# EXCESSIVE DRUG PRICING AS AN ANTITRUST VIOLATION

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Health Care Antitrust in the New Administration
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September 15, 2017

# Common reactions to drug prices in the news

- Revelation
  - traditional media, social media
- Denunciation
  - Congressional leaders; political candidates
  - Congressional hearings
- Explanation
  - we don't get the profits
  - we do, and that's good
  - regulation is to blame
- Expiation
  - coupons, more price discrimination, "lower" list prices
- On to the next…

# Can antitrust help?

- Current efforts
  - reverse payments
  - product hopping
  - collusion
- But not excessive pricing directly
- Can and should antitrust go further?
- Yes
  - Section 2
  - Section 7
  - Section 1

# THE GENERAL PROBLEM

What's wrong with high prices

Dealing with shortages and price spikes

# What’s wrong with high prices?

- Economic view
  - generally bad
  - but: incentives and invitation to enter
- Social view
  - unfairness: exploitation by taking advantage of a particular situation
  - distributive effects: impact on poorer consumers
  - the law has not been indifferent to these effects

# Shortages and price spikes

- Lever Food and Fuel Control Act (1917)
  - prohibiting “unjust or unreasonable” or “excessive” prices
  - for “necessaries”: food, feed, fuel, and fertilizer
  - Constitutional issues: comparison to antitrust laws and NY Emergency Housing Law
  - lesson: guidance from practice; legislative willingness to act
- Electricity price spikes
  - today’s mixed regulatory regime
  - market-set prices, but…
  - price caps and reference pricing to stop “unjustifiably high” prices

# ANTITRUST'S CURRENT APPROACH TO HIGH PRICES

Conventional wisdom

SEPs and FRAND licensing

Excessive pricing outside the U.S.

# Conventional wisdom

- Monopoly pricing: not a violation of Section 2
- Legal support?
- Policy support
  - administrability
    - antitrust courts should not be price regulators
    - business people need clear rules
  - economics: incentives and entry

# SEPs and FRAND

- Patentees' commitments to FRAND licensing
- Fig leaves: enabling practices
  - "false promise" of FRAND licensing
  - seeking injunctions and exclusion orders
  - reneging on a promise
  - the Section 5 diversion
- The take-away: recognizing high pricing as an anticompetitive act

# Excessive pricing outside the U.S.

- U.S. as outlier
- ROW's legal tools and enforcement interests
- Pharma examples
  - South Africa: Hazel Tau (2003); Roche, Pfizer, Aspen Pharmacare investigations (2017)
  - UK: Pfizer (2016)
  - Italy and EU: Aspen Pharmacare (2016; 2017 investigation)
  - China: Zhejiang Second Pharma and Tianjin Handewei (2017)
- Bottom line: a tool used, sparingly but increasingly

