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Karl-Franzens-Universität Graz,

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8th Symposium

New Developments in Clinical Pharmacy and Clinical Pharmacology

June 3-4, 2011
Graz, Austria



- 8:00-9:00** **Registration/Coffee**
 Grand auditorium Aula
 Universitätsplatz 3
 University of Graz
- 9:00-9:30** *Welcome by*
Hartmut Derendorf
 University of Florida
Rudolf Bauer
 Karl-Franzens-Universität Graz
William Riffie
 University of Florida
- 9:30** *Personalized Medicine: Not So Fast My Friends!*
Lawrence Lesko
 University of Florida
- 10:00** *Importance of Drug Transporter Studies In New Drug Discovery
 And Development*
Yuichi Sugiyama
 University of Tokyo
- 10:30-11:00** **Break**
- 11:00** *Evidence for Food As A New Addiction*
Mark Gold
 University of Florida
- 11:30** *Orodispersible Minitablets - A New Option For Pediatric Drug
 Delivery*
Jörg Breitzkreuz
 Heinrich-Heine-University, Düsseldorf
- 11:45** *Current Issues and Perspectives of Biosimilars*
Robert Bell
 Drug and Biotechnology Development, LLC,
 Tampa



Sonja Mayer, PhD, studied pharmacy at the University of Regensburg and got her PhD at the University of Munich, Germany. From 1998 until now she works for the Bavarian Chamber of Pharmacists in Munich, Germany. Her responsibility includes Bavarian Drug Information Centers, further education and Pharmaceutical Care. Dr. Sonja Mayer is author of many publications and oral / poster presentations at international meetings, she is the editor of a book on drug information. She is specialised in drug information, nutritional counseling and homeopathy/naturopathy. She was a co-organizer of the biennial international 6th Global Gator Meeting in Munich (2007). Since 2010 she is business manager of the Bavarian Academy of Clinical Pharmacy.



Paul Doering MS, is Distinguished Service Professor in the Department of Pharmacy Practice at the University of Florida, College of Pharmacy. He is also Co-director of the statewide Drug Information and Pharmacy Resource Center. Mr. Doering received his B.S. degree in pharmacy from the University of Florida in 1972 and continued his training at the same institution, earning the MS in Clinical Pharmacy in 1975. Paul has very strong ties with the practice of pharmacy, having been a practicing pharmacist both in the hospital and community setting. A member of many local, state, and national pharmaceutical societies, Paul is a Past-President of his local pharmacy association. For his hard work with students, Paul has been recognized four times as Teacher of the Year for the College of Pharmacy. In March, 1990, Mr. Doering was awarded Fellowship status in the APhA's Academy of Pharmacy Practice and Management. In 1993, Mr. Doering received one of two Teaching Incentive Awards given to College of Pharmacy faculty at the University of Florida. Mr. Doering was promoted to Distinguished Service Professor in April 1995, the University's highest honor which can be awarded to a faculty member. He is the first professor in the College of Pharmacy's 70-plus year history to be recognized in this way.



Stephanie Läer is Professor of Clinical Pharmacy at the University of Düsseldorf with a background of a Pharmacist, a Clinical Pharmacologist as well as a Pharmacologist and Toxicologist. She founded and established the Department of Clinical Pharmacy at the University of Düsseldorf in 2004. The department is at the interface between Pharmacy and Medicine. The main research area of this institution is the optimization of drug therapy for children. Her research was supported by non-profit and profit funding and honored with awards like the Dr. Martini Foundation, of the Bundesverband Herzranke Kinder, of the Hexal Kinderinitiative gGmbH, the “*Presidential Trainee Award 2009*” of the ASCPT, the Lars Boraeus award 2009 of the European Society of Paediatric Pharmacology.



Karen Whalen, PharmD, BCPS received her Doctor of Pharmacy degree from the University of Florida. She then completed a Pharmacy Practice Residency at the Moses Cone Health System in Greensboro, North Carolina, followed by a Primary Care Residency at the James A. Haley Veterans’ Hospital in Tampa, Florida. Following residency training Dr. Whalen was a faculty member in the Department of Pharmacy Practice at Nova Southeastern University (NSU) for twelve years.

