Overview: Barriers to Competition

- Barriers Are: Good and Bad, Big and Small
- Some Are Good
- Many Are Bad
- Consequences of Barriers
- Policy Implications
- Conclusion

Not All Barriers Are Created Equal

- Broadly speaking, barriers to biosimilar entry have mixed effects:
  - Some are appropriate for protecting producers and consumers
  - Others thwart healthy competition and a robust biosimilars market
- But barriers to biosimilar utilization are uniformly undesirable

Good Barriers

- Barriers are good if they create appropriate monopoly periods for reference products

Bad Barriers

- Barriers that impede biosimilar utilization hurt competition and reduce consumer welfare
  - Myopic contracting practices by payers
  - “Rebate traps”
  - Frivolous late-stage patents
  - Inadequate physician and patient education

Consequences of Bad Barriers

- Undue barriers to biosimilar entry and utilization have many consequences
  - Excessive monopoly rents
  - Higher patient cost
  - Less biosimilar discounting
  - Fewer biosimilar competitors

3 Uncertainty Is a Unique Barrier

- A final barrier: the uncertainty associated with the viability of the biosimilars market
  - Uncertainty of reference product price
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3 Policy Implications

- Policies to combat barriers to biosimilars should heed three principles:
  - Predictability. Biosimilar manufacturers should be reasonably able to anticipate the cost (including duration) of barriers to entry
  - Minimal market interference. Minimize (to the extent possible) costs related to approval
  - Maximum market receptivity. Educate physicians, payers, and patients

3 Conclusion

- Many of the barriers that impeded biosimilar entry after enactment of BPCIA have been mitigated as FDA and the courts have resolved legal and regulatory uncertainties
- Inefficient and costly barriers remain, and policymakers, manufacturers, and payers all have a role to play in reducing those barriers