The Forced Switch: Implications for the Biotech and Pharma Industries

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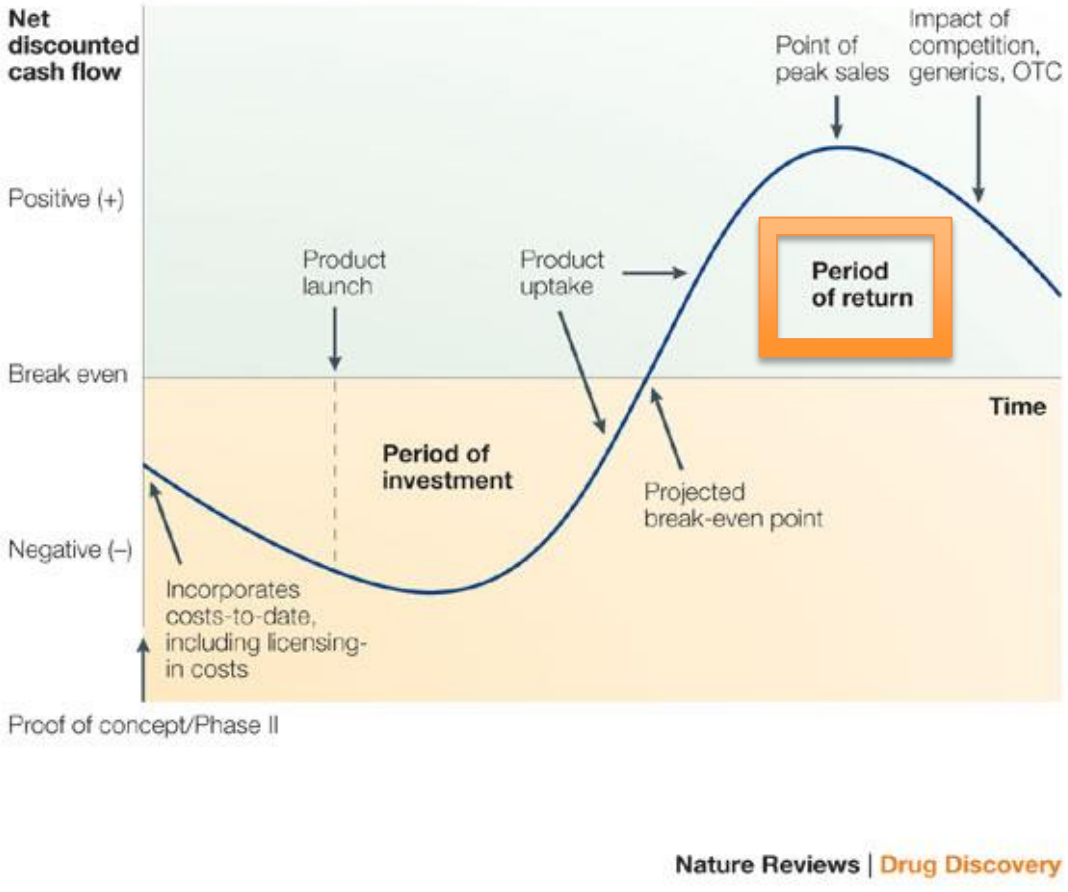
How do Biotech and Pharma Make Their Profits?

- **Odds:**
  1/5000-10000 drugs make it to market
- **Cost:**
  ~$4-11B including failed candidates
- **Time:**
  10-15 years from drug discovery to sale



Regulatory Determinants of Period of Return

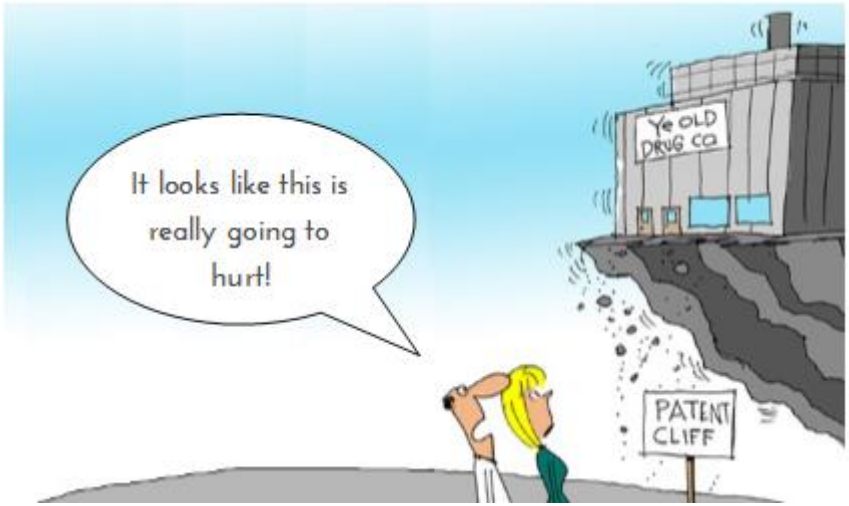
- **Patents**
  - Expire 20 years from filing
- Typically >20 years from patent to FDA approval
  - Impetus for Hatch-Waxman Act (1984)
- **Data Exclusivity:** Companies cannot apply for market approval using the competitor's data.
- **Market Exclusivity:** If a New Molecular Entity (NME) is approved, a generic version cannot be approved for five years.
- The former, de facto, means the latter.
  - In USA, usually D.E. time = M.E. time
  - This can vary by country or future legislation

