How Pharma Gets to Price Like This and

State Challenges to Controlling Drug Costs

State Gov'ts Carry A Lot of Rx Costs

- State taxpayers typically fund some portion of pharmacy benefits for 25% **or more** of the state population.
  - Medicaid
  - State and Local Employee and their dependents
  - State and Local Retirees (with Medicare Part D)
  - State Corrections, Local Jails
  - State and Local Public Health
  - State Higher Education employees and student health services
- State tax expenditures for health insurance premiums, healthcare costs (as applicable, not all states)

States: Hobbled in Addressing Rx Costs

- State Employee Expertise Lacking
  - Extremely complex and opaque marketplace
- Federal Laws and Case Law
  - Patent case law
  - Freedom of Speech
  - Trade Secrets law
  - Recent important US Supreme Court wins on state regulation of ERISA plans (Rutledge, 12/2020) and state regulatory authority relative to Dormant Commerce Clause (Ross, 5/2023) – make bolder state action possible.
- Pharma lobby power
  - Fund patient groups to lobby and object
  - Hire almost all, if not all, lobby firms in a state capital
    - Few lobbyists remaining to assist in Rx change policies

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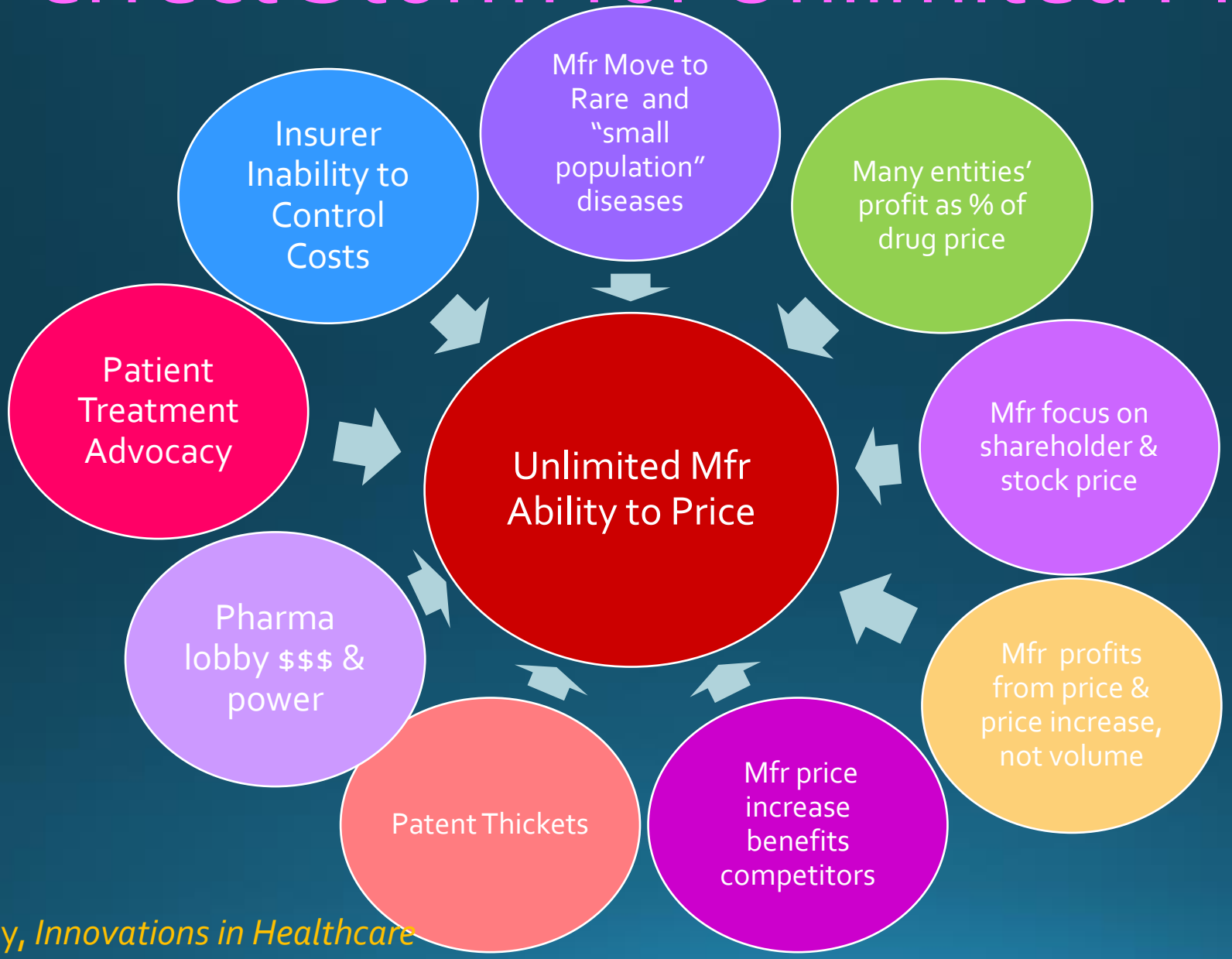
The Perfect Storm for Unlimited Pricing



