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# The Competition Prescription

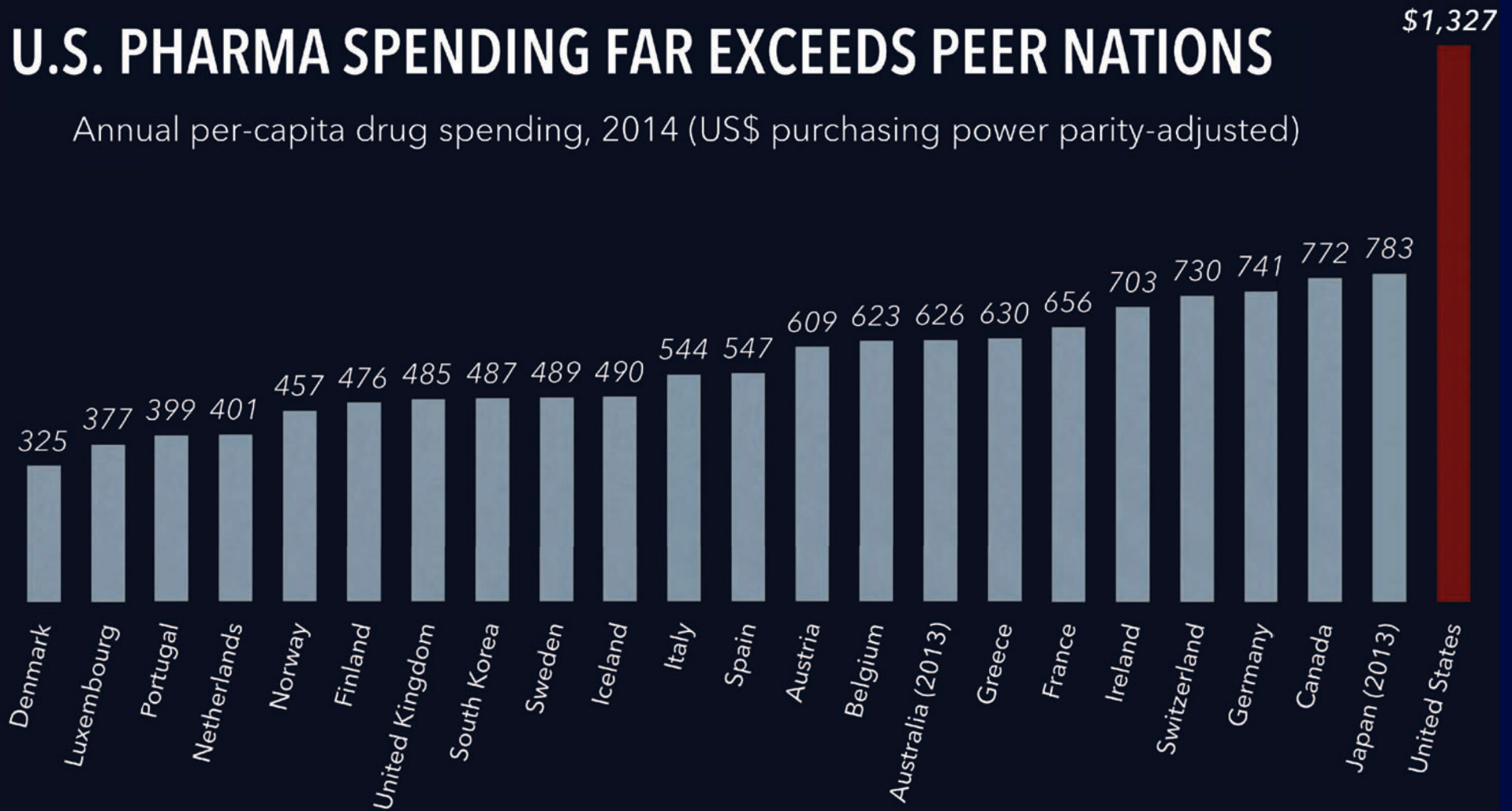
A Market-Based Plan for  
Making Medicines Affordable

