - Dr. Indranil Nandi
12:30 pm - 1:00 pm  Generics in the Pharmaceutical Industry - Dr. Bilge Selvi
1:00 pm - 1:45 pm  Complementary Lunch
1:45 pm - 2:15 pm  Generic Pharmaceutical - Portfolio Selection and Optimization - Dr. Ricky Suchak
2:20 pm - 2:50 pm  Emerging Issues in Hatch-Waxman and BPCIA Patent Litigation Navigating Uncharted Territory - Dr. Martha M Rumore
2:55 pm - 3:25 pm  Emerging Markets Considerations for Biosimilar Development and Registration Dr. Christopher J Leintz
3:30 pm - 4:00 pm  Development and Manufacturing of Biosimilars - Dr. Michiel E Ultee
4:05 pm - 4:35 pm  Academic-Industry Collaborations: Practical Insights - Dr. Paramita Basu
4:35 pm  Closing Remarks  
   Dr. Zvi Loewy, Professor and Chair Pharmaceutical and Biomedical Studies

Light refreshments following closing remarks.
“Generic Drugs”

Mariana Babayeva, M.D., Ph.D. is an Associate Professor at Touro College of Pharmacy, NY. Dr. Babayeva has over 10 years of experience in clinical practice. Over the past years her research efforts have generated collaborations with well-known universities such as LIU, UNC, and Rockefeller as well as the pharmaceutical industry. Dr. Babayeva has conducted national and international pharmaceutical research projects.

“Product Selection and Launch Optimization in the Generic Pharmaceutical Industry”

Dr. Indranil Nandi is currently Vice President R&D at Vertice Pharmaceutical responsible for research regulatory and external development partnership. Dr. Nandi comes to Vertice pharmaceutical from Impax, CA where he most recently served as Vice President, Generic Research & Development. In Impax, he was responsible for CMC development activity for Generic and Branded pipeline. Prior to Impax, Dr Nandi held positions of increasing responsibilities in Sandoz Inc including last position as Executive Director, Portfolio, Project management and Scientific affairs. He also worked in various positions in R&D in Par Pharmaceuticals, NY and Geneva Pharmaceuticals, NJ. Dr. Nandi has over 15 years experiences in product development of ANDA including First to File and 505 (b)(2) products in various dosage forms. He also has extensive experiences in portfolio & project management, development operations, licensing, due diligence, remediation programs and R&D strategy. He is coauthored various scientific publication and patents and patent applications. He also delivered invited talks in the area of drug delivery and generic portfolio and project management strategy in various national and international symposiums. Dr Nandi received a Master of Business administration from Rutgers, State University of NJ; a Ph.D in pharmaceutical sciences from St. John’s University, NY and a Master’s degree in pharmacy from Birla Institute of Technology and Sciences, India.

“Generic Drugs in Transdermal Dosage Forms”

Fotios Plakogiannis, Ph.D. in Pharmaceutics is a retired Professor of the Arnold & Marie Schwartz College of Pharmacy, L.I.U. Dr. Plakogiannis served in the College of Pharmacy for 45 years of which for 45 years was Director of the Division of Pharmaceutical Sciences. Has published closed to 100 scientific papers in peer review journal and the majority of them was in the area of Transdermal Delivery. Currently, he is the Managing Director of the Transdermal Research Pharm Laboratories, LLC.
Dr. Martha Rumore, PharmD, JD, MS, LLM, FAPhA

Dr. Martha Rumore is a Fellow of the American Pharmacists Association and Associate Professor at Touro College of Pharmacy where she teaches Pharmaceutical Law and Drug Information. She also taught Drug Regulatory Affairs and Food, Drug Cosmetic Law at Long Island University College of Pharmacy. In 2016 she was appointed to the ACPE Board of Directors. Dr. Martha Rumore is also presently an Oncology Pharmacist (alternating weekends for 22 years) at Beth Israel Medical Center, Mt. Sinai.

