The Interplay of Economic and Clinical Issues Panel Discussion

Regulation of Follow-on Biologics: Ensuring Quality and Patient Safety
Jefferson School of Population Health Policy Forum

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Historical Perspective

• By the time Congress was debating the Hatch-Waxman act, the chemically-based pharmaceutical industry was over a century old and represented a stable and mature business system with respect to its basic science, business model, and regulatory regime

• While the act achieved its objective of generating price competition and thus savings, it also produced several unintended consequences:
  
  – Higher pricing and more aggressive marketing to increase short term revenues
  
  – Greater focus on developing drugs for only largest potential indications
  
  – Higher number of compounds in development reaching “no man’s land” within a few years of patent
Key Questions

• There are obvious similarities between the pre-Hatch-Waxman Pharma industry of 1983 and the Biotech industry of today – but there are also certain clear structural differences

  – How important are those differences?
    • Science
    • Business Model
    • Regulatory
    • Patients & Consumers

  – What unintended consequences would similar legislation have on the biotech industry?

  – Are the objectives of price competition and savings achievable?

  – What will happen to largest funders on innovation, the companies themselves?

  – How can Michael Porter help illuminate this conversation?