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# U.S. PHARMA SPENDING FAR EXCEEDS PEER NATIONS

Annual per-capita drug spending, 2014 (US\$ purchasing power parity-adjusted)

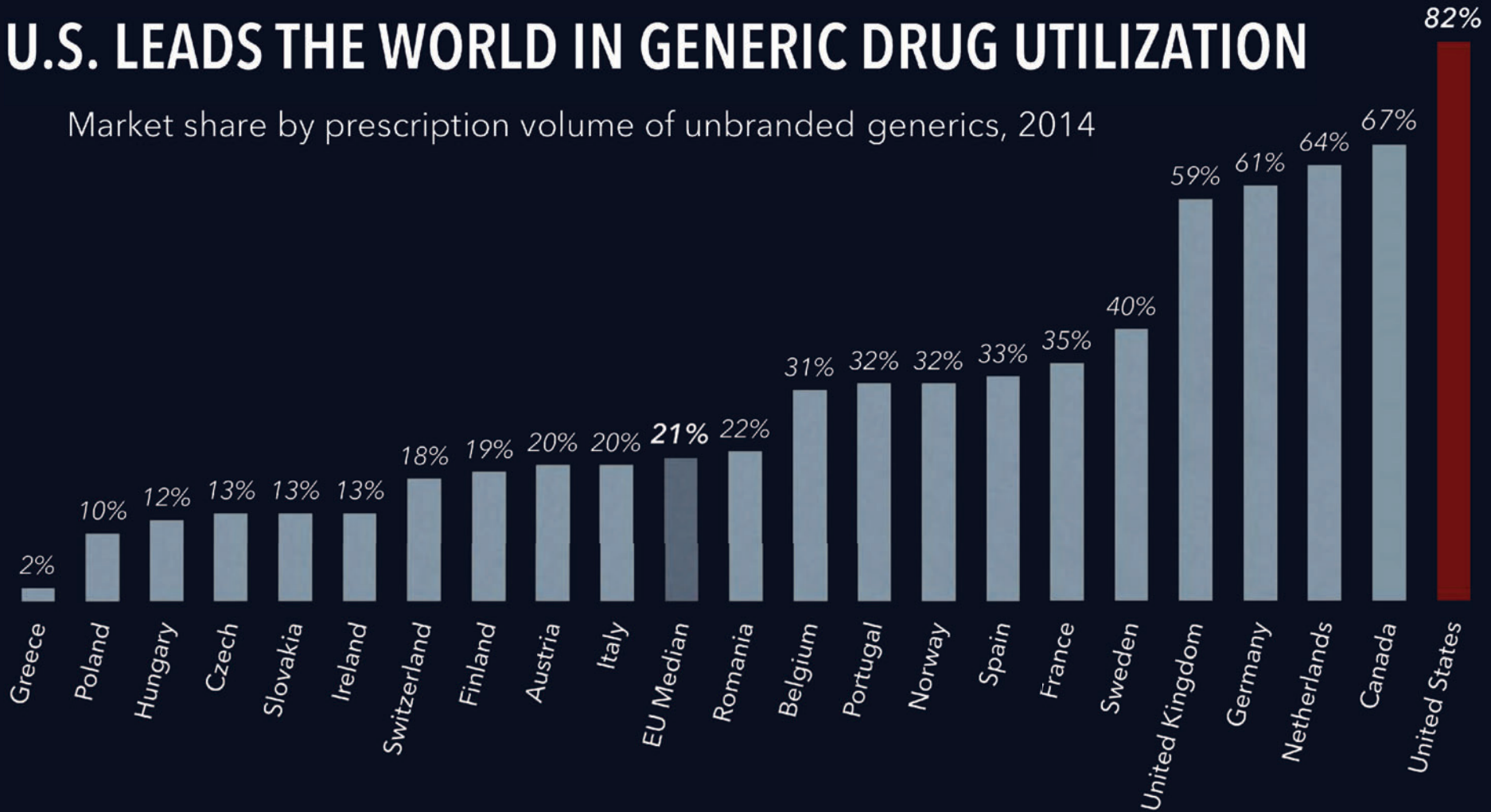


Source: OECD, QuintilesIMS, FREOPP analysis

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# U.S. LEADS THE WORLD IN GENERIC DRUG UTILIZATION

