Barriers to Biosimilars

FDA/FTC Workshop on a Competitive Marketplace for Biosimilars

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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
  - BPCIA created an explicit barrier to biosimilar entry: 12 years of exclusivity
    - (I would have preferred 7 years!)
  - Valid patents create additional barriers to biosimilar competition and reward innovation
- Regulations to ensure biosimilar safety and efficacy are, in principle, good barriers

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

Uncertainty Is a Unique Barrier

- A final barrier: the uncertainty associated with the viability of the biosimilars market
  - Uncertainty of reference product price
  - Legislative, legal, and regulatory uncertainty
  - Competitor biosimilar behavior
  - Future market receptivity
- These uncertainties encourage manufacturers to wait

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

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