Drug Shortages

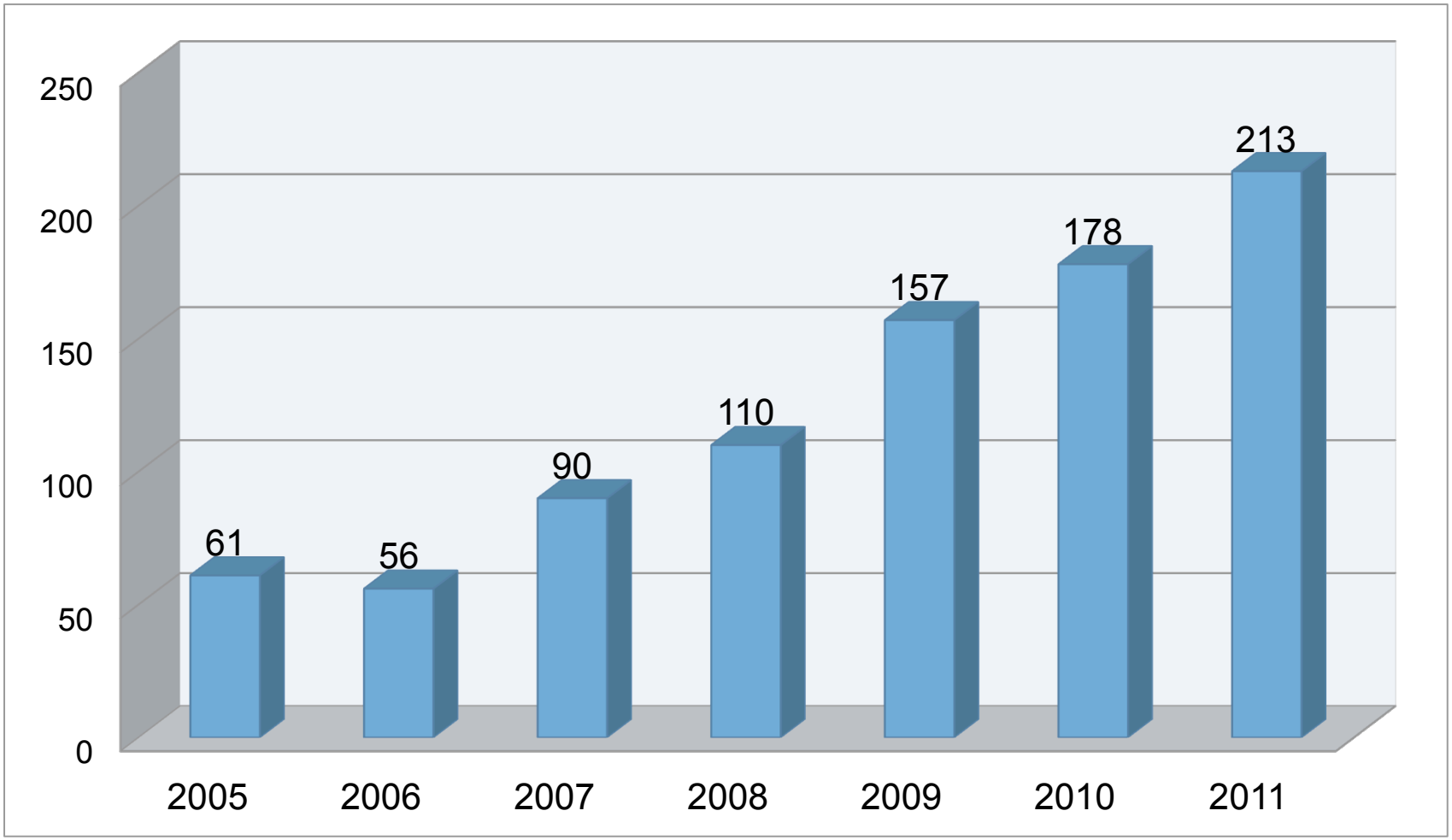
Congressman Bill Cassidy M.D.
Louisiana 6th Congressional District

Drug Shortages: Overview

- Background
- Symptom Causes:
  - Quality/Manufacturing issues
  - Regulatory Scrutiny
  - Grey Market
  - Loss of normal market forces
- Current situation
- Possible policy responses

