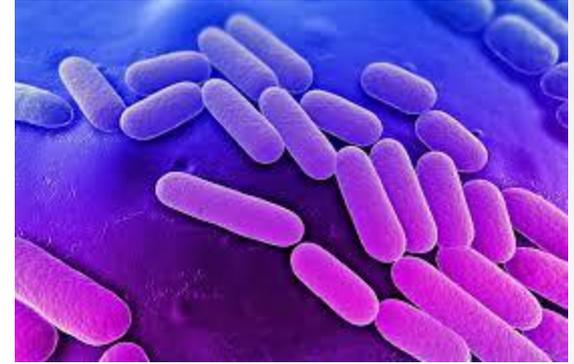




MARKET ENTRY REWARDS AS A PULL INCENTIVE FOR ANTIBIOTIC DEVELOPMENT

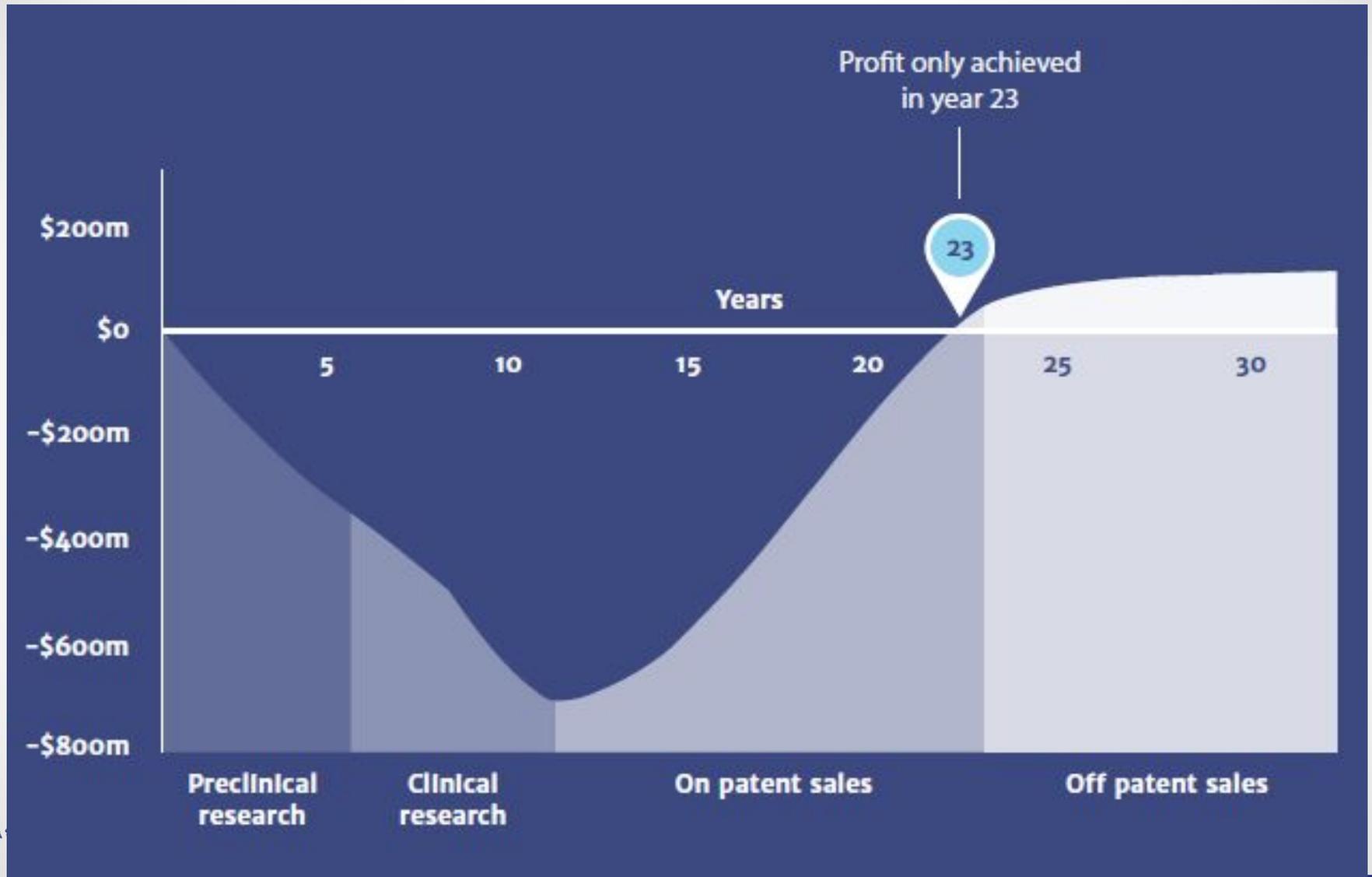