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Industry Shift to Small Population Treatments

- A specific industry strategy to pursue treatment areas where insurer cost containment power is reduced and patient advocacy is high. Examples
  - Rare diseases – 30M people/330M total population (rare disease affects <200000 people)
  - Cancer – 1.9M new cases/year
  - Lupus – 1.5M people
  - MS -- 1M people
  - All autoimmune disorders – 10M
- 42M/330M = ~13% of population and counting
- Pricing model will generate phenomenal/unaffordable? Costs
- FDA rare disease designation confers additional lucrative benefits to manufacturers beyond patent and other FDA incentives for drugs generally.

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Example of Trend: Sanofi to Exit Diabetes and Heart Disease

- **"[*Sanofi CEO*] Hudson said he expects sales of Sanofi's vaccines business to grow at mid-to-high single digits. It [*the company*] will focus on oncology, hematology, rare disease, neurology, and the Chinese market, where Sanofi has been strong. It will give top priority to six experimental drugs, including two for hemophilia and single entrants in rare disease, cancer, infection, and multiple sclerosis.**
- That transition will come at a cost. Sanofi was built on Plavix, one of the best-selling heart drugs ever. It currently sells Lantus, a long-acting insulin that was the best-selling insulin in the world. But Sanofi will exit research in diabetes and cardiovascular disease, finishing studies on a major diabetes medicine it is developing without plans to bring it to market." Stat News 12/9/2019

Who Benefits (or Not) From High Drug Prices?

- Entities that benefit from high prices often oppose policy that reduces Rx costs
  - Manufacturers
  - Wholesalers
  - Research Centers/Universities
  - Pharmacy Benefit Managers
  - 340B Entities (hospitals and others)
  - Pharmacies (notably chain pharmacies)
  - Physician Specialists (depending on the reimbursement formula)
- Entities that do not benefit are not well resourced for the fight
  - Consumers
  - State and local government programs

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How the Industry is Incentivized to Focus on Stock Price

- Pharma:
  - Merck CEO 2018: $21M total compensation/ $19M in stock and pension
  - J&J CEO 2018: $20M total compensation/$14M stock and options
  - Abbvie $24M, Amgen $22M, BMS $20M, Gilead $19M and so on in 2021
  - Many levels of pharma company leadership compensated with stock grants
- Similar situations in other industries but there is more pressure on product price in those industries.
- Wall Street Rx stock valuation based on *expected* revenues. Meeting expectations via price rise is much more certain than relying on sales growth. Revenues can increase while sales stay flat or reduce

Result of Industry Use of Price and Price Increases to Meet Wall Street Expectations

BCBS Study shows *price* drives spending rather than utilization volume (more prescriptions) for branded products

Drug Type	Annual Utilization Δ	Annual Price Δ	Annual Spending Δ	Cumm Spending Δ 2010-2016
Generic	9%	0%	9%	64%
Brand	-6%	17%	10%	76%

BCBS Blue Health Intelligence Report: Rising Cost for Patented Drugs Drive Growth of Pharmaceutical Spending in the US

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Competition Does Not Reduce Prices

Does competition equal lower prices? MS drugs defied cost logic as challengers swarmed in

by Kyle Blankenship , Fierce Pharma, Aug 29, 2019

"The average price of self-administered disease-modifying therapies for MS quadrupled between 2006 and 2016 as a rush of competitors flooded the market, according to a new study published in JAMA Neurology."

Note: MS Society generally supports Rx cost controls now whereas most patient groups do not

Prices Increases Even Benefit Competitors

High Launch Prices and Price Increases Clear a Price Path for Therapeutic Branded Competitors

Patented Innovator Drug	**$$$** Launch Price	**$$$$** Price Increase	**$$$$$** Price Increase	**$$$$$$** Price Increase	**$$$$$$$** Price Increase	**$$$$$$$$** Price Increase	**$$$$$$$$$** Price Increase
Patented Therapeutic Competitor		**$$$$** Launch Price	**$$$$$** Price Increase	**$$$$$$** Price Increase	**$$$$$$$** Price Increase	**$$$$$$$$** Price Increase	**$$$$$$$$** Price Increase
Generic #1					**$$$$$** Launch Price	**$$$$$$** Price Increase	**$$ Price Decrease**
Generics #2 & 3							**$$ Launch Price**