Periods of Marketing Exclusivity Vary by Drug Type

	Years of Exclusivity
New Molecular Entity	5
New Indication/Dosage	3
Orphan Drug	7
Biologics*	12

*Any medicinal product manufactured in or extracted from biological sources. (e.g.: vaccines, blood or blood components, allergenics, somatic cells, gene therapies, tissues, recombinant therapeutic protein and living cells.)

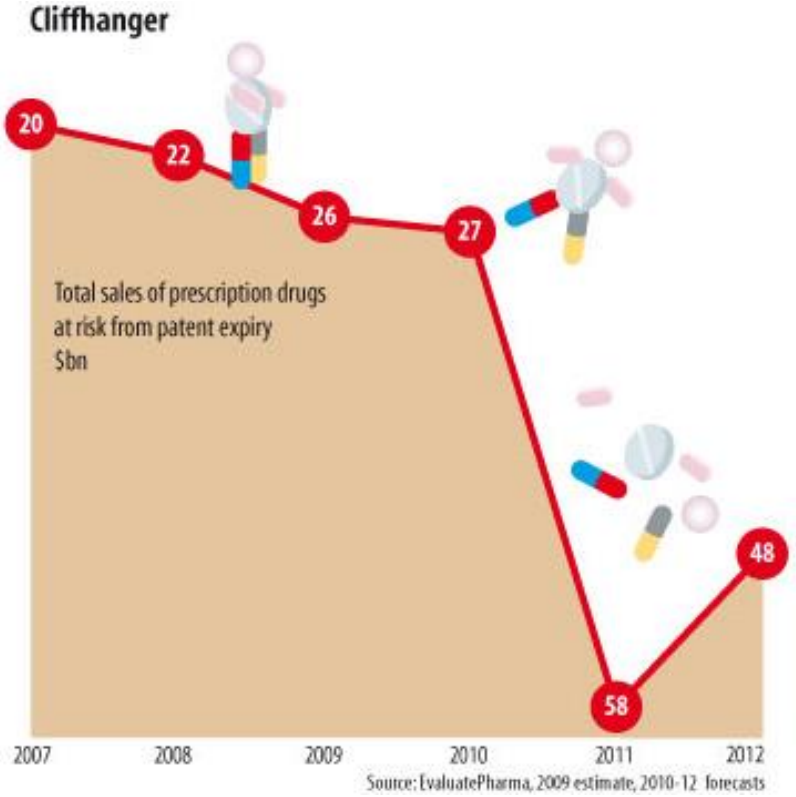
What Happens After Exclusivity Ends?