While at NSU she was an eight-time recipient of the Golden Apple Award for Teaching Excellence. In 2008, Dr. Whalen joined the University of Florida College of Pharmacy as Assistant Director of the St. Petersburg Campus. Currently, she serves as Clinical Associate Professor in the Department of Pharmacotherapy and Translational Research and Director of the Master of Science in Pharmacy with a concentration in Clinical Pharmacy degree program. Dr. Whalen is active in local, state and national pharmacy organizations, and currently serves as Chairman of the Board of the Florida Pharmacy Association.

12:00 Presentation of GlobalGator Award

Previous Awardees:

2009: Willy Roth

2007: Markus Brewster

2005: Hans Schreier

12:15 *Determining Bioequivalence Of Inhaled Beta-2 Agonists*
Leslie Hendeles
University of Florida

12:30-13:30 Lunch

13:30 *Chinese Herbal Medicine from a Western Perspective*
Rudolf Bauer
Karl-Franzens-Universität Graz

13:45 *Impaired Host Defense And Detoxification In Various Disease States*
Teruo Murakami
Hiroshima International University

14:00 *Mechanism-based Analysis of Chronic, Progressive Diseases*
Stephan Schmidt
University of Leiden

14:15 *Discovery of Drugable Targets Using In Vivo Combinatorial Screenings*
Wouter Driessen
M.D. Anderson, Houston

14:30 *Pharmacodynamic Evaluation And Dose Optimization Of Voriconazole*
Kazuro Ikawa
Hiroshima International University

- 15:00** *Are We Minding the Gap? Determination of Equivalence Beyond Healthy Volunteers and Before Epidemiological Studies*
Stephan Müller
Mundipharma, Limburg
- 15:15** *Role of Reactive Oxygen Species in Formation of Kidney Stones*
Saeed Khan
University of Florida
- 15:30** **Break**
- 16:00** *Errors in Healthcare: What can go wrong?*
Tom Johns
University of Florida
- 16:15** *The German “Dextromethorphan”-Story – Dangerous Dreams*
Stephanie Läer
Heinrich-Heine-University, Düsseldorf
- 16:30** *Going Global with Clinical Pharmacy: A New UF Master’s Program*
Karen Whalen
University of Florida
- 16:45** *MTM in Germany*
Sonja Mayer
Bavarian Chamber of Pharmacy
- 17:00** *Reflections on a Long Teaching Career*
Paul Doering
University of Florida



Saeed R. Khan, PhD, is a Professor in the Department of Pathology, Immunology and Laboratory Medicine in University of Florida College of Medicine. Dr. Khan’s research involves investigation of kidney stone. Dr. Khan has so far published over 300 articles, 130

in refereed journals. He has served and continues to serve on various panels reviewing research grant applications. He has received the University of Florida Research Achievement Award, College of Medicine Faculty Research Prize in Basic Science as well as the University of Florida Research Foundation Professorship. He has given keynote addresses, and plenary and state of the art lectures at conferences and symposia both at national and international meetings including meetings in Australia, Britain, China, France, Germany, India, Italy, Japan, Pakistan, South Africa, Sweden, Switzerland and Taiwan.



Thomas Johns PharmD is currently the Assistant Director of Pharmacy Services, Department of Pharmacy at Shands Hospital at the University of Florida. He holds an appointment as a Clinical Assistant Professor at the UF College of Pharmacy, Gainesville, Florida. His area of responsibility includes medication safety, drug policy development and implementation, quality improvement and

regulatory compliance. He received his Doctor of Pharmacy degree in 1992 from the UF College of Pharmacy, followed by an ASHP accredited specialty residency in Adult Internal Medicine at the VA Medical Center in Gainesville, FL. He obtained Board Certification in Pharmacotherapy in 1996. Other interest areas include improving patient safety and medication error prevention in rural hospitals. He continues his work with FL Critical Access Hospitals as part of a medication safety program supported by the State of Florida Office of Rural Health. Dr. Johns has served as President of the Florida Society of Health-System Pharmacists (FSHP). Achievements include being named the FSHP Pharmacist of the Year and receipt of the FSHP Medication Safety Award.