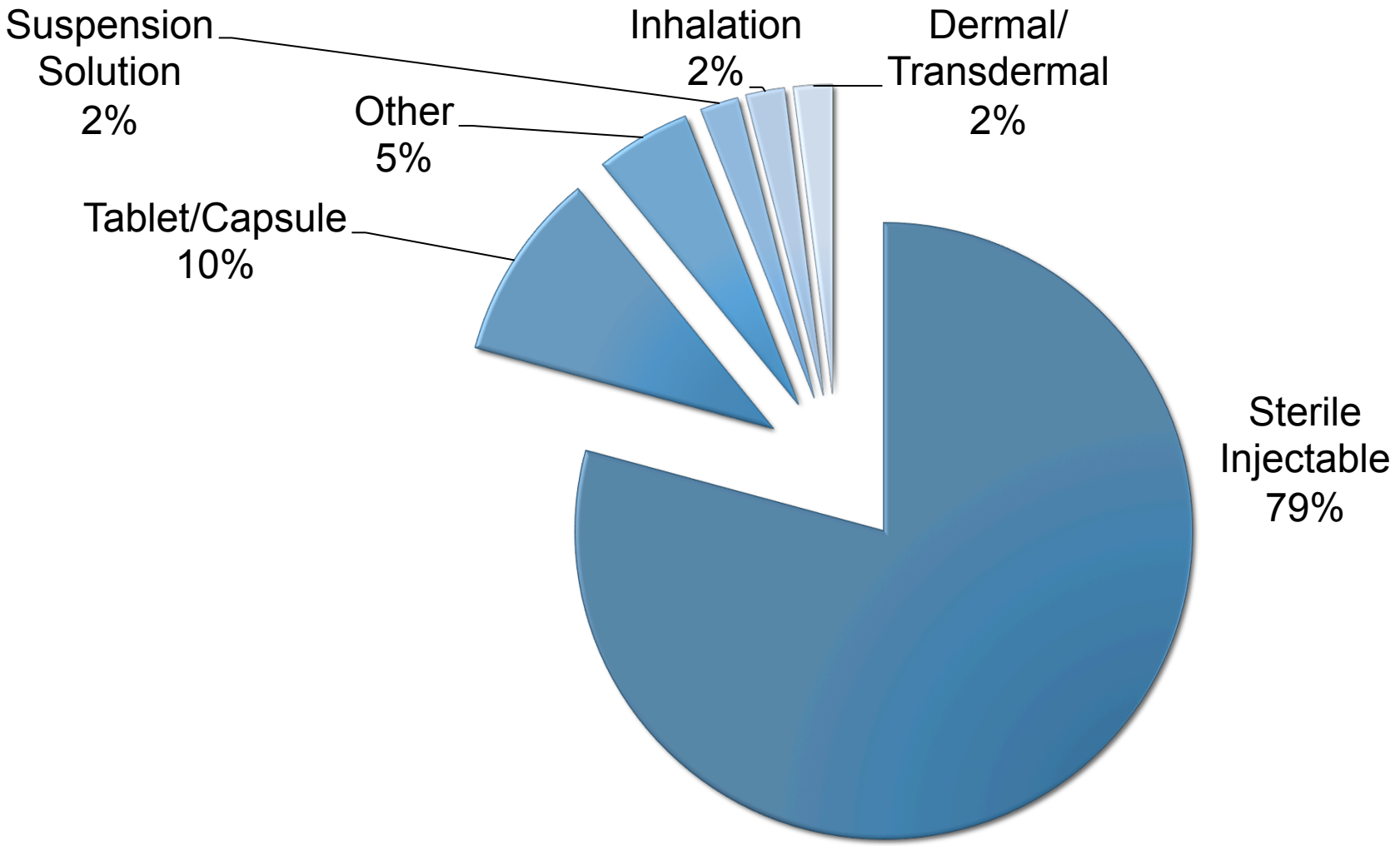
Background on the U.S. Drug Shortage Dilemma

Number of Drugs in Short Supply in the U.S. (2005 – 2011)



Source: FDA. “A Review of FDA’s Approach to Medical Product Shortage.” October 2011.