Market share by prescription volume of unbranded generics, 2014

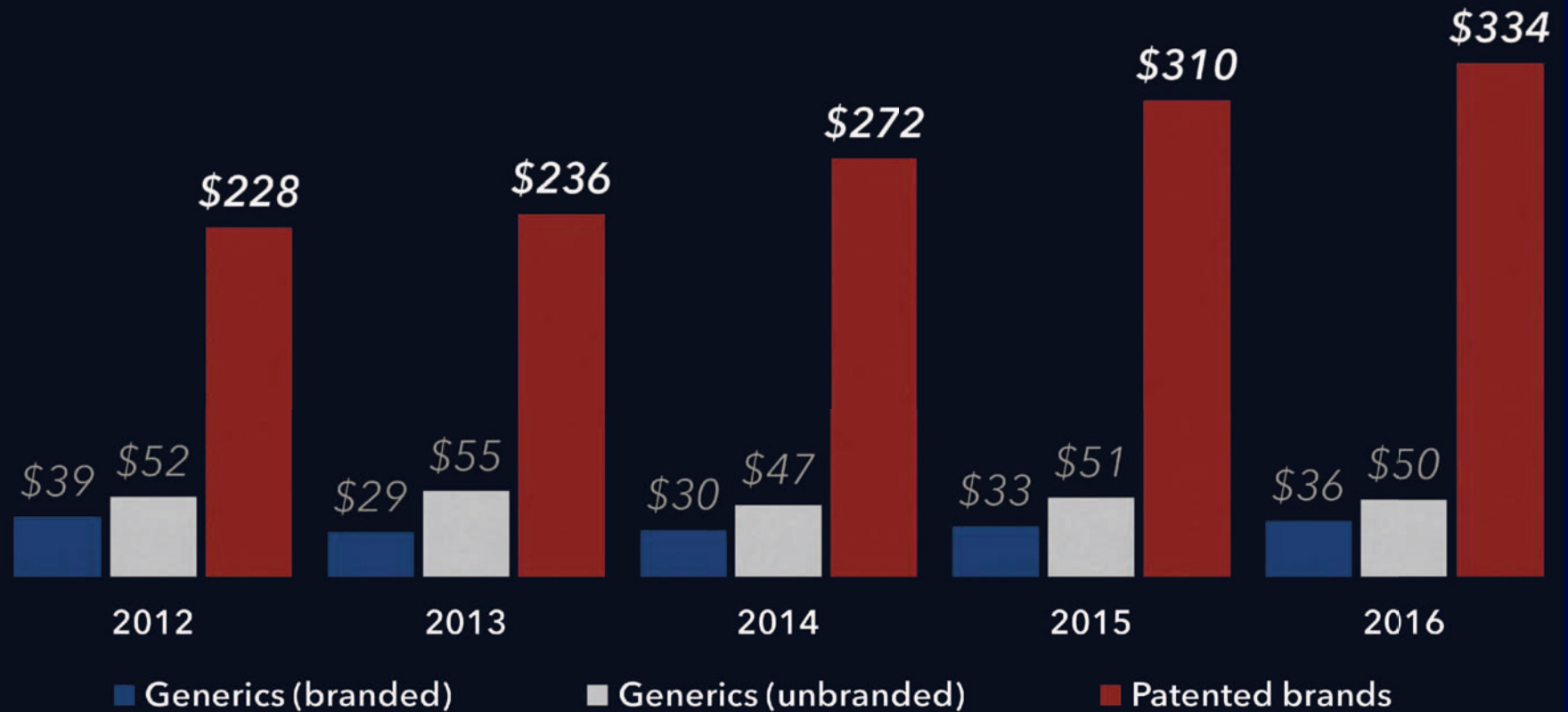


Source: QuintilesIMS, FREOPP analysis

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# BRANDED SPENDING IS EXPLODING; GENERICS DECLINING

Annual U.S. invoice sales (billions)