Kazuro Ikawa PhD is the Associate Professor, Department of Clinical Pharmacotherapy, Hiroshima University. He started his carrier as a clinical pharmacist at Oita Medical University Hospital (Apr 1994–Aug 1999), worked as a reviewer for drug approval at Ministry of Health, Labor and Welfare (Japanese FDA) (Sep 1999–Jun 2003), and then transferred to Hiroshima

University. His research mainly focuses on clinical pharmacokinetics and pharmacodynamics at target sites especially for antimicrobial agents. Recently, he studied more about site-specific PK-PD of antibiotics at Dr. Derendorf's laboratory as a Short Term Scholar, Department of Pharmaceutics, University of Florida (Jul–Sep 2010; please see the picture). He is a coauthor of more than 70 (English) and 20 (Japanese) publications, and his work is recognized by 3 domestic awards from Japanese Society of Chemotherapy, Japanese Society of Clinical Pharmacology and Therapeutics, and Pharmaceutical Society of Japan.



Stefan Müller PhD, is an employee of Mundipharma Research GmbH&Co KG and currently scientific advisor in Pharmacological Intelligence. His responsibilities include coordinating the evaluation of new project proposals, competitor intelligence and scientific support for business development-driven evaluation of new in-licensing opportunities and potential in-house developments. Previous

functions were in Analytical Development, Project Management and Regulatory Affairs. He has a pharmacy degree from the Johannes-Gutenberg University in Mainz and was a graduate student in the Department of Pharmaceutics, UF, where he acquired his Ph.D. and a national research award of the American Association of Pharmaceutical Scientists (AAPS) for Graduate Students, section PK, PD and Clinical Sciences.

**17:15 Alumni Gathering/Clinical Pharmacy Program
WPPD**

19:45 Reception and Group Photo

GatorFest

Festive Dinner

Alte Universitaet

Hofgasse 14, 8010 Graz

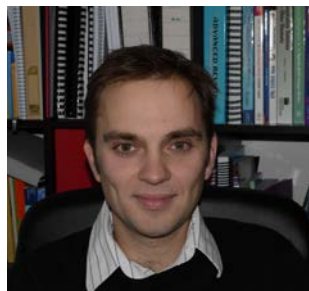
**Late Night: Nightcap
Hotel Weitzer, Engelreich**

2009	7th Symposium	Stresa, Italy
2007	6th Symposium	Munich, Germany
2005	5th Symposium	Leuven, Belgium
2003	4th Symposium	Vienna, Austria
2001	3rd Symposium	Dresden, Germany
1999	2nd Symposium	Reims, France
1997	1st Symposium	Münster, Germany



Larry Lesko, PhD, Director of the Office of Clinical Pharmacology at the FDA's Center for Drug Evaluation and Research, will lead the UF's new pharmacometrics and systems pharmacology initiative in the interdisciplinary Institute of Therapeutic Innovation at the UF Research and Academic Center, now under construction in Orlando. He will assume his new duties July

1. Dr. Lesko is also Chair of the Clinical Pharmacology Section of the Medical Policy Coordinating Committee, and Co-Chair of the Biopharmaceutics Coordinating Committee, in CDER that is responsible for developing guidances for industry. Dr. Lesko currently represents FDA on the Common Technical Document (Efficacy) Working Group in the International Conference on Harmonization. Dr. Lesko was previously Associate Director of Research at the FDA where he was responsible for developing and managing the Product Quality Research Program in the Office of Generic Drugs (1992-95). Prior to joining FDA, Dr. Lesko was Vice President of PharmaKinetics Laboratories (1988-92) and Associate Professor of Pharmaceutics at the University of Maryland at Baltimore (1981-88). He also held an appointment in the Laboratory of Neuroscience, National Institute on Aging, National Institutes of Health, from 1985-1988 investigating the effects of age on the pharmacokinetics and pharmacodynamics of drug substances. He was a Laboratory Director in the Clinical Pharmacology Division of the University of Massachusetts Medical Center from 1979-1981 and was on the faculty of the Massachusetts College of Pharmacy from 1973-1979. Dr. Lesko received his B.S. and Ph.D. degrees in pharmaceutics from Temple University in Philadelphia, Pennsylvania and was board certified in Clinical Pharmacology by the American Board of Clinical Pharmacology in 1992. In 1998, Dr. Lesko was awarded the Outstanding Alumni Award from Temple University. He is a member and Fellow of American Association of Pharmaceutical Sciences and serves as Chair of the Drug Development and Regulatory Science Section of American Association of Clinical Pharmacology and Therapeutics. Dr. Lesko is a Fellow and a member of the Board of Regents of the American College of Clinical Pharmacology.