Drug Shortage by Route of Administration (2010 - 2011)



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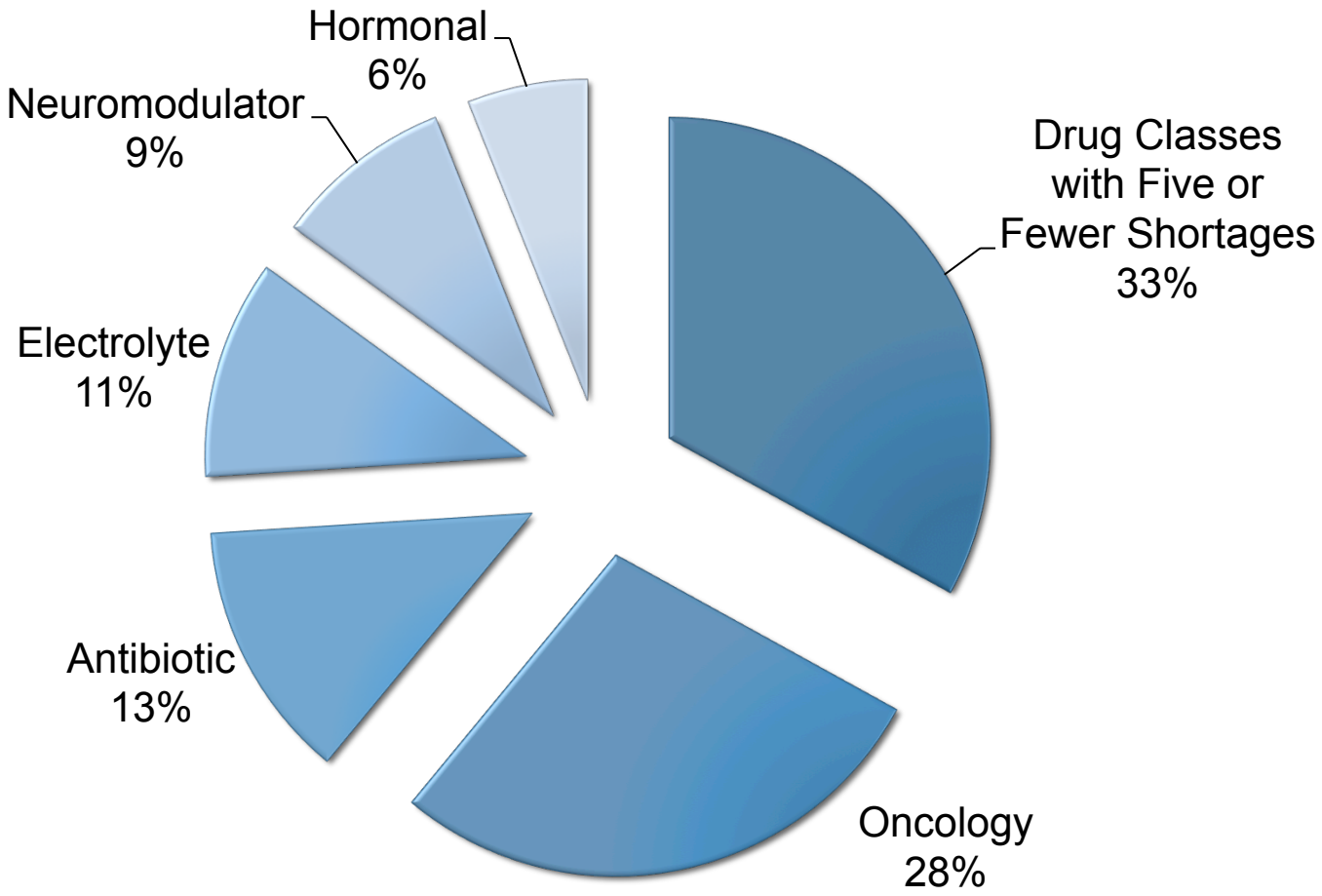
What makes generic sterile injectables different from other branded non-injectable drugs?