Source: QuintilesIMS, FREOPP analysis

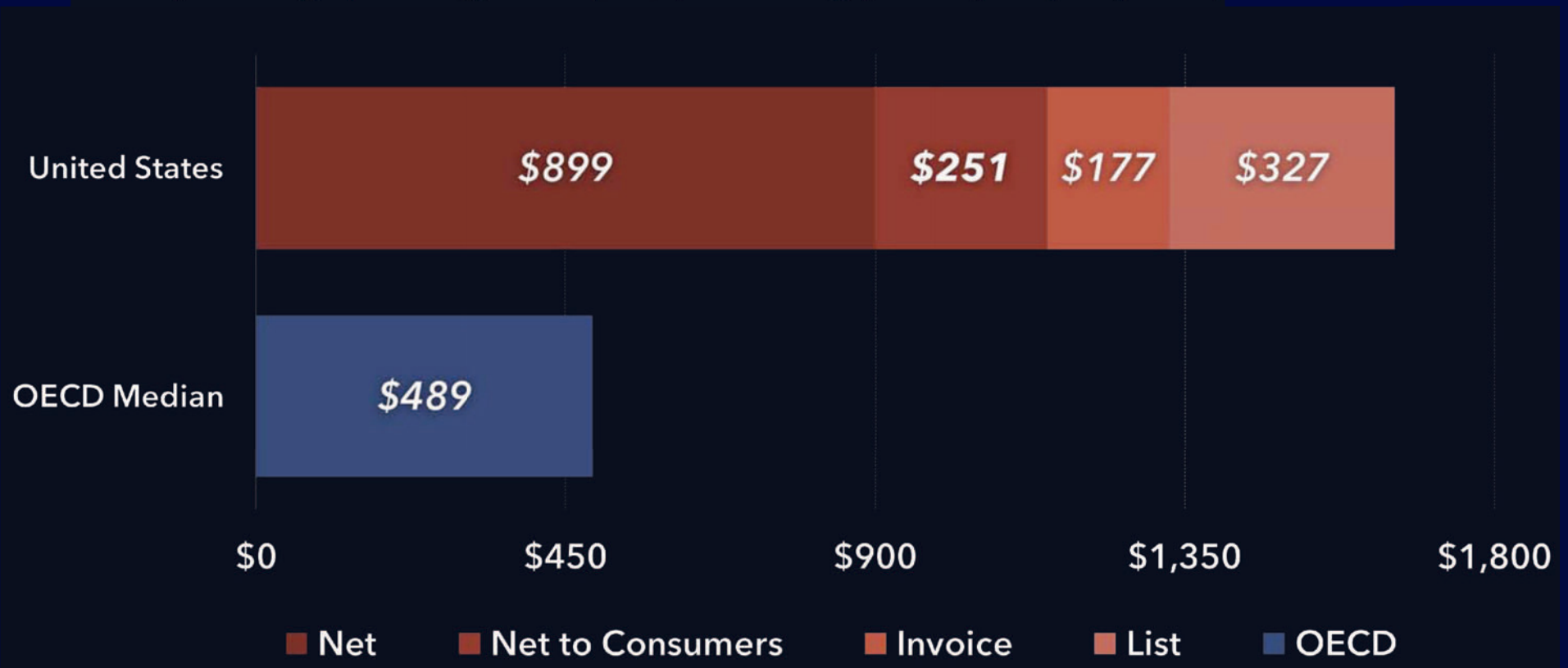
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# UNDERSTANDING NET PRICING VS. LIST PRICING

