Regulation of Follow-on Biologics: Ensuring Quality and Patient Safety

Panel: The Interplay of Economic and Clinical Issues: Safety and Liability; Cost & Access

Judith K. Jones, MD, PhD

Assessing the safety of biologics and biosimilars has many challenges, including:

- Some lack of direct relationship to "pharmacokinetics," since PK concepts differ:
  - Role of direct PK of protein/peptide
  - Role of altered DNA or RNA and resulting proteins
  - If induced protein is the active agent….what is its t ½?
- For *<u>population</u>* safety, pharmacoepidemiology methods used for drugs are not always applicable
  - Detection of exposure (insurance codes)
  - Measuring exposure (kinetics, duration of effect vary
  - Dosing and methods of administration

- Risk management strategies may be difficult to design…and establish effectiveness