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Overpatented, Overpriced America's Bestselling Drugs of 2019 Source: https://www.i-mak.org/2019-bestselling/

Drug	Total patent applications	# Patents Issued	% Filed after FDA approval	Duration of patent protection	Patents filed in U.S. vs. Europe	Patents filed in U.S. vs. Japan
Xarelto	51	32	41%	33.5	1.5x	1.6x
Revlimid	196	109	74%	40.4	2.6x	2.6x
Opdivo	84	44	70%	35.1	2.2x	2.0x
Keytruda	129	86	50%	34.6	1.0x	1.2x
Imbruvica	165	88	55%	29.2	3.6x	3.9x
Humira	257	130	90%	39	3.3x	4.1x
Eylea	89	58	53%	39.7	3.2x	4.9x
Enbrel	68	39	76%	47.5	2.1x	2.6x
Eliquis	49	31	37%	33.8	2.7x	3.1x
Avastin	222	75	80%	41.6	2.4x	2.1x
Average	131	69.2	63%	37.5	2.5x	2.8x

Overpatented, Overpriced America's Bestselling Drugs of 2019 Source: https://www.i-mak.org/2019-bestselling/

Drug	On U.S. market since	Generic / biosimilar approved by FDA (year)	Generic / biosimilar on the U.S. market since (year)
Xarelto	2011	-	-
Revlimid	2005	-	-
Opdivo	2014	-	-
Keytruda	2014	-	-
Imbruvica	2013	-	-
Humira	2002	2016	-
Eylea	2011	-	-
Enbrel	1998	2016	-
Eliquis	2012	-	-
Avastin	2004	2017	2019
Average	2008.4		

Overpatented, Overpriced America's Bestselling Drugs of 2019 Source: https://www.i-mak.org/2019-bestselling/

Drug	% Price increase 2014-2019	>10% Medicare annual price increase	>5% Medicaid annual price increase
Avastin	21%	-	-
Eliquis	58%	18%	8%
Enbrel	84%	17%	14%
Eylea	16%	-	-
Humira	69%	17%	16%
Imbruvica	42%	19%	-
Keytruda	147%	23%	-
Opdivo	167%	19%	26%
Revlimid	34%	14%	9%
Xarelto	71%	18%	9%
Average	71%		

Industry Spending to Thwart Change

- Pharma Lobby Power
  - Federal (most companies and trade assn spending 2022) $262M
  - State (total all companies and trade assns. 2020) ~$5M

    Source: OpenSecrets.org
- Pharma funds disease groups/patient advocacy groups which align with key industry coverage/payment policy views
  - $680M to patient groups in 2018 – **by just 6 companies**

    Source: Fierce Pharma 10/9/2019

(Note: state and patient group data not updated)

Patient Treatment Advocacy

- Disease groups do raise money for R&D for bench science and clinical trials then hand off molecule to pharma for commercialization
  - Strong advocates for access/coverage
  - No discussion of price until recently
  - Example of research-oriented patient groups
    - Cystic Fibrosis
    - Hemophilia
    - Multiple Sclerosis

Lots of Room for Lower US Prices & *continued* R&D

- Top pharma companies spent $56B more on stock buybacks and dividends than they spent on R&D in last 5 years (US House Govt Oversight Comm 7/2021)
- Pharma return on investment is $14:1 for cancer drugs (WHO 2018)
- R&D of $7.2B for 10 cancer drugs, revenue of $67B (JAMA 9/2017)
- US-based Rx companies earned 176% of their *worldwide* R&D budget from just the portion of US prices that are above the prices charged in other countries (Health Affairs Blog 3/2017)
- Large pharmaceutical manufacturers could absorb an 11% profit reduction and still have a more effective return on capital compared to other industries (West Health, 11/2019)

Rules of Thumb for Market Change

- Price has to be transparent
  - On-invoice discounts and prices – minimize rebates
  - Lower price/cost must get to the pharmacy counter
    - If pharmacy is paying and billing high cost, system cannot really change
  - Back end rebates cannot be the basis of cost/spending control
  - High prices and rebates have lead to stunning levels of market dysfuntion
- Focus on Affordability, Not Value
  - Every drug is valuable, if not invaluable, to the patient for whom it is intended
  - Every invaluable drug is not affordable
  - Affordable pricing expands access, value-based pricing likely will not.
    - Expands patient access to drug
    - Expands manufacturer access to the market – faster uptake of costly drugs

Thank You!

Drugs Don't Work if People Can't Afford Them

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