- Generic sterile injectables are both expensive to produce and to store
- Manufacturing process is complex
- Margins are small

Drug Shortages by Class (2010 - 2011)



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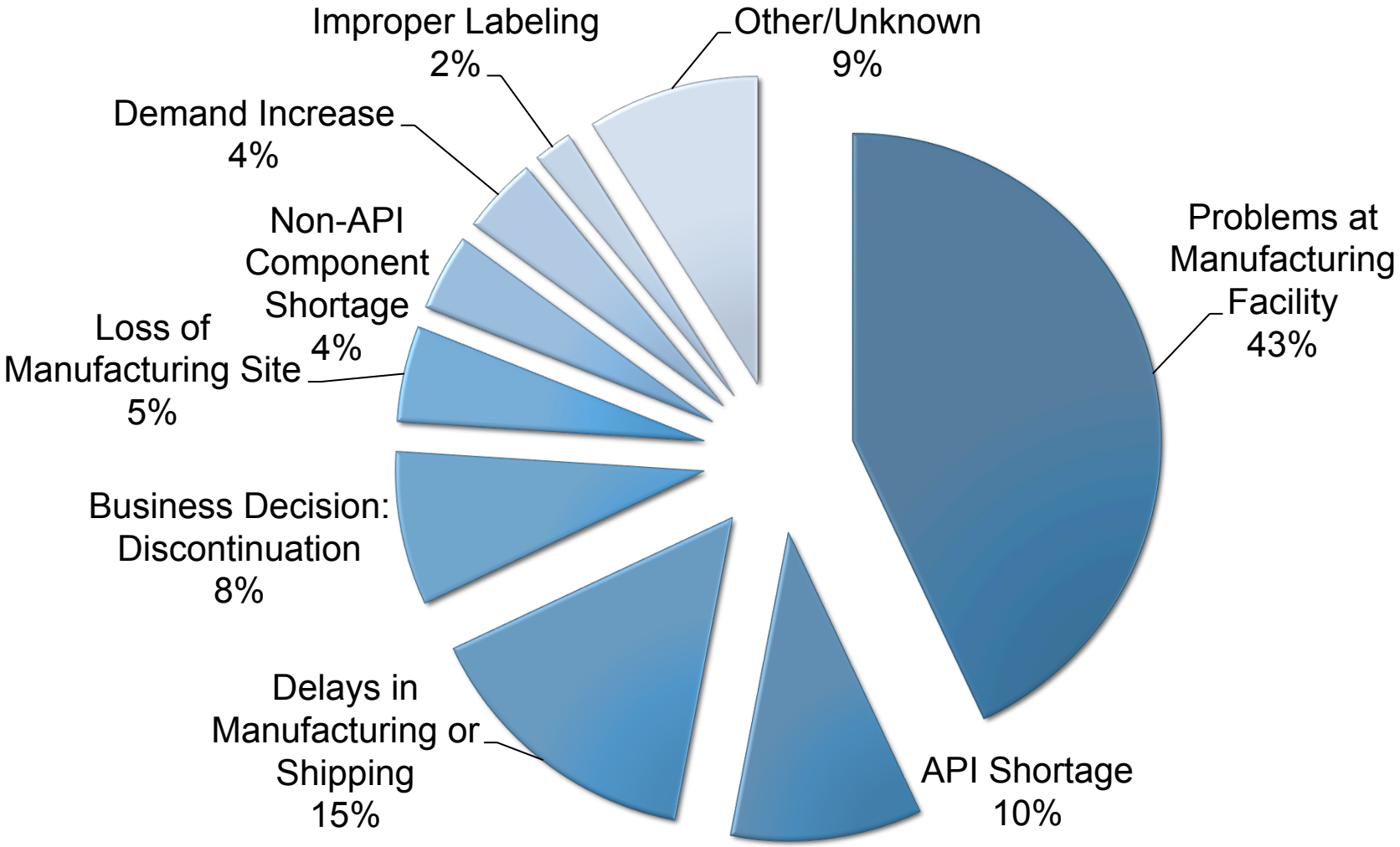
Symptoms & Causes of Generic Drug Shortages

Symptom/Cause of Generic Shortages: Quality/Manufacturing Issues

- Generic injectables are commodities with low margins.
- Low margins led to consolidation of manufacturers
- Some drugs in shortage have only one manufacturer
- Low margins de-incentive upgrading/modernizing facilities
- Low margins may compromise quality control

Primary Reason for Disruption in Production & Supply (2010 - 11)



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Symptom/Cause: Regulatory Scrutiny

- Since 2008, FDA Oversight has increased
- In the last few years, about 100 injectables recalled/year.
- Since 2012, FDA working with industry to avoid shortages.
- Number of shortages is decreasing
- Regulatory oversight should not be scaled back.

