MARKET ENTRY REWARDS AS A PULL INCENTIVE FOR ANTIBIOTIC DEVELOPMENT

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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...

[Diagram showing financial timeline with profit only achieved in year 23.]
Product Launches: New Antibiotics vs. Other Brands

Sales of Recently Launched Antibiotics ($M)

- Avycaz*
- Teflaro
- Zerbaxa*
- Sivextro
- Dalvance*
- Orbactiv*

![Bar Chart 1](image)

Sales of Other Products ($M)

- Januvia
- Lyrica
- Spiriva
- Vyvanse
- Xifaxin
- Eliquis
- Xarelto
- Symbicort
- Linzess
- Teflaro

![Bar Chart 2](image)

*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 that 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)

- Revenues delinked from consumption
- Consumption directed by public health policy, no sales and marketing costs
- Price at cost which enables global access

Diagram from DRIVE-AB
Thank you

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