



Your Generics and Biosimilars Industry

Generic Drugs – Facing Threats to Sustainable Competition & Supply

Federal Trade Commission Workshop | November 8, 2017

Overall U.S. Prescription Drug Market

Brands account for only

11% →

of prescriptions
(500 million)

yet are

74%

of the cost.
(\$333.9 billion)

Generics account for

89% →

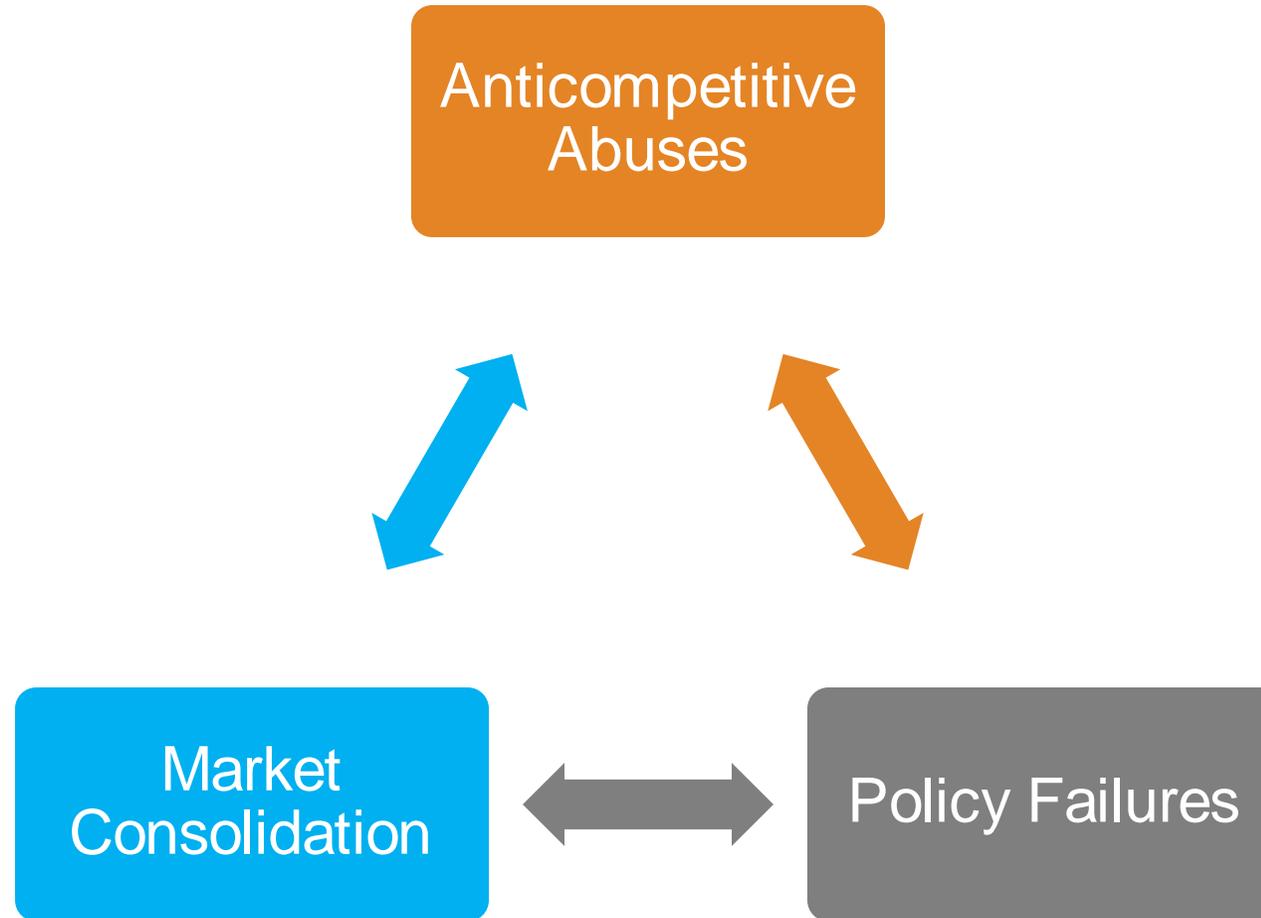
of prescriptions
(3.9 billion)

but are just

26%

of the cost.
(\$116.1 billion)