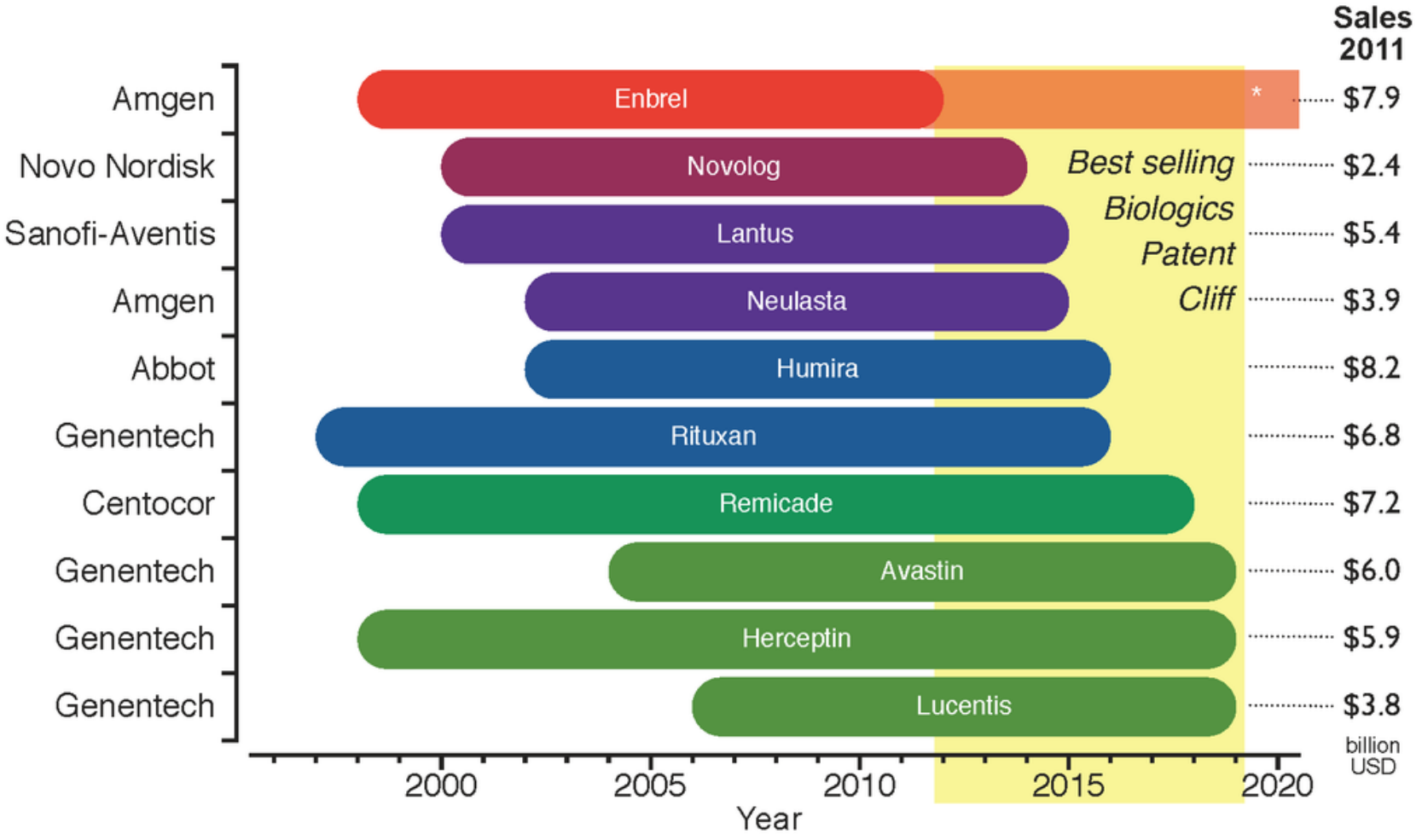
The Patent Cliff

- Generics enter the market and revenues of 'pioneer' version tumble
- Mainly affects 'blockbuster' products (>$1B in revenue/year)

The 2011 Patent Cliff (Small Molecules)



2012-2019 Patent Cliff (Biologics)

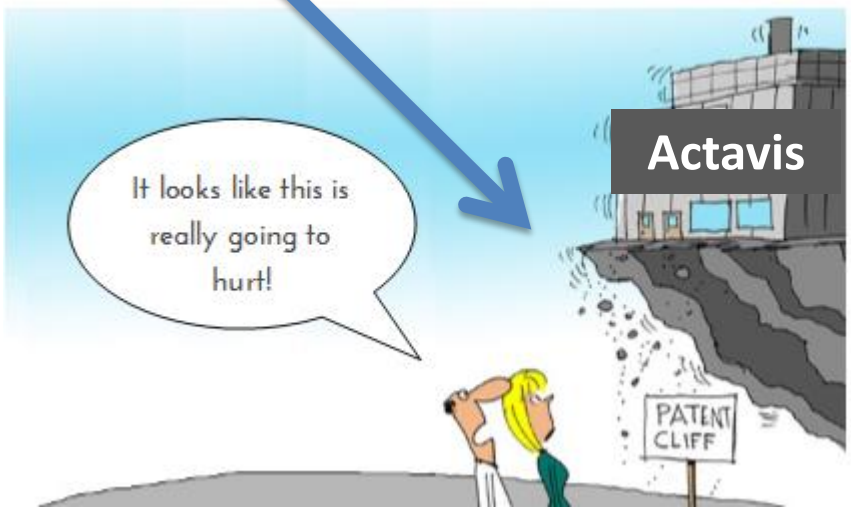


Patent Cliffs Are Inevitable

How Can Biotech/Pharma Add Value To Their Preexisting Drugs?