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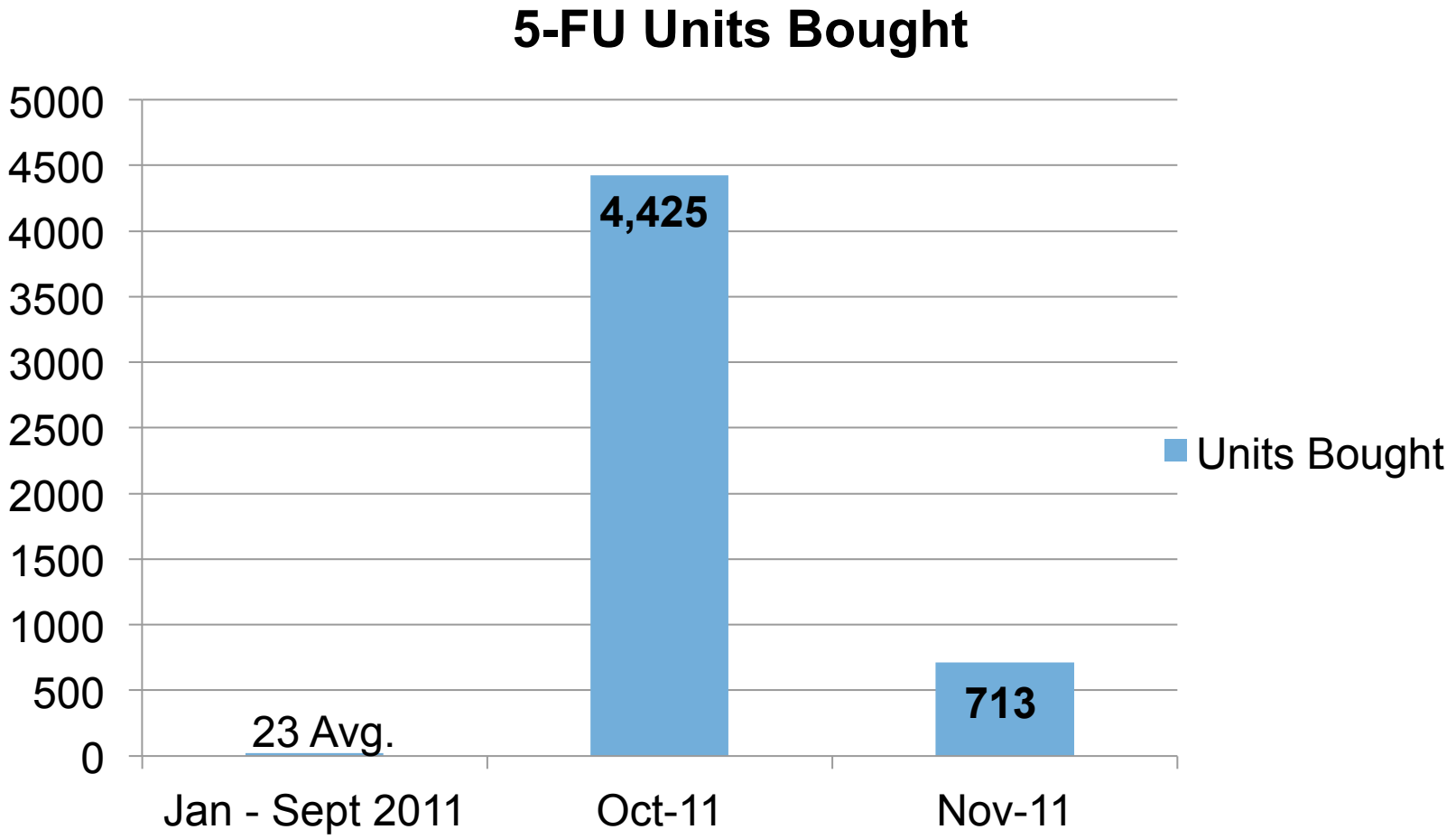
Symptom/Cause of Generic Shortages: "Grey Market"

- Grey market: Drugs bought not for use but for re-sale
- Drugs in shortage can be re-sold multiple times
- Markups can exceed 1,000 percent

Case Study:
Small Cancer Treatment Center Drug Orders



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HHS ASPE Issue Brief: Economic Analysis of the Causes of Drug Shortages (October 2011)

"Among the group of drugs that eventually experience shortage, average prices decreased in every year leading up to shortage. In contrast, the average prices of drugs that never experienced a shortage over this period did not change substantially either in the earlier or later period."