Stephan Schmidt, PhD received his B.S. in Pharmaceutical Sciences from the Friedrich-Alexander University in Erlangen, Germany in 2004 and his license to practice as a pharmacist in Germany in 2005. He obtained his Ph.D. in Pharmaceutical Sciences on "Pharmacokinetics/Pharmacodynamics of oxazolidinones and beta-lactams"

from the University of Florida in Gainesville, USA in 2008 under the supervision of Prof. Hartmut Derendorf. Dr. Schmidt joined the Division of Pharmacology at the Leiden/Amsterdam Center for Drug Research as a post-doctoral fellow in January 2009, where he is a member of the TI Pharma mechanism-based PK-PD modeling platform under the supervision of Prof. Meindert Danhof. His primary research interest is on the development of mechanism-based disease system models for chronic, progressive bone diseases



Wouter Driessen, PhD is a postdoctoral fellow in the David H. Koch Center at the University of Texas M. D. Anderson Cancer Center in Houston. He obtained his BS and MS in pharmaceutical sciences from the Utrecht University in The Netherlands and a Ph.D in pharmaceutics from the University of Florida – Gainesville with a focus on nanoparticle preparation and

characterization. His current research interest is in the area of in vivo target discovery using combinatorial libraries, ligand-directed compound delivery and molecular imaging



Rudolf Bauer, PhD graduated in 1984 from the Institute of Pharmaceutical Biology, University of Munich, 1990 habilitation in Pharmaceutical Biology at the Faculty of Chemistry and Pharmacy, University of Munich; Since 2002 he is full professor of pharmacognosy at University of Graz, Austria, since 2004 he is serving as Head of the Institute of Pharmaceutical Sciences at University of Graz. Since 2008 he is also Head of TCM Research Center Graz – medicinal Plant Research. Besides he is acting as a guest professor in several universities in China. He has long experience in natural product chemistry, analysis and the bioassay-guided isolation of constituents from medicinal plants with immunomodulatory, anti-inflammatory, ant anti-cancer activity. One of his major fields of expertise is “Echinacea” and Chinese medicinal plants. He has published ca. 270 research papers. In 2010, he has been awarded with the Norman R. Farnsworth Excellence in Botanical Research Award of the American Botanical Council. He is past president of the Society for Medicinal Plant and Natural Product Research (GA) and Editor of *Planta Medica*. Prof Bauer is member of the expert groups on herbal drugs and Chinese herbs of the European Pharmacopoeia Commission and actively involved in the development of monographs for the European Pharmacopoeia; he is also member of the TAM Advisory Board of the Austrian Minister of Health.



Teruo Murakami, PhD conducts various research on bionic design, bioengineering and tribology such as biomechanical and biotribological studies on natural synovial joints and joint prostheses (artificial joints). The excellent low friction and long durability of natural synovial joints are evaluated from the viewpoint of adaptive multimode lubrication. The appropriate procedure for optimum design of joint prostheses are investigated by application new tribo-materials and geometric design. Some studies focus the micro- and nanoscopic biomechanics in articular cartilage, chondrocytes and related molecules. The mechanism of remodeling mechanisms in cartilage and bone are explored. In the life support technology, the bionic design of robot arm is carried out. To improve the lubricating performance of biodegradable lubricants, the detailed lubrication mechanism with vegetable oils is examined in relation to the constituent composition and effectiveness of anti-oxydant additive.