Case: Actavis' Namenda (Memantine)

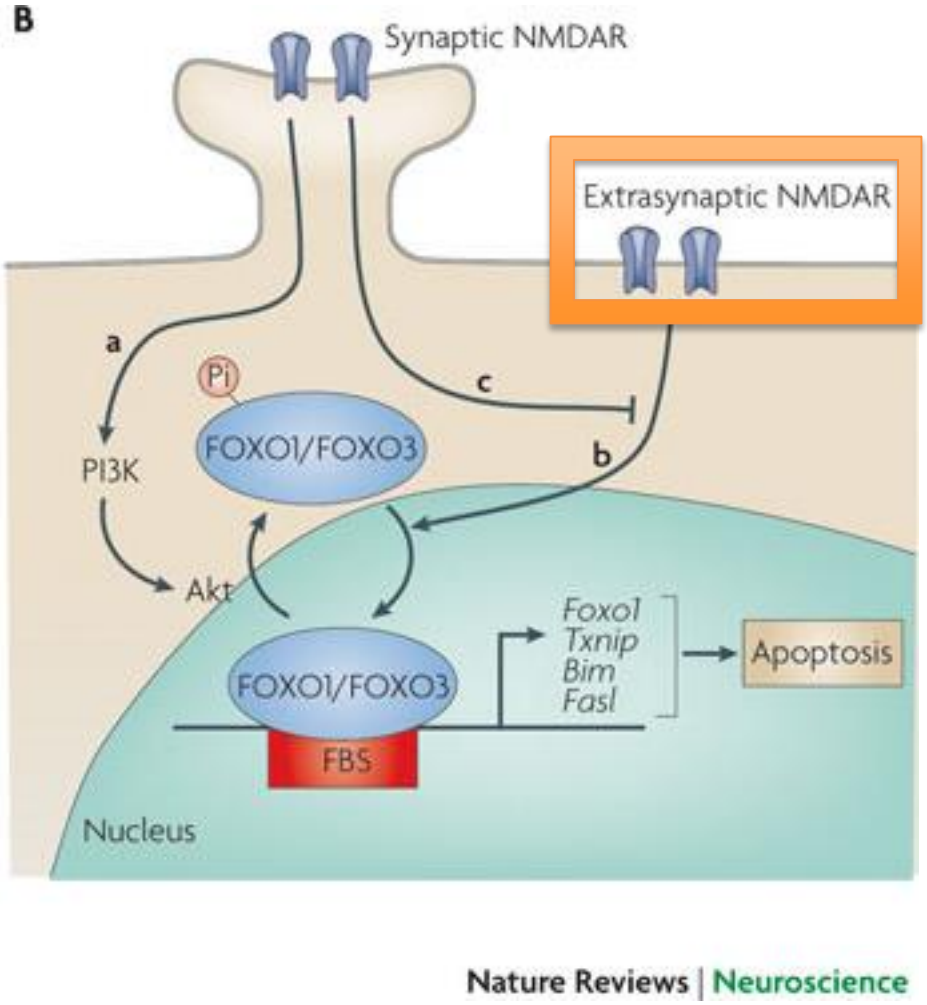
July, 2015



Market Cap: $75B

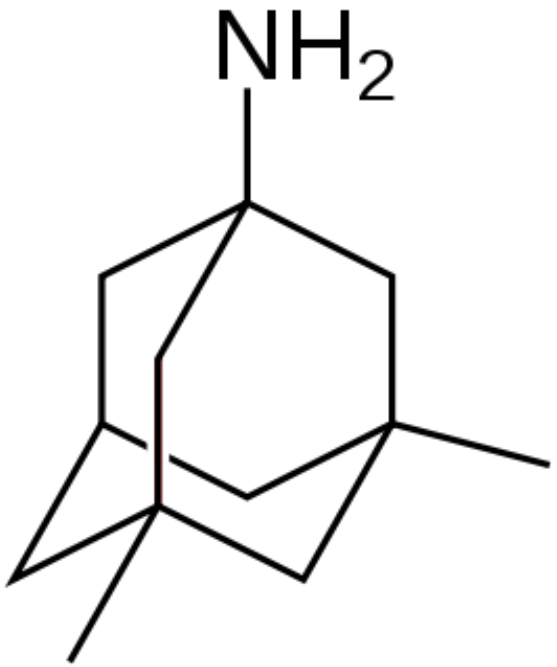
Namenda is Prescribed for Alzheimer's

- Developed by Forest Labs
  - Acquired by Actavis in Feb. 2014 for $25B
- Counteracts hyperactive glutamatergic transmission, which results in **neuronal excitotoxicity** via activation of **extrasynaptic NMDA receptors**