Source: ASPE Issue Brief, "Economic Analysis of the Causes of Drug Shortages," October 2011.

Symptom/Cause: Shortages not triggering higher prices &/or greater supply

- Concentration of manufacturers
- High quality standards creating difficulty to enter
- Group Purchasing Organizations (GPO)
- 2003 Medicare Modernization Act (MMA) & ASP+6%
- 340B

Group Purchasing Organizations

- 1987 law allows GPOs to charge vendors fees
- Critics allege that GPOs are selling market access
- Limits number of manufacturers
- Decreases margins

2003 Medicare Modernization Act (MMA)

- Physician reimbursement is set at **Average Sale Price (ASP) + 6%**
- Providers paid the ASP+6% established 6 months prior to actual purchase
- This has effect to encourage rapid adoption of generic drugs
- Price can drop by as much as 90% after a patent expires

MMA: Six-Month Lag in price

- Once prices fall to nadir, margins are minimized, manufacturers drop out
- If manufacturers raise prices, purchasers of drugs paid 6 month old price and therefore “upside down” on price
- Limits ability of another manufacturer to enter market with higher priced product

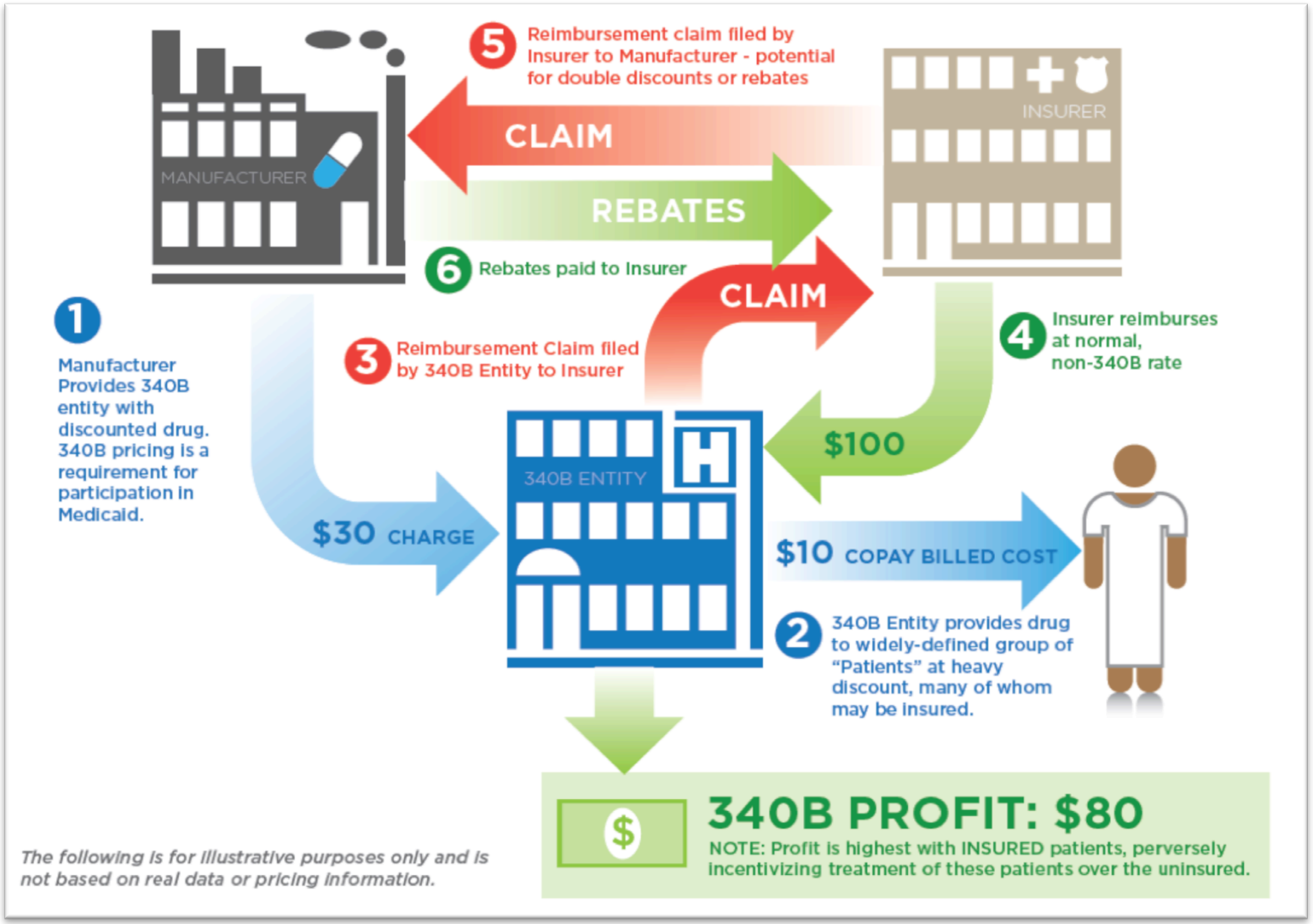
340B Program

- Gives discounted pricing to “Covered entities”
- Covered entity is typically FQHC, non profit hospital
- Only for out patient drugs
- Not purchased through a GPO
- Problem: “Patient” is not defined

340B Program: “Patient”

- Issue is if “Patient” is a Medicaid, Medicare or uninsured patient seen contemporaneously at the hospital
- OR
- If “Patient” is any patient seen at hospital?

How 340B Entities Profit from the Program



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Current Situation

WALL STREET JOURNAL
Drug Makers' Rising Interest in Injectables Could Ease Shortages

By JONATHAN D. ROCKOFF

- Companies hope to ask for a higher price.
