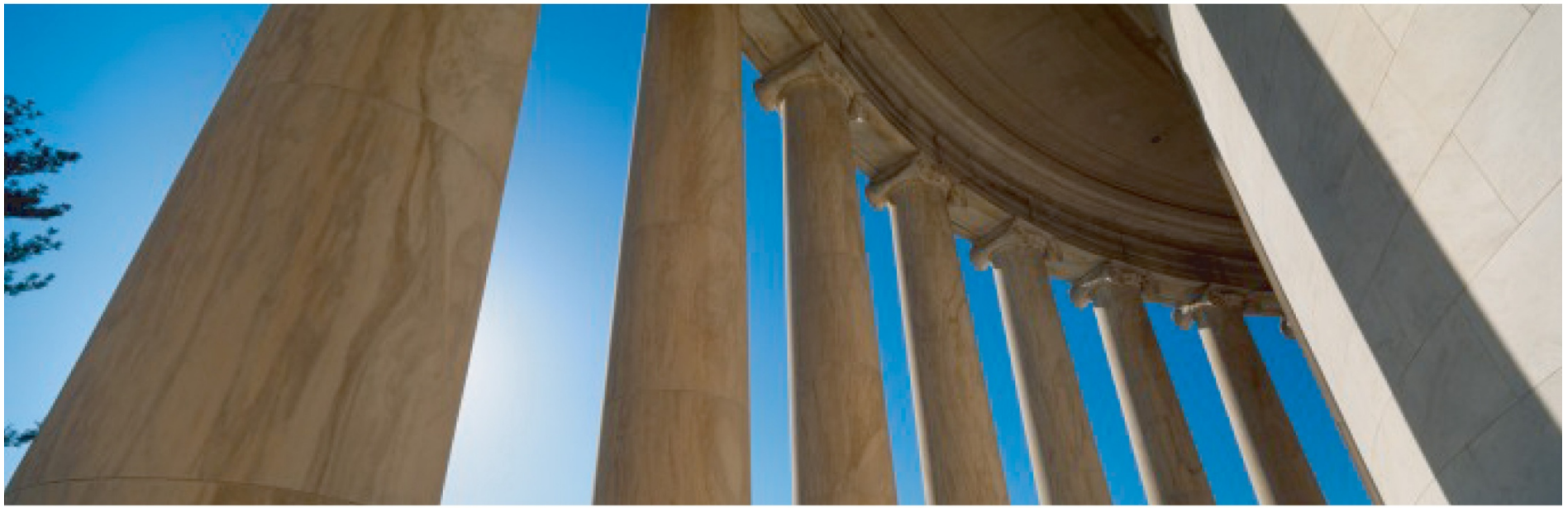
Striking the Balance: Opportunities to Promote Drug Competition



Alex Brill, July 18, 2017

FDA Public Meeting “The Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access”

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Drug Competition Is Multifaceted

Four Types of Competition among Pharmaceuticals

- **Generic to Brand**: Generic drugs compete with their brand counterparts
- **Generic to generic**: Generics compete with each other
- **Brand to brand**: Brand drugs compete with other brands in the same drug class
- **Biologic to biosimilar**: Biosimilars compete with their reference products (outside the scope of this discussion)

Balancing Competition and Innovation Policy

- Competition Policy Need Not Interfere with an Innovation Policy Agenda
  - Just as Samsung spurs Apple to innovate better iPhone technology, the threat of generic entry or entry of a competing brand can spur pharmaceutical innovation
  - There is a risk that this innovation is small and not meaningful (for example, “evergreening”), but it has the potential to be significant
- Policy Considerations for FDA
  - FDA faces an increasingly sophisticated pharmaceutical marketplace where both brand and generic manufacturers are more strategic
  - Periodic reevaluation of the appropriateness and effectiveness of innovation policies and competition policies is warranted

Misuse of REMS ETASU

- Use of REMS ETASU and REMS-Like Programs to Block Generic Competition
  - FDA sometimes requires REMS programs to ensure the safety of certain prescription drugs
  - Brand drug manufacturers have been accused of using REMS and other restricted access programs to block generic manufacturers' access to drug samples
  - Restricted access drug segment comprises 74 drugs with total sales of nearly $23 billion in 2016 (Brill, 2017)
  - $5.4 billion/year in unrealized pharmaceutical savings if generic versions of forty REMS and similarly restricted drugs were allowed to come to market. $1.8 billion of that total accrues to the federal government ((Brill, 2014)

Gaps in Generic Competition

- Lack of any ANDA for Certain Brand Products
  - More than 200 brand drugs lack patent protection and exclusivity but do not have an approved generic competitor
  - A generic exclusivity can encourage generic entry for brand products that lack patent protection and exclusivity
- Lack of Sufficient Number of ANDAs to Maximize Competitive Market Dynamic
  - When there are more than four generic manufacturers for a given product, prices decline significantly (Reiffen and Ward, 2005)

Single-Minded Policy Focus on Innovation

- Lack of Resources for to Brand-to-Brand Competition
  - Existing expedited approval pathways favor products addressing unmet needs or offering significant clinical advancement
  - Worthwhile objectives, but at the expense of approving brand products that offer the opportunity to compete directly with existing products

Conclusion

Key Takeaways

- The FDA has an active and critical impact on pharmaceutical competition (not just innovation)
- Competition not only leads to lower prices but can encourage additional innovation among pharmaceutical products
- But, inadequate incentives for innovation may deter new and efficacious products
- In the pharmaceutical sector, public policy must strike a balance between incentives for competition and innovation