Namenda (Memantine) is an Uncompetitive NMDAR antagonist

- Preferentially targets extrasynaptic NMDARs
- Low affinity & high on/off rate
  - Preserves physiological response to glutamate from pre-synaptic neuron
- Mild and infrequent side effects



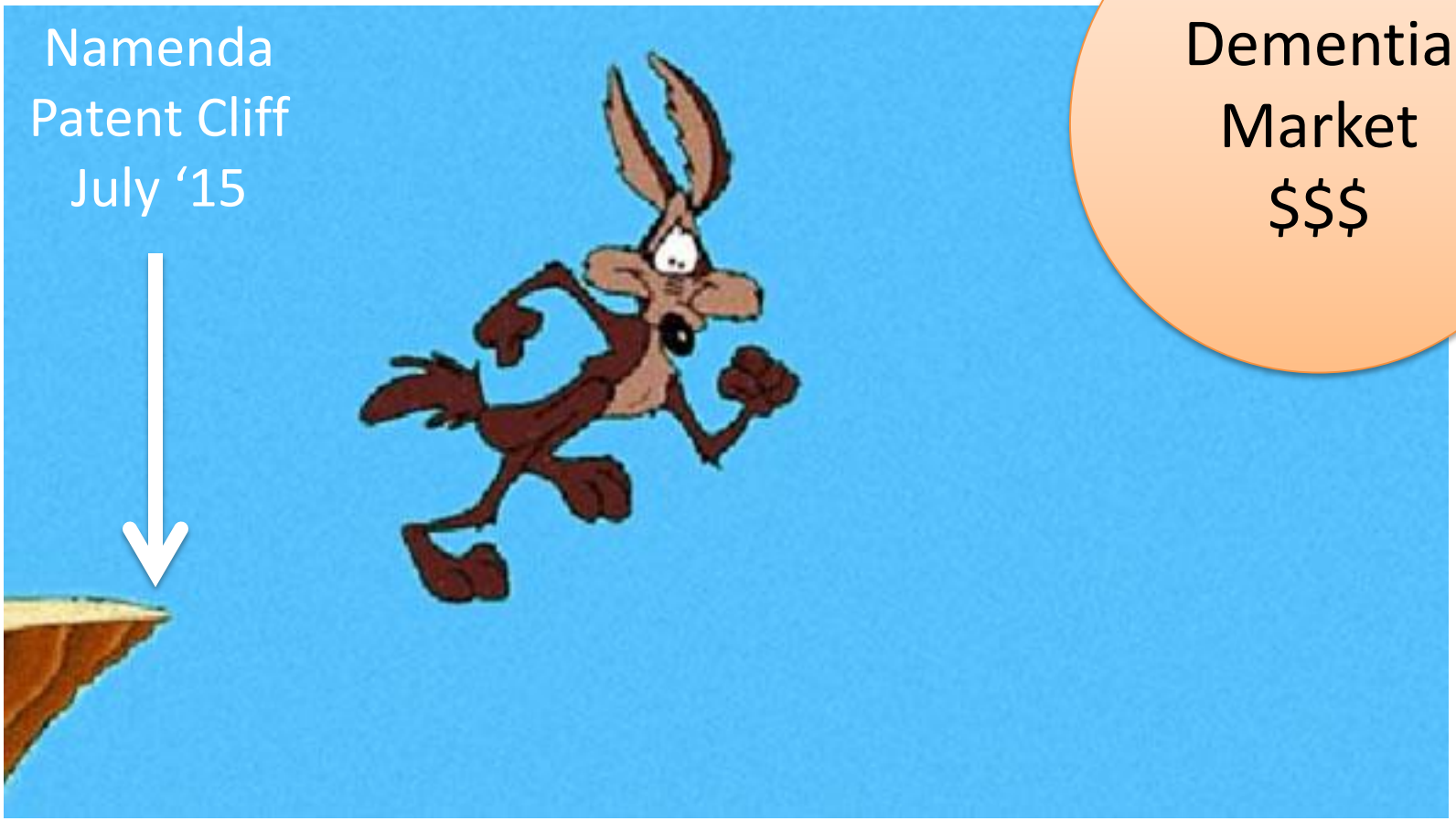
Namenda Has Two Indications

- **Alzheimer's Disease**
  - Limited to moderate and severe cases
- **Dementia with Lewy Bodies**
  - Alpha-synuclein and ubiquitin clumps in neurons
  - Shared characteristics with AD and PD
  - Affects 1.3M people in US

