Clinical Pharmacology Subcommittee (CPSC)

ACPS Presentation, March 12, 2003

Jürgen Venitz, MD, Ph.D.

Goals of the Advisory Subcommittee:

To provide expertise and feedback to ACPS, specifically in the areas of:

Exposure-Response Modeling (Pharmacometrics)
Pediatric Clinical Pharmacology
Pharmacogenetics

CPSC Membership (October 23, 2002):

William J. Jusko, Ph.D. (Acting Chair)
Professor, Dept. of Pharmaceutics
State University of New York at Buffalo School of Pharmacy, Buffalo, NY
Former ACPS Member

Hartmut Derendorf, Ph.D.
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University of Florida College of Pharmacy, Gainesville, FL

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GlaxoSmithKline, Research Triangle Park, NC

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Lewis B. Sheiner, MD
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Jürgen Venitz, MD, Ph.D. (FDA Sabbatical)
Associate Professor, Dept. of Pharmaceutics
Virginia Commonwealth University School of Pharmacy, Richmond, VA
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Edmund V. Capparelli, Pharm.D.
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Gregory L. Kearns, Pharm.D.
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David Flockhart, MD, Ph.D.
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Howard L. McCleod, Pharm.D.
Associate Professor, Departments of Medicine, Pharmacology and Molecular Biology
Washington University, St. Louis, MO

Wolfgang Sadee, Ph.D.
Professor and Chair, Dept. of Pharmacology
College of Medicine and Public Health, Ohio State University, Columbus, OH
Current ACPS Member

Inaugural Meeting on October 23, 2002

Topic # 1:

Consideration of investigational pharmacokinetic studies to identify patient populations at risk:
Methods used to adjust dosing regimens given the availability of exposure-response information

FDA presentation: case studies and a model for the future
Peter Lee, Ph.D.

Evaluation of methods and clarifying questions
Richard Lalonde, Pharm.D.
Lewis Sheiner, Ph.D.

Using exposure-response relationships to define therapeutic index: a preliminary approach based on utility functions
Jürgen Venitz, MD, Ph.D.

Topic # 2

Use of exposure-response relationships in the Pediatric Study Decision Tree: Questions to be asked using the FDA pediatric database

Introduction (FDA)
Arzu Selen, Ph.D.

Medical and clinical pharmacology perspective on the pediatric study decision tree and experience to date
Rosemary Roberts, MD

Topic # 3

Scientific and practical considerations in the use of pharmacogenetic tests to determine drug dosage and administration

Current experience and clinical pharmacology perspective
Lawrence Lesko, Ph.D.

Assessment of TPMT testing and impact on risk management
Richard Weinshilboum, MD, Ph.D.
Mary Relling, Pharm.D.

CPSC Membership (March 2003):

Jürgen Venitz, MD, Ph.D. (Chair)
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Current ACPS Member

Next Meeting on April 22 and 23, 2003

Tentative Agenda

Topic # 1

Quantitative risk-benefit analysis using exposure-response for determining dose adjustment for special populations

Topic # 2

Pediatric population pharmacokinetics study design template and analyses of the FDA pediatric database

Topic #3

Pharmacogenetics: improvement of existing drug treatments

Topic #4

Drug interactions: metabolism and transport-based