Sustainable Generic Competition Is Threatened



Anticompetitive Behavior Prevents Competition

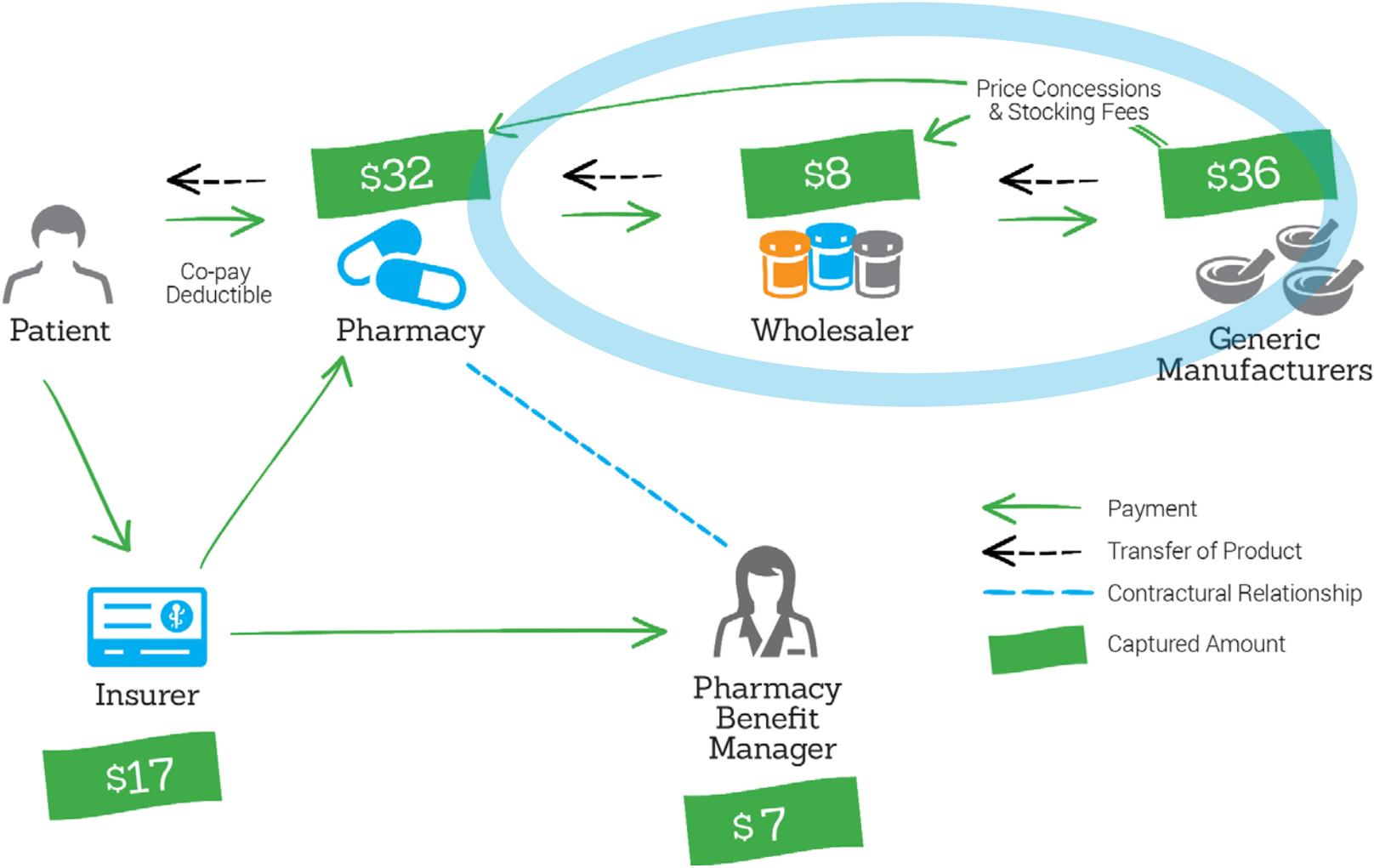
“We know that sometimes our regulatory rules might be ‘gamed’ in ways that may delay generic drug approvals beyond the time frame the law intended, in order to reduce competition...

I understand that generic sponsors are willing to buy these products at fair market value; but, in some cases, branded companies may be using regulatory strategies or commercial techniques to deliberately try to block a generic company from getting access to testing samples.”