In USA, Dementia Drugs Target a Big Market

- Total cost of dementia in US: **$200B**
- Prevalence in US will **double by 2040**
- 15% of people >71 have dementia **(~5M)**
- **1 in 3 seniors** dies with AD or another dementia

How Can Actavis Maintain Revenue?

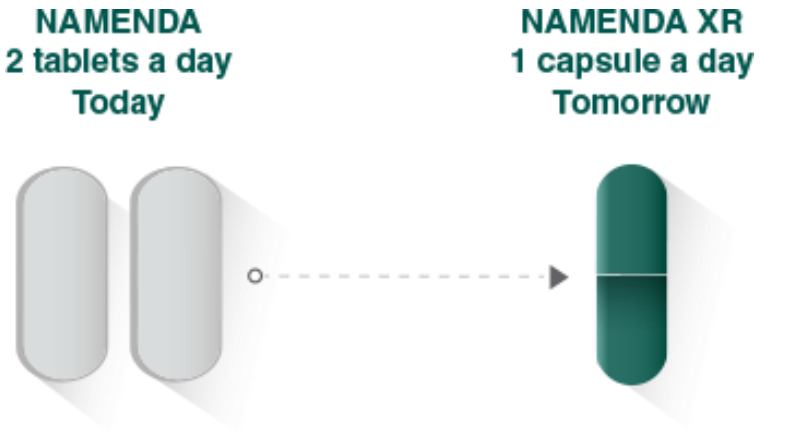


One Answer: The Forced Switch

Definition: Patients are switched to a ‘new’ drug before the generic arrives. These patients are more likely to remain on the newer medicine even after a lower-cost generic becomes available, at which point, the original drug is no longer for sale.

Namenda XR is the 'New Drug'

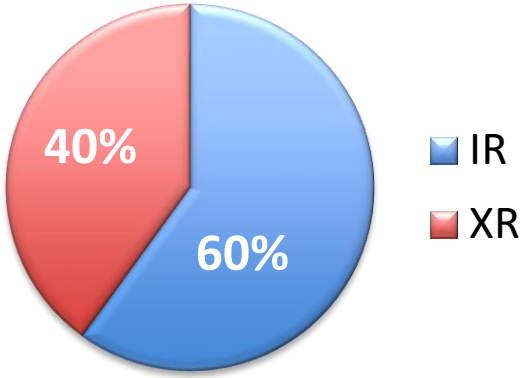
XR vs. IR Improvements
1. Taken once a day vs. twice
2. Can be 'sprinkled' on food for patients with trouble swallowing



