



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

R. T. (Terry) Hisey
Vice Chairman and U.S. Life Sciences Leader
Deloitte LLP

April 21, 2009

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?

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