# APPLYING ANTITRUST TO EXCESSIVE DRUG PRICING

Post-acquisition price surges

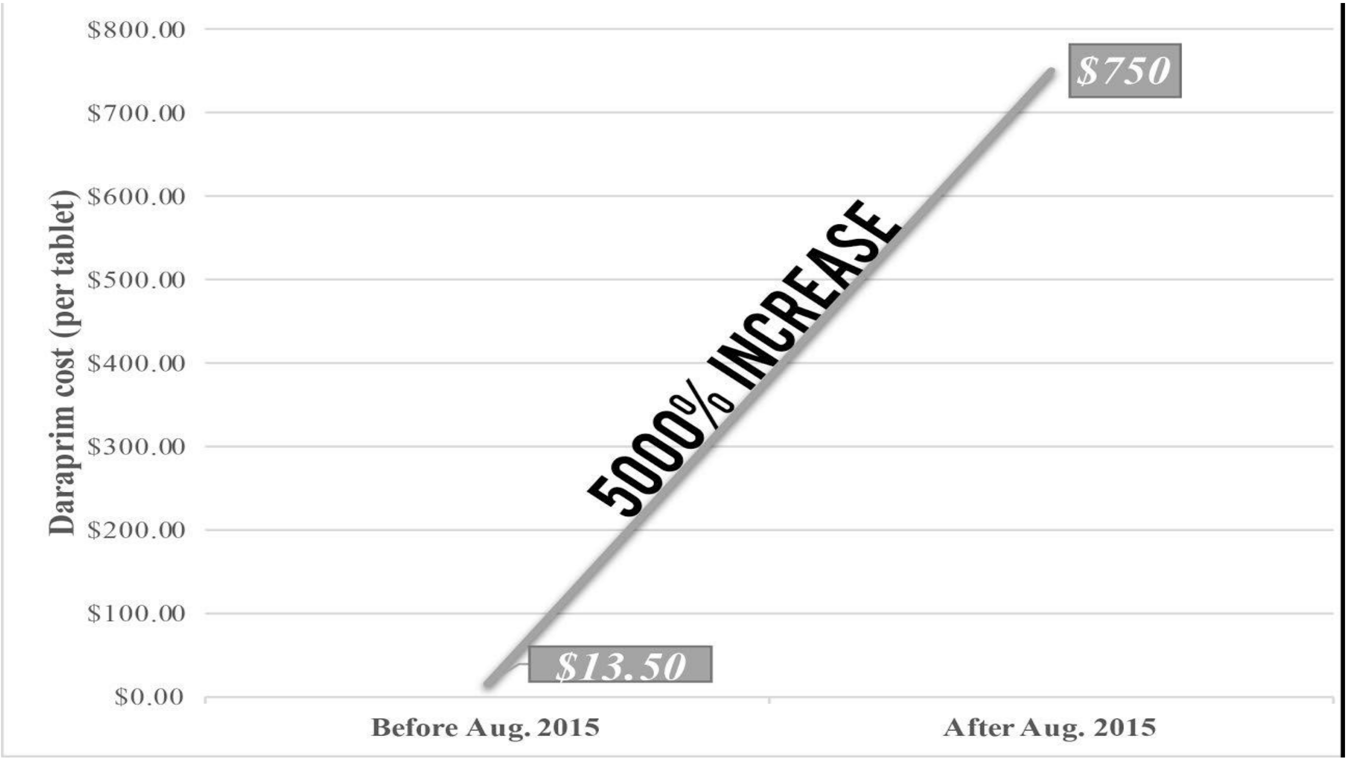
Gradual price increases in brand-protected market

Collusive price increases

# Post-acquisition price surge: Daraprim

- Therapeutic use: treat toxoplasmosis (can affect AIDs patients) and malaria
- Dosage: 3 or 4 pills/day; 1-3 weeks, reduced for 4-5 weeks
- Patent protection: 62-year old drug, off patent
- FDA approved: 1953
- Acquired August 2015 (owned by GSK until 2010)
- Price increase (immediate): $13.50/pill to $750 in one year
- Defense: profits are a “great thing”; will use them to finance future research

# Post-acquisition price surge: Daraprim



# Antitrust analysis: Daraprim

- Section 2: charging excessive prices
  - immediate price-spike: evidence of exploitation
  - extreme price rise: evidence of lack of relation of price to costs and reasonable return on capital
  - lack of patent protection: innovation premium has already been paid
  - entry: shadow entry-deterrence strategy
- Section 7: acquiring Daraprim
  - change of strategy: the bad maverick
  - unilateral price increase

# Post-acquisition price surge: Calcium EDTA

- Decades-old intravenous treatment for severe and life threatening cases of lead poisoning, which are relatively uncommon (50 serious cases in 2015)
- Acquisition history
  - drug owned by Graceway
  - acquired by Medicis out of bankruptcy in 2011
  - Valeant acquires Medicis in 2012 for $2.6 bb
- Shortages in supply under Medicis ownership fixed by Valeant in 2013

# Post-acquisition price surge: Calcium EDTA

- Post-acquisition price surge, pricing/box
  - 2012 - $950 (Medicis)
  - 1/14 - $7,116 (Valeant)
  - 12/14 - $26,927 (Valeant)
- Valeant response: prices necessary to insure "consistent supply of a product with high carrying costs and very limited purchase volume of 200-300 units per year"