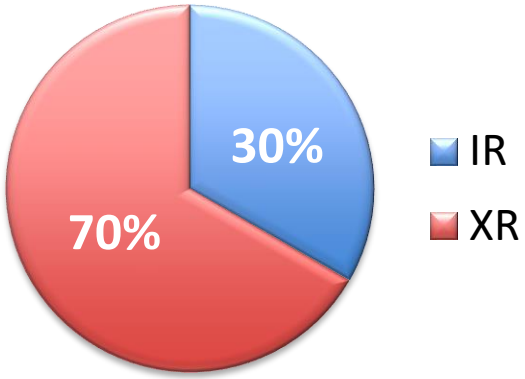
Generic Available July 2015

Off Patent in 2025

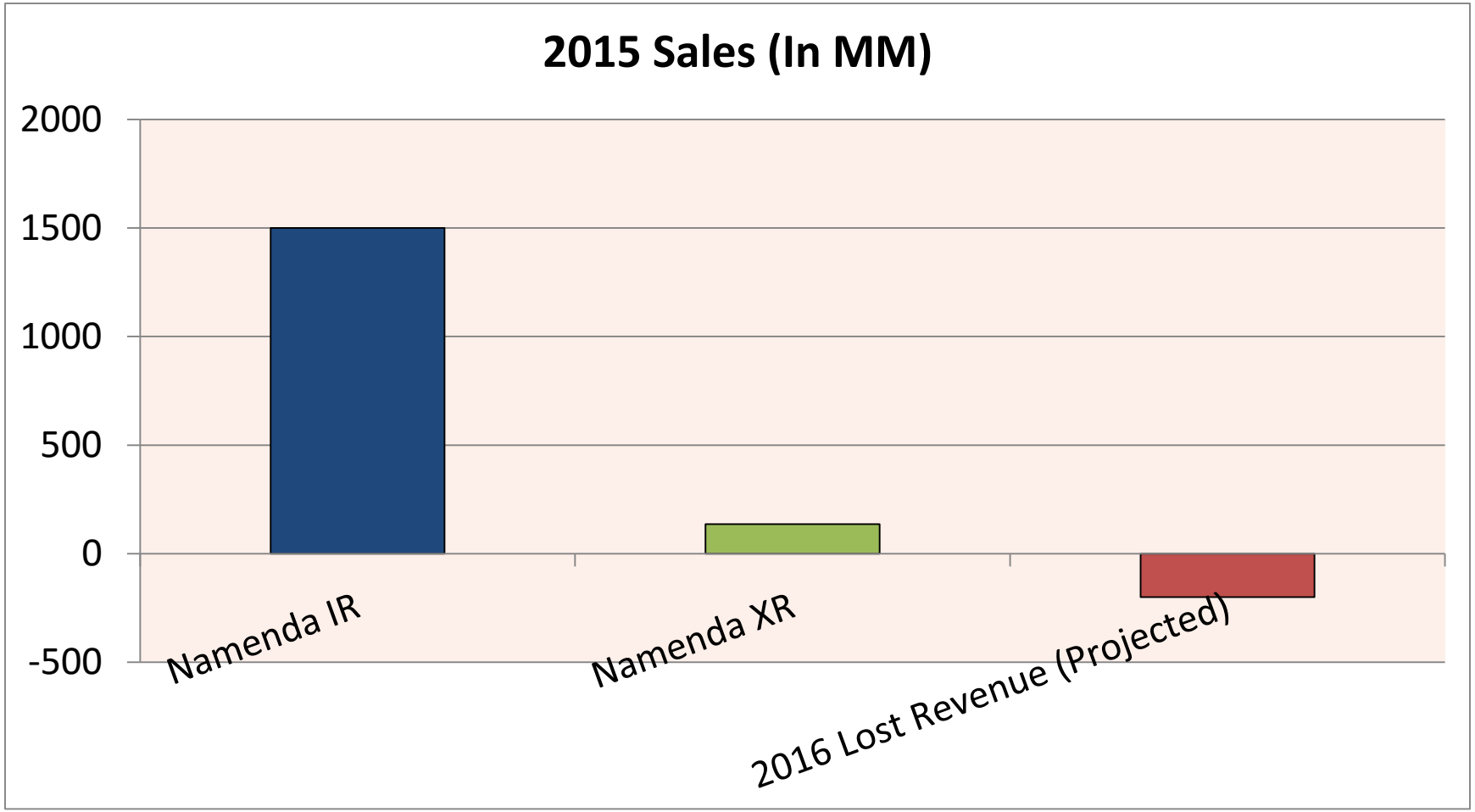
Present % of Rx's



Goal % of Rx's



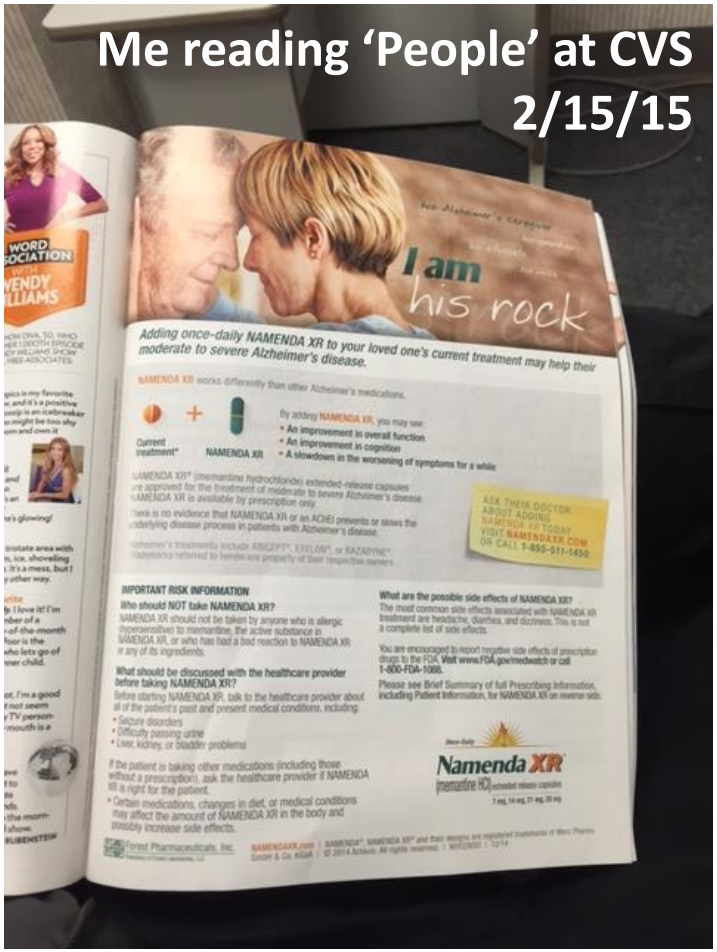
Current and Forecasted Namenda Revenue Streams