Joe Larsen, Ph.D.
BARDA
December 2016

The BARDA Model

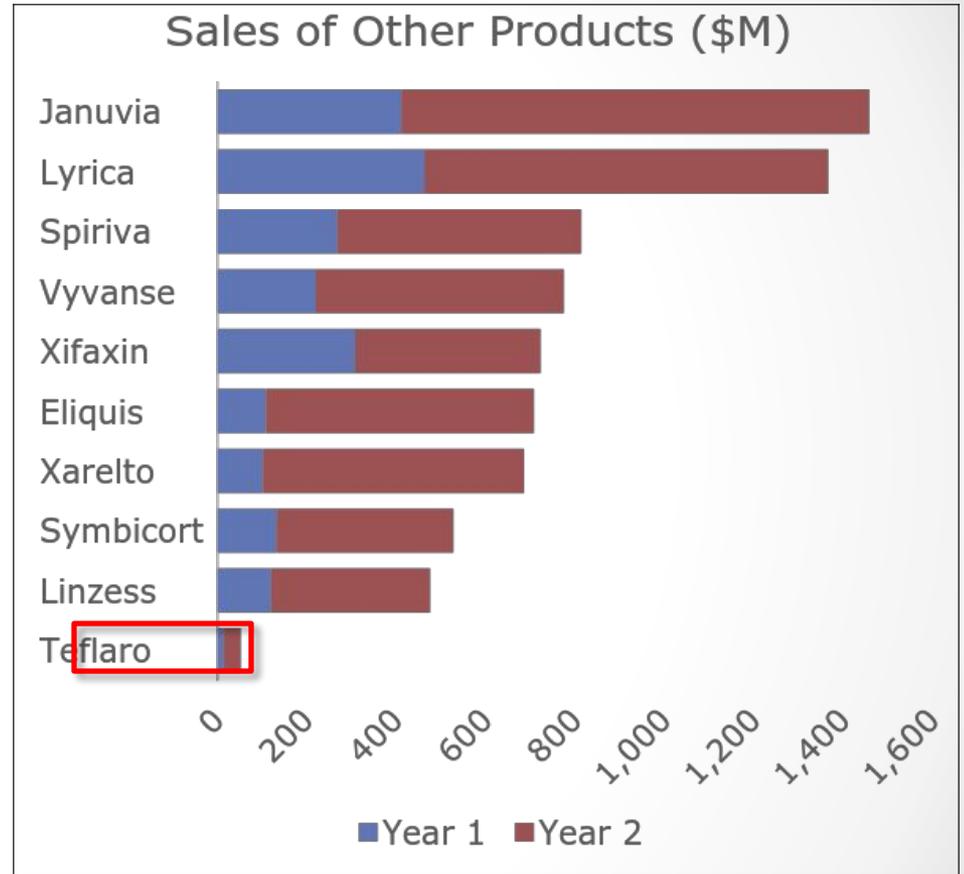
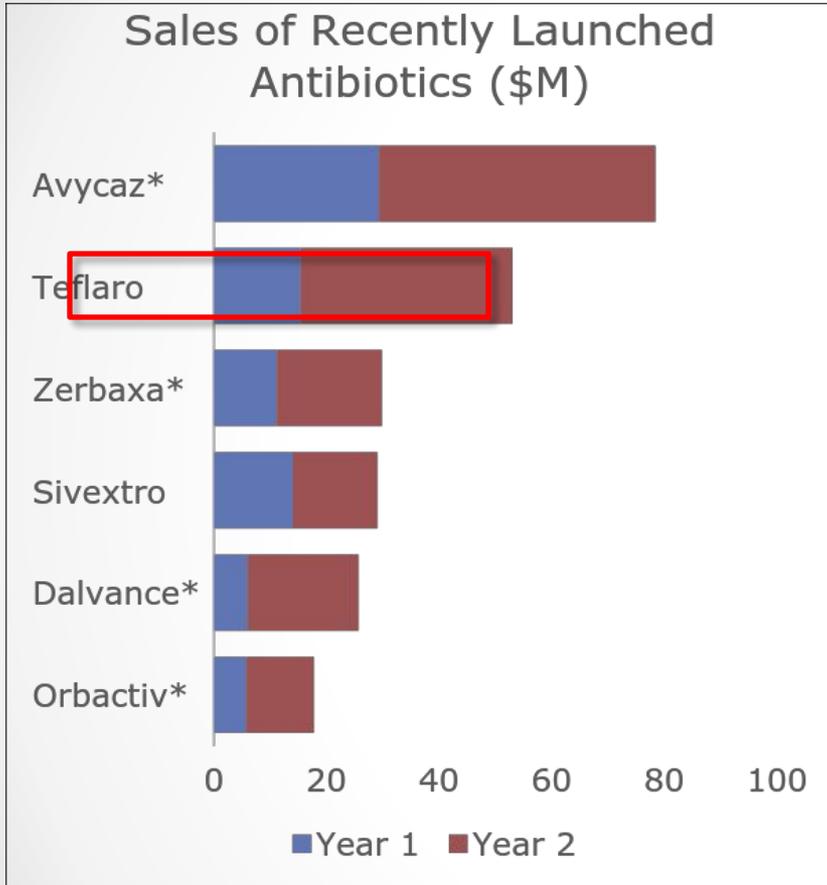