- For example, BD will market prefilled syringes, allowing them to charge more due to increased efficiency
- Market is cyclical
- In 2008-9 several drugs went off patent and so companies most likely under utilizing their production capacity.

President Obama's Executive Order (2011)

- Directed FDA to address shortages
- Increased reporting by manufacturers facing supply issues
- Increased monitoring by the FDA
- No mention of economics behind shortages

Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012

- Reporting and Task Force Requirements
  - Task Force Report on Long-Term Strategic Plan due to Congress (Summer 2013)
  - End-of-Year reports by FDA to Congress on how shortages were addressed
- January 2014 GAO Report (to include exploration of market factors)

FDASIA of 2012

- Six-Month Notification to FDA regarding shortage
  - No penalty for non-compliance
- Expedited Facility Inspections and New Application Reviews
- FDA can alter inspection schedule to address most pressing need first

FDASIA of 2012

- Work to resolve manufacturing & quality issues
- Expedite FDA inspections and reviews of various submissions from manufacturers to alleviate the shortage
- Identify additional manufacturers willing to initiate or increase production
- Qualify new sources of raw material if shortage

FDASIA of 2012

- Enforcement discretion, ex: temporary foreign import of product in shortage
- Exercise enforcement discretion to permit distribution of a product in shortage, if this would not cause undue risk
- Ex. allowing product with particulate matter to be distributed with use of filter to eliminate the particulates

Current FDA Action to Prevent Shortages

Agency's Most Common Actions to Prevent a Drug Shortage:

1. Expediting review of new manufacturing sites, new suppliers, and specification changes (71%)
2. Exercising regulatory flexibility and discretion (20%)
3. Asking other firms to increase production (7%)