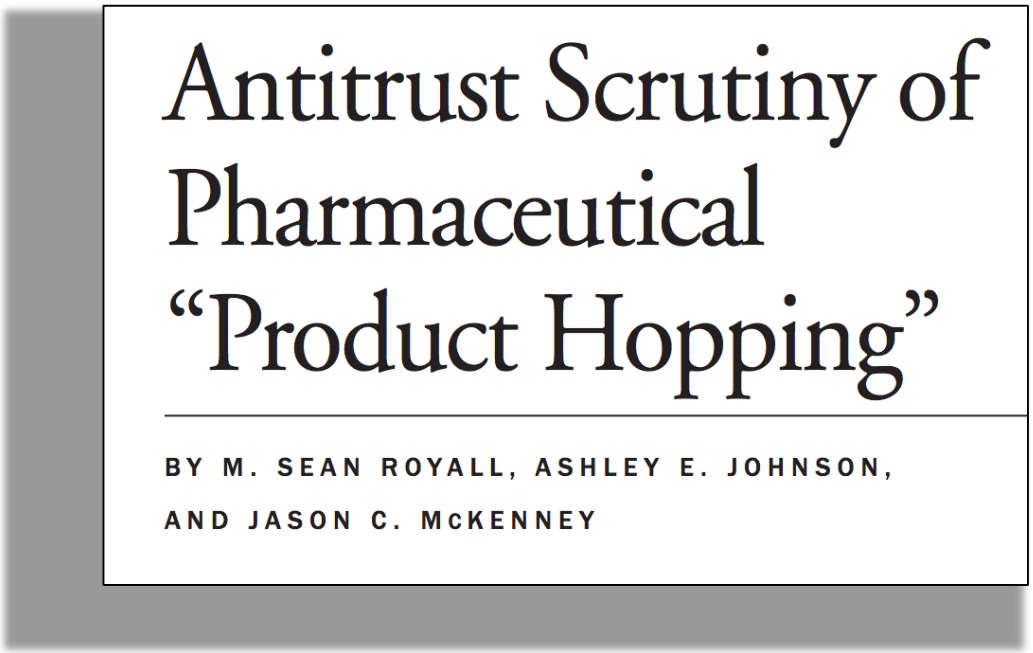
NY State Attorney General Finds This Suspect (Sep. 2014)

Actavis Responds to Threats Against Namenda XR

- Jan. ‘15 – Direct to Consumer Ad Campaign
- Wholesale discounts on XR (5% less than IR)
- Differential pricing and specialized contracts with Medicare
  - 70% of Namenda Rx’s are under Part D plans



From the Antitrust Law Journal…



"… [a] relatively recent phenomenon, and the law remains very much in flux."

Namenda Lawsuit Timeline

- **Sep. ’14:** NY state Attorney General files lawsuit
- **Dec. ’14:** Federal court issues injunction preventing Actavis from pulling Namenda from shelves
- **Feb. ’15:** Response comes from Appeals Court
  - *This ruling will determine industry sales strategies for the foreseeable future*

Ok, Let's Discuss

- What is 'anti-competitive' vs. savvy business practices?
  - Should a company be forced to sell a product?
    - Will companies have to argue that their product lacked demand?
  - Should 'the market' choose the better product?
    - What about compromised patient populations?
- Obligations to shareholders vs. patients
- Ethical – Pharmacoeconomic Disservice
  - Higher health care costs vs. profitability