- Pharmaceutical manufacturers point out that list prices don't reflect the net revenue they actually receive
  - **List price**: wholesale acquisition cost (WAC); rarely paid in practice
  - **Invoice price**: prices after discounts to bulk purchasers (wholesalers / distributors); **16%** lower than list price on average
  - **Net price**: prices after rebates to pharmacy benefit managers and co-pay assistance payments to consumers; **33%** lower than invoice price on average
- But: Net prices don't reflect the actual cost to consumers
  - Not all of the rebate is passed down to consumers in the form of lower premiums
  - Co-pay assistance leads to **higher premiums**, by encouraging utilization of high-priced drugs and evading cost controls

# NET PRICES UNDERESTIMATE REAL CONSUMER COSTS

Per-capita drug spending, 2014 (US\$ purchasing power parity-adjusted)

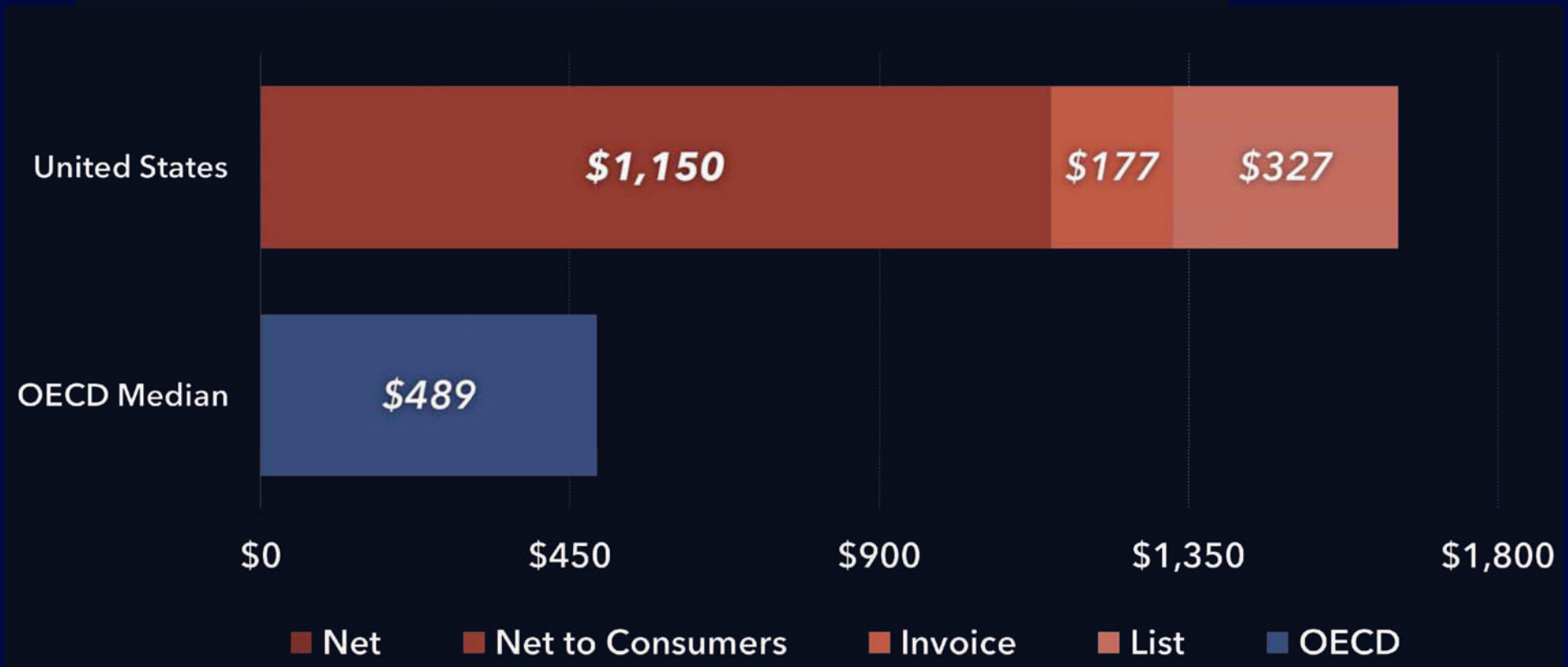


Source: OECD, QuintilesIMS, FREOPP analysis

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# NET PRICES UNDERESTIMATE REAL CONSUMER COSTS

Per-capita drug spending, 2014 (US\$ purchasing power parity-adjusted)