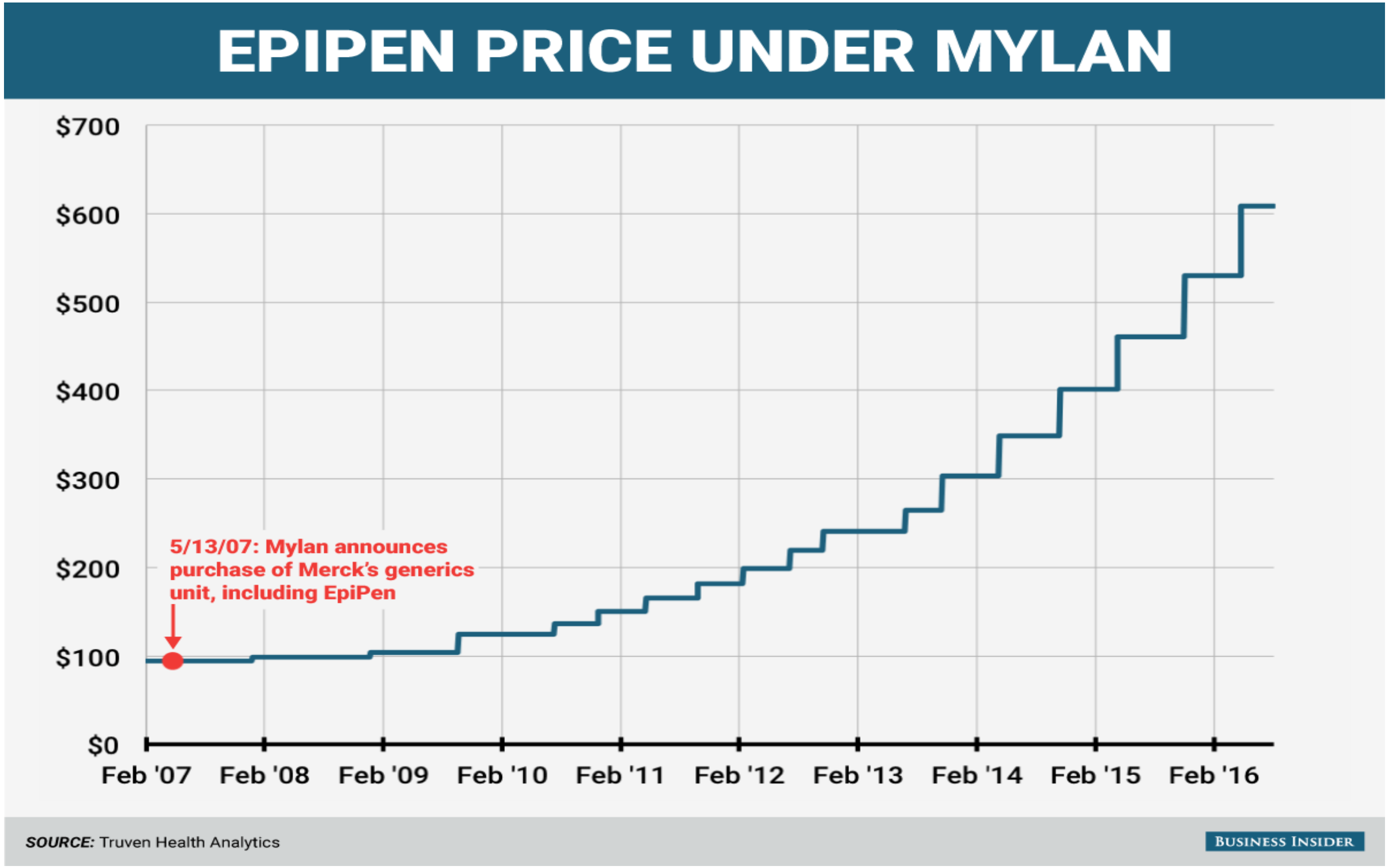
# Antitrust analysis: Calcium EDTA

- Section 2
  - price-spikes, although not as immediate as Daraprim
  - extreme price rise, plus yardstick comparison to other markets
  - lack of patent protection
  - entry: small market, low manufacturing cost
  - possible efficiency justification:  fixing manufacturing problem
- Section 7: Valeant’s “disruptive pricing” acquisition strategy

# Gradual price rise: EpiPen

- Used to treat anaphylaxis, serious allergic reaction from, e.g., insect bites, food, asthma
- Mylan acquires marketing rights in 2007 (Merck KGaA acquisition); Meridian (Pfizer sub) is the manufacturer
- Patents
  - drug is off-patent; Meridian patents cover delivery system and pen cap
  - infringement suit against Teva (generic entrant), settled 2012 to allow entry in 2015 (10 years before patent expiration)
- School Access to Emergency Epinephrine Act of 2013, called "EpiPen" legislation, giving funding preferences for schools maintaining emergency supplies of epinephrine

