

Can Clinical Pharmacology Break Down Barriers to Generic Substitution?

Robert Lionberger
Office of Research and Standards
Office of Generic Drugs, CDER, FDA

ACCP

September 24, 2018

Generic Substitution

- Key part of the US healthcare system
- Almost all of the drugs clinical pharmacologist use are supplied in their generic version
 - ~90% of current US prescription are filled with a generic



Clinical Pharmacology is a Core Scientific Foundation for Generics

- The generic drug system relies on bioequivalence studies in (mostly) healthy subjects
- Generic drugs are given to patients
- Clinical Pharmacology explains why this works



Clinical Pharmacology Explains Observations

- Clinical Pharmacology explains how factors such as
 - Body weight, renal impairment, gene expression, drug-interaction ...
 - Impact drug exposure and clinical response

Variability

- Clinical Pharmacologists know that if you dose a patient on two separate days, you may observe two different responses due to many sources of variability
 - This is true if both doses are the brand product

The Challenge for Generics

- If you give brand product and then the patient switches to generic and you observe a difference
 - Is this because there is normal variation?
 - Is this because there is a difference between brand and generic?

Agenda

- Today we have four talks that are variations on this theme
 - **Impact of Variation in the Physical Characteristics of Generic Drugs on Adherence & Patient Experiences**
 - **Batch-to-batch Variability & Implications for the Generic BE Standard**
 - **Bioequivalence & Clinical Implications of Generic Bupropion**
 - **A Model- & Systems-based Approach to Assess & Ensure Generic Substitution**