Source: OECD, QuintilesIMS, FREOPP analysis

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# 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

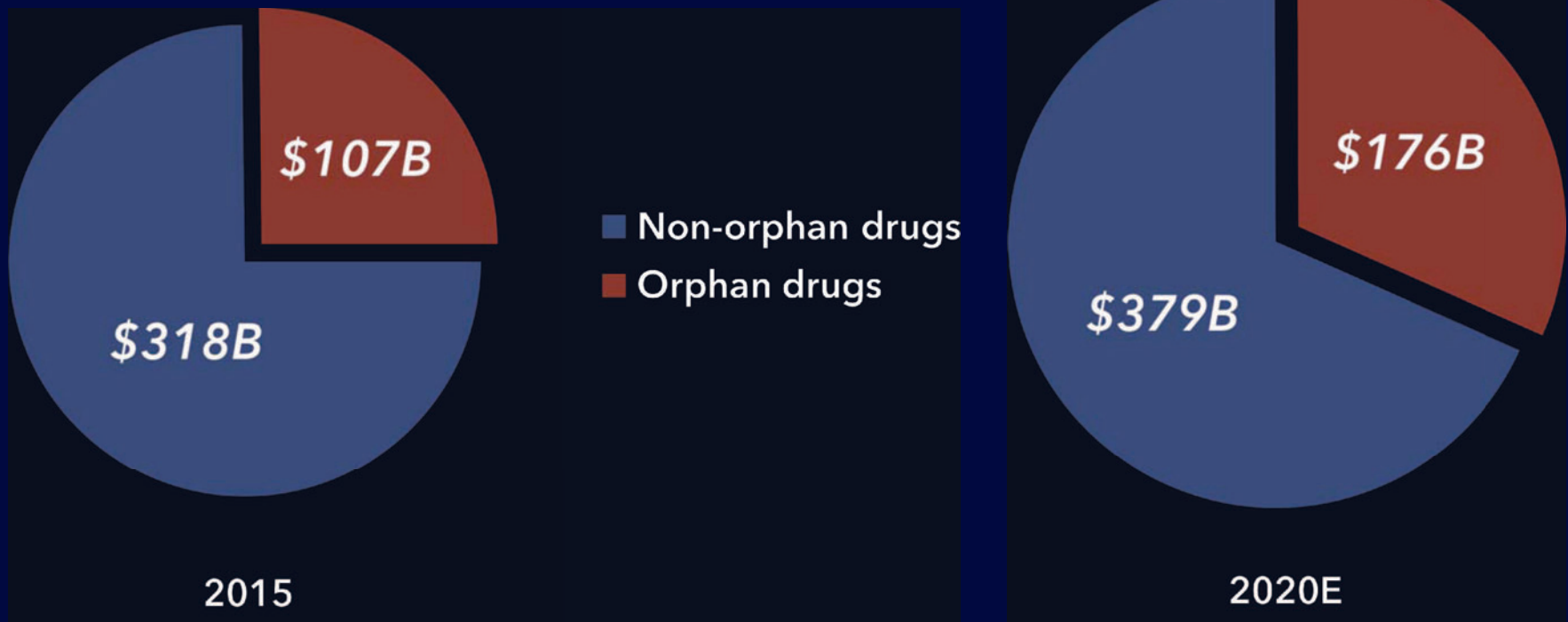


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# ORPHAN DRUG SPENDING IS DEVOURING THE BUDGET

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



Source: American Journal of Clinical Oncology, QuintilesIMS, FREOPP analysis

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# 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**
  - Hatch-Waxman Act of 1984 vs. Biologics Price Competition & Innovation Act of 2009
  - 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 COMPETITION PRESCRIPTION

A Market-Based Plan *for* Making  
Innovative Medicines Affordable

Avik S. A. Roy

The Foundation *for* Research  
*on* Equal Opportunity 



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The Foundation *for* Research  
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