# The rising prices of EpiPen



# Antitrust analysis: EpiPen

- Gradual price increase v. price spikes
  - caution on exploitation
  - but: post-"EpiPen bill" price surges
  - evidence of price discrimination with exclusion
- Innovation incentives
  - drug out-of-patent, but injector has some (weak) protection
  - some evidence of superior product (injector)
- Entry
  - weak entrants, high entry prices
  - strong trademark in life/death product

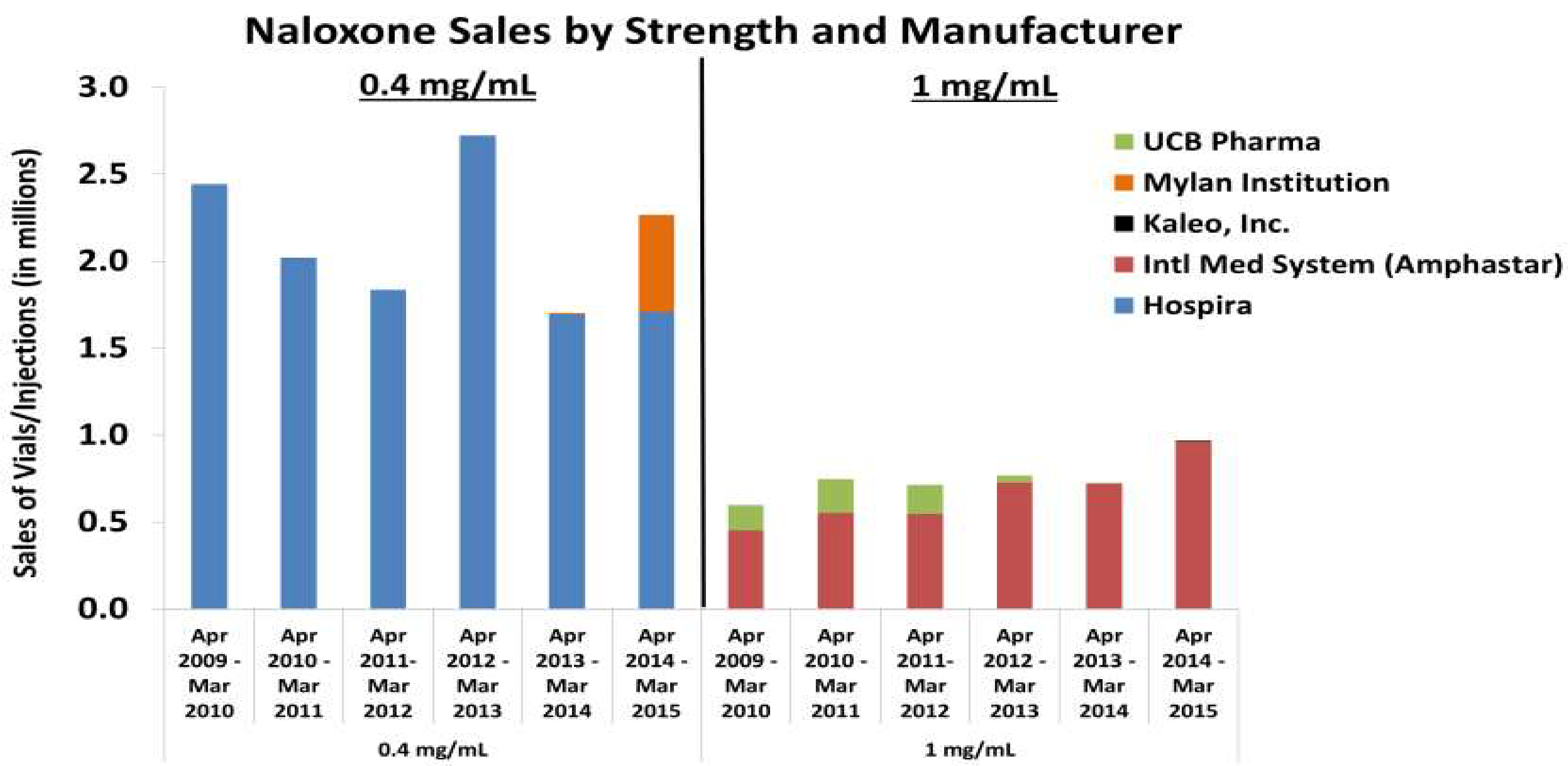
# Collusive price increases: Naloxone

- Drug used to prevent opiod overdose (from heroin, morphine, and oxycodone); particularly effective in emergency use by police, EMS, and other first responders
- Patented in 1961, now generic
- Can be administered by injection or by nasal spray
  - injectable: Mylan, Amphastar, and Hospira
  - auto-injector: Evzio (Kaléo), 2014 FDA approval
  - nasal spray: Narcan (Adapt Pharma), 2015 FDA approval

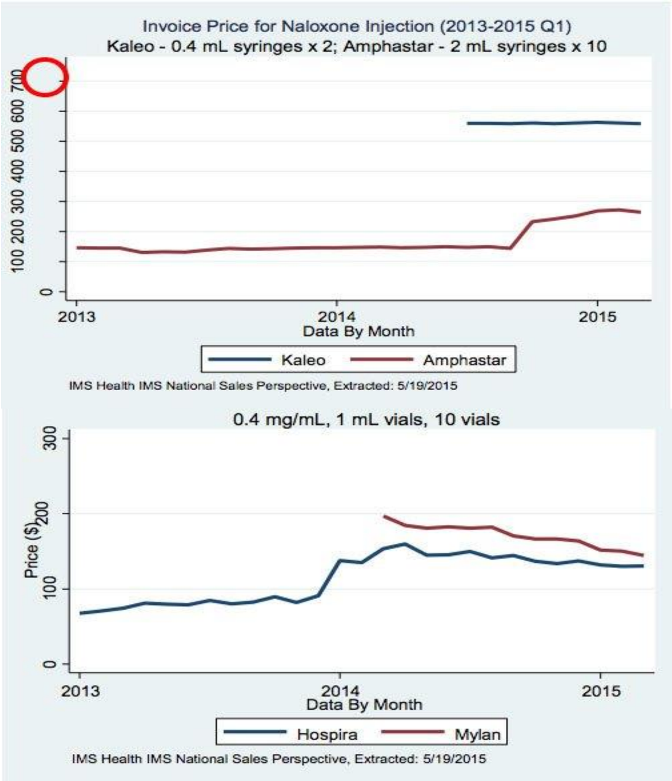
# Naloxone: pricing

- Hospira
  - $1.84 (2 vials) in 2005; $31.64 in 2014
  - 2014 price about 50% higher than 2013
- Mylan: enters in 2014 at higher price than Hospira
- Amphastar: 60% price increase in September 2014
- Evzio (auto injector): $575 in 2014 to $3750 in 2016
- Narcan (nasal): introduced in 2015 at $125 for two doses
- FDA Study (2015)
  - price increases occurred in January 2014 for the 0.4 mg/mL strength and in September 2014 for the 1 mg/mL strength
  - since then, prices remained elevated

# Naloxone: each strength is sold primarily by one company



# Naloxone entry and pricing: FDA study



# Antitrust analysis: Naloxone

- Section 1
  - division of markets
  - non-competitive pricing
- But: is there overt collusion?
  - Turner's argument: same standard for oligopolistic pricing as Section 2, so concern for excessive pricing as anticompetitive
  - simultaneous price spikes for emergency-use drug
  - innovation incentives: out of patent drug, weak incentives for injectable version
  - ineffective entry
  - "plus factors"?

# CONCLUSION

# Antitrust and excessive drug pricing

- Antitrust can and should be used to stop excessive drug pricing, for economic and distributional reasons
- A jurisprudence of excessive drug pricing can be developed, focusing on:
  - price spikes
  - excessive divergence between price and costs
  - comparative market prices
  - entry barriers: patents, trademarks, shadow entry-deterrence pricing strategies
  - efficiency justifications

# Antitrust and excessive drug pricing

- Antitrust has some comparative institutional advantages over regulation
  - antitrust courts will never become industry price regulators
  - antitrust is fact-driven, with tools to examine conduct in particular markets
  - antitrust enforcement agencies have guidance tools to make enforcement more predictable
- Dems' "better deal"? — there is no first-best alternative