Alex Brill, July 18, 2017
FDA Public Meeting “The Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access”
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)
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.
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))
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)
Lack of Resources for 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
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