- The BARDA model works to address market failures
 - 25 Products FDA approved/cleared for biothreats and pandemic influenza
 - 15 Products stockpiled for emergency use
- This model is being successfully applied to antimicrobial resistance
 - Utilization of novel public:private partnerships to incentivize antibiotic research and development
 - 6 products in Phase III clinical development
 - Establishment of CARB-X

The Current Model...



Product Launches: New Antibiotics vs. Other Brands



*Projected Sales (year 2)
Source: NSP \$ Sales, IMS 2016



Innovation in Antibacterial Drug Development

- Not occurring at the pace we need
 - No new drugs to treat gram negative infections in over 45 years
- 37 candidate antibiotics in Phase II/III clinical development
 - Versus over 500 for oncology
- Era of commercialization not innovation
 - Few companies have internal research programs
 - Innovation left to biotech companies
 - Very fragile market



Incentives to develop new antibiotics?

Factors:

- Uncertainty in use at launch
- Stewardship means limited use
- Generics can be effective for most infections
- Lower returns generally than other therapeutic areas
- Increasing appropriate use limits use-impacts revenue
 - Need a different model



Incentives need to:

- Improve Net Present Value
- Possess minimal disruptive effects
- Reward Innovation
- Ensure Conservation
- Not impact patient access



De-linkage Model

- Antibiotics are one of the only class of drugs whose use diminishes utility
- How do we ensure antibiotics are available while not driving inappropriate use?
- De-linkage models seek to “delink” profit of antibiotics from the number of units sold
 - Allow a known return on investment (ROI)
 - Can build in provisions for stewardship and conservation



Market Entry Rewards (Partial Delinkage)

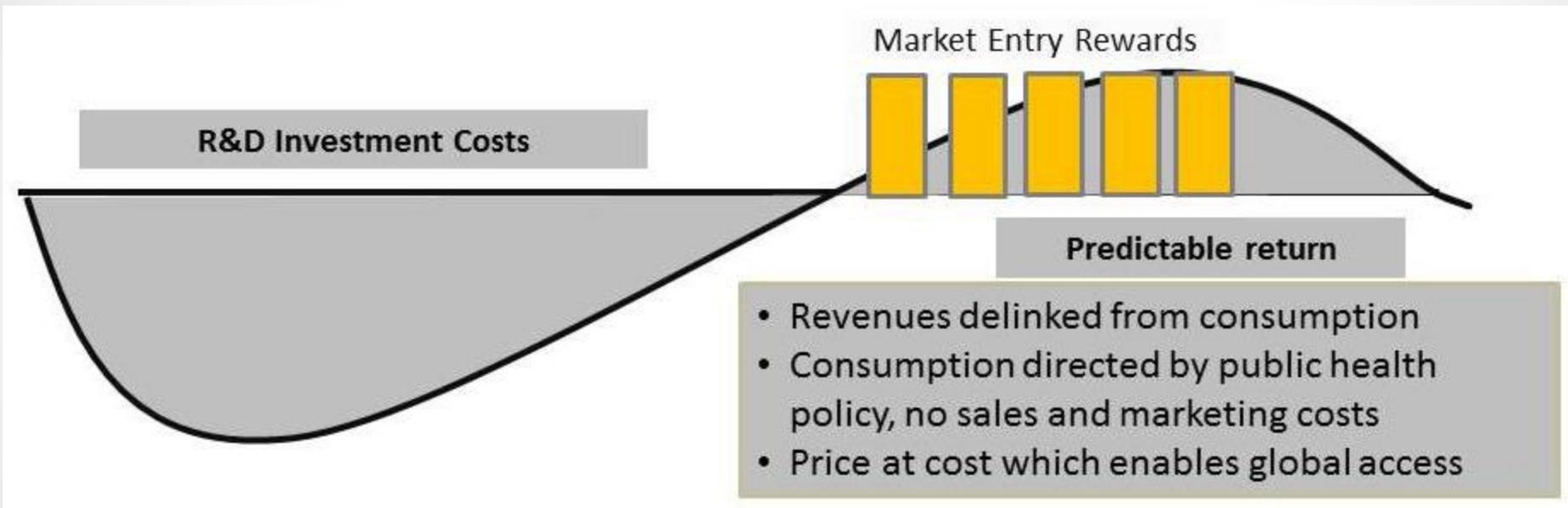


Diagram from DRIVE-AB

Thank you

joseph.larsen@hhs.gov

202-260-0050