Dr. Martha Rumore is also presently Of Counsel at the law firm of Sorell, Lenna & Schmidt. She is admitted to the NY, NJ and DC bars and is registered to practice before the U.S. Patent & Trademark Office. Dr. Rumore focuses on pharmaceutical and medical device intellectual property including all aspects of patent law: prosecution, opinion work, litigation and transactional matters. Martha has authored freedom-to-operate, patentability, invalidity, infringement and non-infringement opinions, including opinions supporting Paragraph IV certification under the Hatch-Waxman Act. She has over eight years of law firm experience counseling on early market opportunities for generic clients particularly in the area of Paragraph IV matters and has also prepared ANDAs and 510K applications. She has experience in all facets of ANDA litigation-expert witness reports, depositions, scientific document review, complaint and answer, motion practice. Representative generic cases she has handled include Glaxo v. Andrex Pharmaceuticals, Medpointe v. Hi-Tech Pharmacal (2nd chair), and Schwartz Pharmaceuticals v. Sun Pharma. She teaches Food, Drug & Cosmetic Law at Touro Law School.

Academic-Industry Collaborations: Practical Insights

Dr. Paramita Basu is an Associate Professor in the department of Pharmaceutical & Biomedical sciences at Touro College of Pharmacy. In her current academic position and her past experience as a research scientist in the diagnostic industry, she has acquired extensive college teaching experience and scientific research experience in the biotechnology industry with a flair for use of modern technology. She has been involved in teaching, coordination and design of graduate level courses in Physiology, Pathophysiology, Clinical Microbiology, Biotechnology, Cell/Molecular Biology. Her research activities include studying antimicrobial resistance mechanisms, host-pathogen interactions, and stress resistance in prokaryotes. In addition, her 10+ years’ experience in research in the academia and diagnostics industry supports her interest in bioassay design and development.

Dr. Basu obtained her bachelor’s degree in Physiology from University of Calcutta, followed by a Master’s degree in Pharmaceutical Biotechnology from Jadavpur University, India and a Doctoral Degree in Molecular Biology from St. John's University. Her thesis centered on molecular mechanisms of acid resistance in E. coli and it’s small colony variants.

Emerging Issues in Hatch-Waxman and BPCIA Patent Litigation Navigating Uncharted Territory

Martha Rumore, PharmD, JD, MS, LLM, FAPhA

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Dr. Ricky Suchak, Director Portfolio Management, Head Portfolio Management, Sandoz US.

Ricky Suchak is responsible for creating competitive pipeline strategy to achieve growth targets, formulating strategic portfolio plan for key focus therapeutic franchisees for Sandoz. He is responsible for portfolio strategy for Generics, OTC and Life Cycle Management/505(b)(2)s product portfolio. He manages internal and external portfolio across BD&L partners and multiple global development centers. Mr. Suchak is also part of Mergers & Acquisitions team and is involved in BD&L deal valuations, risk analysis and due diligence process. He has been working with Sandoz for 4 years.

Before Sandoz, Ricky worked in Forest Laboratories, Actavis, and Shire Laboratories for 8 years in various scientific and operational capacities such as Global Technology Transfer leader, Senior Product development Scientist, where he was responsible for development, tech transfer and commercialize new products and delivery technology, while leading cross-functional local and global teams. He has developed and filed multiple ANDAs (that include First to Files), developed 505(b)(2)/NDA that resulted in successful clinical outcome and developed novel drug delivery technology to screen new molecules for pre-clinical studies. He has also filed patents applications.

Ricky has Bachelors in Chemical Engineering (India), Masters in Chemical Engineering (University of Maryland College Park) and MBA from New York University - Stern School of Business.

“Emerging Markets for Considerations for Biosimilar Development and Registration”

Dr. Christopher J Leintz is a Director, EM Biosimilar Regulatory Strategy at Pfizer. He has extensive experience in global drug and biologic development and commercialization in the pharmaceutical and biotechnology industries, with extensive experience in oncology, neuroscience, immunology, antivirals, and women’s health.