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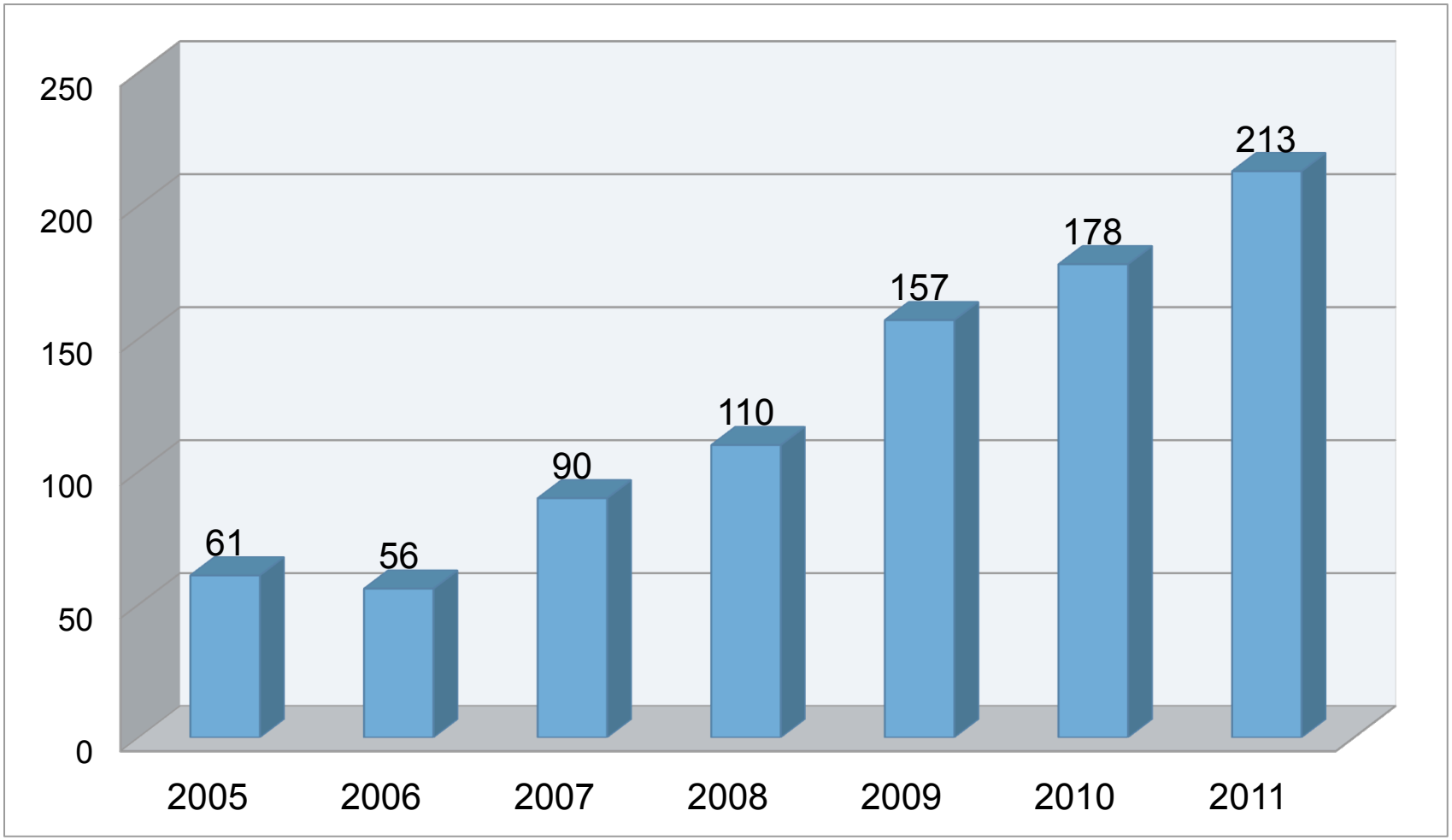

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Issue with FDA Approach

- FDA and HHS studies – no focus on underlying economic issues
- While regulatory scrutiny has increased, it may not be sole cause of shortages.

Potential for a Worsening Situation

- **Affordable Care Act**
  - Independent Payment Advisory Board (IPAB)

- **Efforts at Deficit Reduction**
  - Tighten reimbursements even more
  - ASP + 3% proposal floated around

Recommendations for Moving Forward

Patient Access to Drugs in Shortage Act of 2012 (HR 6611)

- Changes Medicare reimbursement for generic injectables with 3 or fewer active manufacturers:
  - Wholesale Acquisition Cost (WAC) replaces ASP +6%
- While drugs in shortage, would exempt injectables from:
  - 340B pricing
  - Medicaid rebates
  - ACA manufacturer fees
- Independent Study of Legislation < Three years later

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Follow up

- For a copy of slides or to further discuss, please contact:

- Kristy.Hawley@mail.house.gov