THE U.S. IS NOT A FREE MARKET FOR PRESCRIPTION DRUGS

- Third party purchase of third party insurance
- Legal monopolies (innovative patents)
- Medicare, Obamacare coverage mandates
- Insurer antitrust regulations (unlevel playing field)
- FDA drug development mandates (cost of R&D)
- Artificial monopolies for off-patent drugs
  - Orphan drugs, drugs that predate FDA, delivery devices, REMS
- Competitive barriers for biosimilar drugs
- Bias against “me-too” and clinically equivalent drugs
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ORPHAN DRUG SPENDING IS DEVOURING THE BUDGET

U.S. spending on orphan drugs, 2015 actual vs. 2020 estimated (Billions)

2015
$318B
$107B

Non-orphan drugs
Orphan drugs

2020E
$379B
$176B

Source: American Journal of Clinical Oncology, QuintilesIMS, FREOPP analysis
CONGRESS & FDA HAVE CREATED ARTIFICIAL MONOPOLIES

- Stacked 7-year monopolies for off-patent orphan drugs
- FDA has awarded monopolies for old drugs with new clinical trials
- Lack of FDA pathway for generics with complex delivery
  - E.g. EpiPen (injector), Advair (inhaler), transdermal patches
- Use of FDA risk evaluation & mitigation strategies as barriers to competition (e.g. thalidomide for multiple myeloma)
- **Biosimilars face greater barriers than traditional generics**
  - H-W: 5 years of exclusivity for off-patent drugs; BPCI: 12 years
  - H-W: automatic therapeutic substitution at pharmacy; BPCI: not automatic (state rules vary)
REMOVING FEDERAL BARRIERS TO PHARMA COMPETITION

- Minimize FDA barriers to competition for small molecules
  - Limit stacking orphan drug designations; sunset Unapproved Drugs Initiative; new pathway for generics requiring delivery devices; standardize REMS protocols
- Make biosimilar pathway look more like Hatch-Waxman
- Create Fast Track authority for disease areas with 1-2 available drugs
- Minimize federal drug coverage mandates (Medicare, Medicaid, ACA)
- Migrate Medicare A/B drug coverage into Part D
- Antitrust safe harbors for insurers
- REINS Act for FDA (Congress up-or-down vote for $100MM regs)
- A patient-centered, consumer-driven health care system
THE
COMPEETITION
PRESCRIPTION

A Market-Based Plan for Making Innovative Medicines Affordable

Avik S. A. Roy

The Foundation for Research on Equal Opportunity