Prior to joining Pfizer, Dr. Leintz was the global regulatory lead at Purdue Pharma, LP. He has also held global regulatory leadership roles at Abbott Laboratories, Hospira, and Takeda. He also served in the US Peace Corps in Bulgaria as a representative to the Bulgarian Ministry of Environment and Water.

Dr. Leintz has a Doctorate in Bioethics, a Masters in Public Health Informatics, and a BS in Biology.
“Generics in the Pharmaceutical Industry”

Dr. Bilge Selvi is a Principal Researcher in the Product Development department at Teva Pharmaceutical. She has been at Teva for over six years, her responsibilities are to perform the development activities of NDA and NTE products from the early through the submission stages. He worked at R&D of Forest Labs and Novartis in US and Europe. Bilge received her PhD in division of Pharmaceutical Sciences at the University of Long Island in Brooklyn NY, where she focused on product development strategies for small and large molecules. She earned her B.S in Chemical Engineering at technical University in Turkey.

“Development and Manufacturing of Biosimilars”

Dr. Michiel “Mike” Ultee has more than 30 years of experience in the development of biopharmaceuticals, from research through commercial manufacturing. Recognized as an industry expert on antibodies, fusion proteins and other recombinant proteins, he is a frequent speaker at international conferences and serves on the Editorial Advisory Board of Biopharm International and Bioprocess International.

“The Road to the Biologic IND” is a special program created by Dr. Ultee for those in the research and discovery to understand better the steps and commitments required to successfully develop and manufacture an early-phase biopharmaceutical. This part of the program was recently published in the American Pharmaceutical Review. Additional components of the program included coverage of toxicological and regulatory aspects of the process, presented by his colleagues. The program has now been presented in ten cities across the country, often to capacity crowds.

Dr. Ultee has published a wide variety of papers of all aspects of bioprocessing. These include an in-depth review of antibody purification techniques for the Encyclopedia of Industrial Biotechnology, initially in 1999 and then for its second edition in 2010. Other papers have focused on the production and purification of challenging proteins, including fusion proteins and IgM antibodies. More recently he has presented and published on manufacturing challenges of biosimilars, flexibility in bioprocessing, and the effect of cell-culture conditions on protein glycosylation.

As the scientific co-founder and CSO of Laureate Biopharma and its successor Gallus Biopharmaceuticals, Dr. Ultee developed dozens of proteins into new biopharmaceuticals. He formed Ulteemit BioConsulting in October 2013 to offer expert consultation in the fields of process development and manufacture of protein therapeutics.
OMICS International organizes 1000+ Conferences every year across USA, Europe & Asia with support from more than 1000 scientific societies and publishes 700+ Open access journals which contains over 30000 eminent personalities, reputed scientists as editorial board members.

Biosimilars is a global annual event. The Biosimilars 2016 will bring together scientists, researchers, industry delegates like CEO, Directors, Chief Scientific Officers, Patent Attorneys, Regulatory Officers, Consultants and Clinical Research Organizations spanning over the entire globe. Pan USA there are over 200 companies of Biologics and Biosimilars with more than few thousand researchers delving on these topics. All over the world, there are more than 400 companies with Biologics and Biosimilars in their R&D pipelines and more than 10,000 industries focussing their research work on Biosimilars and Biologics.

The Organizing Committee for Biosimilars 2016 welcomes all industry, academic and regulatory agency personalities to participate at the 6th International Conference and Exhibition on Biologics and Biosimilars during October 19-21, 2016 at Houston, USA. We shall be very happy to learn from you, through your talks and interactions at conference. We believe this conference shall be a knowledge and value addition to all attendees. We look forward towards associating with you at the earliest.

OMICS International is currently bringing forth “International Conference and Expo on Generic Drug Market and Contract Manufacturing” (Generic Pharma 2016) slated on Nov 07-09, 2016 at Barcelona, Spain.

Generic Pharma 2016 is one of the largest gatherings of the global generic industry, attracting attendees from around the globe. This platform provides a unique forum for generic pharmaceutical executives from around the world to network and hear world-renowned experts discussing the latest insight into the international commercial, legal, and regulatory developments concerning the generic pharmaceutical sector.