

# **Biosimilars 2007: An Innovator's Perspective**

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**Jeffrey Chasnow**  
Assistant General Counsel

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# “Biosimilars” Present A Different and More Complex Challenge Than Generic Drugs Did in 1984

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- Significant technical and regulatory issues
  - 1984: Adopted pre-existing standards for bioequivalence
  - Today: FDA has only just begun to develop principles for assessing comparability
  - Congressional action should not outpace scientific/regulatory capabilities
- Broad concerns about proper utilization
  - *“[A] technical and scientific understanding of similarities between two biological products is not enough. We must also understand how health care providers and patients access these products and how they use them in practice . . .”* [HHS Letter to Senate HELP Committee (June 26, 2007) (commenting on draft “Biologics Price Competition and Innovation Act of 2007”)]

## "Biosimilars" Present A Different And More Complex Challenge Than Generic Drugs Did in 1984

- Questions about therapeutic interchangeability and relative cost savings
  - Do cost savings justify therapeutic tradeoffs?
- Unique innovation dynamic
  - Biologics are costlier and riskier than small molecules

# Regulatory Framework: Some Key Elements

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- Clinical trials to ensure safety and efficacy
  - HHS: No waivers of immunogenicity studies
- Clarity and predictability
  - Ensure reviews are consistent with current science
  - Guide applicants in data requirements
  - Enable innovators to gauge risk/reward balance for innovative products
- “Outer boundaries”
  - No wild cards
  - Case-by-case adjudication is appropriate within bright lines:
    - Prior, well-developed guidance
    - Clinical evidence for each indication
    - Distinct non-proprietary names [physician/patient]
  - Senate bill is flawed in failing to set these boundaries

# Interchangeability: Eyes Wide Open

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- Cost/benefit counsels against forced substitutions
  - Modest cost-savings
  - Significant concerns about safety and efficacy
    - *“For many follow-on protein products . . . there is significant potential for repeated switches between products to have a negative impact on safety and/or effectiveness.”* [J. Woodcock, et al., *The FDA’s Assessment of Follow-On Protein Products: A Historical Perspective*, Nature Reviews Drug Discovery (April 13, 2007)]
  - Because of those risks, *“legislation should not allow for determinations of interchangeability at this time.”* [HHS Letter to HELP Committee]
- Biosimilars are best treated as branded competitors rather than generic substitutes

# Data Exclusivity

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- Necessary supplement to patent protection
  - Patent protection may be less secure because of flexibility in “similar” pathway
- Significant base period + additional incentive for new indications/enhancements