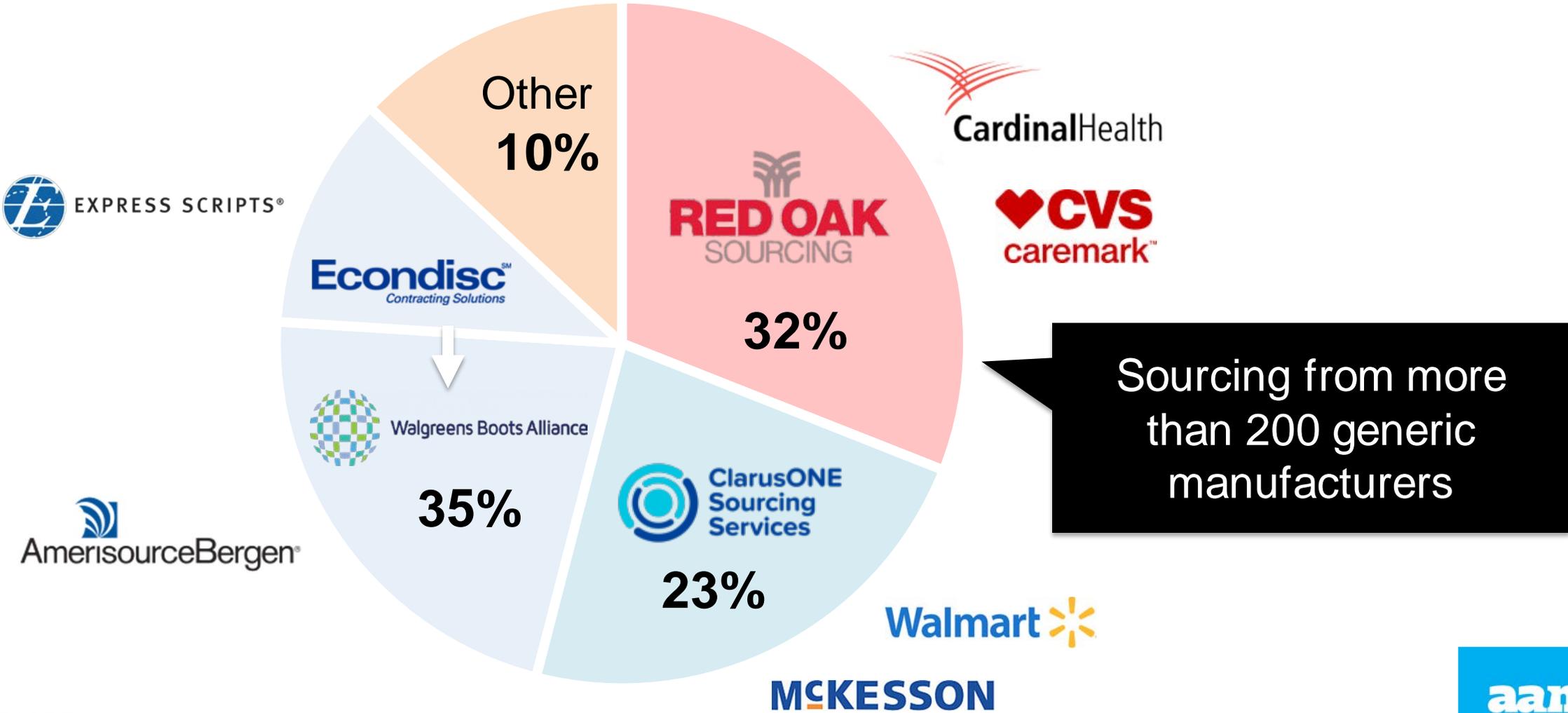
- *FDA Commissioner Scott Gottlieb, M.D.*
June 21, 2017

Understanding the Generic Marketplace

The Generic Drug Market Is Not the Brand Drug Market



Large Buyers Control Almost 90% of Generics



Generics Drug Prices Are Falling Further, Faster



- But the market trends – decreasing prices – are not sustainable.
- In the last year, total generic prescriptions are up 2 percent, but revenue is down 13 percent.
- Policies must safeguard the generic market.
- Otherwise, manufacturers may be forced to exit unprofitable markets – harming patients through potential drug shortages.

Purchasers Reinforce Deflationary Trends

- We have yet to see generic deflation ease from its current high single digits (-7% to -9%) where it's been for about three quarters now.

–AmerisourceBergen CFO Tim Guttman (August 2017)

- [The] challenge and headwind we faced in the last half of the year was the rate of generic deflation.

–McKesson CFO James Beer (May 2017)

- We now expect full year pharma segment profit to decline to low double digits versus the prior year. This is primarily due to the previously mentioned generic market pricing.

– Cardinal CFO Michael Kaufmann (May 2017)

Impact on Patient Access & Outcomes

Drug Shortages Threaten Patient Outcomes

- Generic drugs seem particularly susceptible to drug shortages, potentially related to existing market incentives as well as low reimbursement.
- Responding to a series of drug shortages in 2011, Dr. Scott Gottlieb testified before Congress that many such shortages were a direct result of low reimbursement for older, low-margin products and that “many hospitals are being forced to ration key medicines and patients to sit on waiting lists for vital drugs.”

The FTC and FDA Should...

- Support legislative solutions to anticompetitive, regulatory gamesmanship like REMS abuse
- Monitor IP abuses, in particular relating to sovereign immunity, that prevent generic and biosimilar competition
- Investigate whether purchaser consolidation creates anticompetitive risks

The continued sustainability of generic, and the promise of patient access through biosimilar, competition depends on active policy engagement.

A young woman with dark hair, wearing a white lab coat, is smiling warmly at the camera. She is standing in a pharmacy, with shelves of various medications visible in the background. The lighting is bright and even.

Thank You

Association for Accessible Medicines

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