Yuichi Sugiyama, PhD Yuichi Sugiyama is the Professor, Department of Molecular Pharmacokinetics at the University of Tokyo since 1991. He is a coauthor of more than 550 publications in international journals as well as 270 book chapters and review articles. His research focuses on two areas: 1) Physiologically based pharmacokinetics: 2) Molecular pharmacokinetics of drug transport in liver, kidney, intestine and brain. His work is internationally recognized by prestigious awards, including, "AAPS Distinguished Pharmaceutical Scientist Award, 2003", FIP Hoest Madsen Gold Medal in 2009. "Medal with Purple Ribbon" given by Government in 2010. According to a recent report of ISI Essential Science Indicators, Professor Sugiyama has been ranked as the top (#1) cited scientist in the field of Pharmacology & Toxicology. He served as the chairman of Board of Pharmaceutical Sciences in FIP (2000-2004) He also served as the president of both “International society for the study of xenobiotics (ISSX)” and “Japanese Society for Xenobiotic Metabolism and Disposition (JSSX)” in 2006 and 2007.



Mark S. Gold, M.D., is a Distinguished Professor of Psychiatry, Neuroscience, Community Health & Family Medicine and Anesthesiology at the University of Florida College of Medicine. He is also a member of the McKnight Brain Institute. Dr. Gold is Chief of the Addiction Medicine Division in the Department of Psychiatry and the department's Associate Chair for Education. Dr. Gold's pioneering work

on the brain systems underlying the effects of opiate drugs led to a dramatic change in the way opiate action was understood. Gold was the senior author on the discovery paper and was awarded a patent for the discovery of clonidine (Catapres) which remains widely used for opiate withdrawal and pain management. During the mid-1980s Gold and colleagues developed a new theory for cocaine action in the brain. Gold's work on cocaine led to a complete change in thinking about cocaine's addiction liability, acute and chronic actions. Dr Gold, a Distinguished Fellow of the American College of Pharmacology has made many contributions to the understanding of the second hand effects of all drugs that are smoked and the consequences of expired medications in closed spaces such as an operating room. Since its inception, Dr. Gold has been listed as one of the Best Doctors® in America.



Robert Bell, PhD is a comprehensive consortium of experienced clinicians, pharmaceutical scientists, regulatory strategists and business development experts that provide product and business development assistance and solutions for the pharmaceutical, biotech, medical product and related industries. From project conception to product launch, D&BD provides a focused approach to the pharmaceutical and clinical development of drugs,

devices and biologics for regulatory submissions. D&BD has extensive experience with all phases of product development, including pre-clinical, clinical (Phase I-IV), CMC (analysis, formulations, process, production), outsourcing, CRO oversight and regulatory interactions, document preparation, review and filings.



Jörg Breitkreuz, PhD studied Pharmacy from 1987 to 1991 at the Westphalian Wilhelms-University of Münster, Germany. He finished his PhD in 1996 at the Institute for Pharmaceutical Technology and Biopharmaceutics in Münster under supervision of Prof. Rüdiger Gröning. From 1996 to 1997 he joined Thiemann Arzneimittel GmbH in Waltrop, Germany, as the head of Product Coordination. In 1997 he went

back to the university in Münster to work on his habilitation thesis (2004) on pediatric drug formulations. In 2004 he became professor for pharmaceutical technology at the Institute of Pharmaceutics and Biopharmaceutics at the Heinrich-Heine-University in Düsseldorf, Germany. Since 2009 he is the head of the Pharmacy department in Düsseldorf. In 2010 the non-profit International Association of Pharmaceutical Technology (APV) elected him for the president. His research focuses on pediatric and geriatric drug formulations, development of orphan drugs and process analytical technologies. Joerg Breitkreuz is member of the European Paediatric Formulation Initiative (EuPFI). He is involved in numerous development projects for pediatric drugs



Leslie Hendeles, Pharm.D., is a Professor in the College of Pharmacy and also in the Department of Pediatrics at the University of Florida. He earned his Pharm.D. degree at the University of Southern California. Among his current research interests are the improvement of adherence to asthma medications and delivery of inhaled drugs to young children. He is a consultant to FDA's Pulmonary Division, and previously served on the Coordinating Committee

of NIH's Asthma Education Program, as well as CDC's Expert Panel on Asthma Guidelines for Emergency Medical Services. Dr. Hendeles provides advice on drug therapy and teaches in the Pediatric Pulmonary Clinic at the University of Florida.