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The Policy Pincer: Rising Drug Costs and Declining Access

Innovation incentives and the role of ‘value’

- Drug development is risky and expensive
    - Long time horizon
    - Low success rate
    - Large capital outlays
    - Only makes sense if return for successes is large
- For drug development we have created a structure that provides this
    - Temporary monopoly rights to drug innovators when successful

The Reward Box

Revenue associated with pharmaceutical innovation

INNOVATION PERIOD

MONOPOLY PERIOD

COMPETITIVE PERIOD

POSITIVE (+)

REVENUES

$0

NEGATIVE (-)

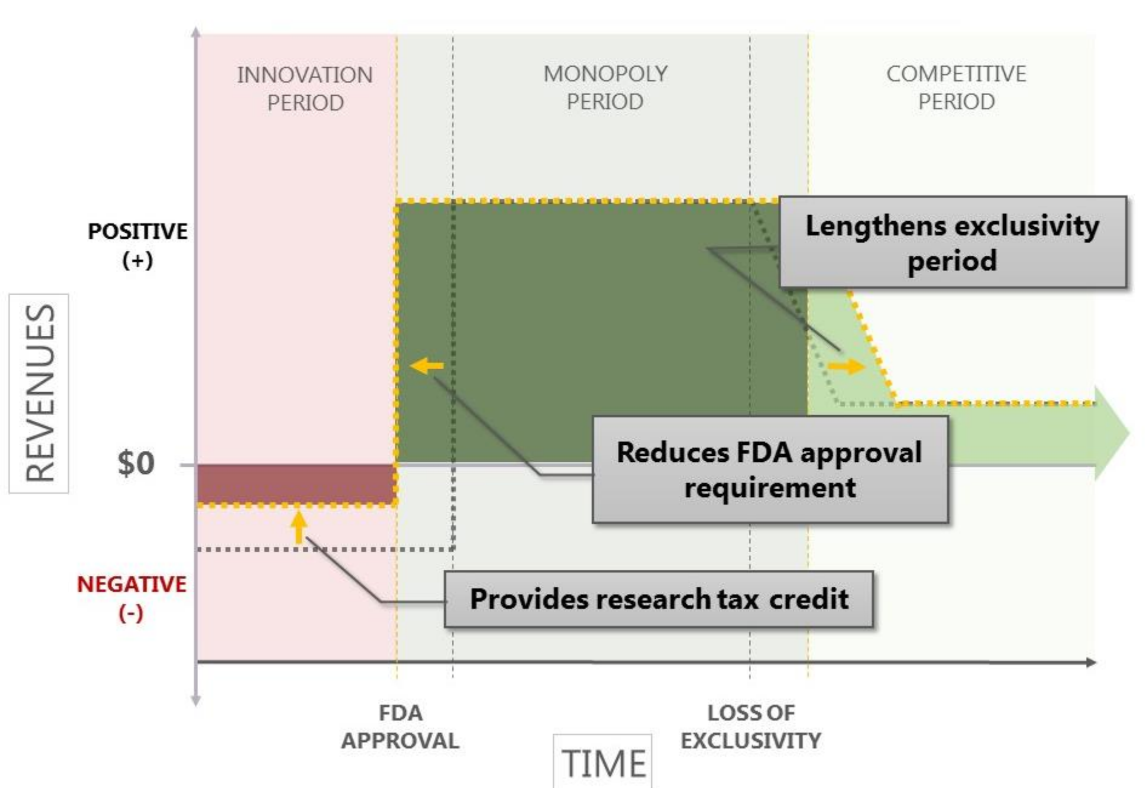
FDA APPROVAL

LOSS OF EXCLUSIVITY

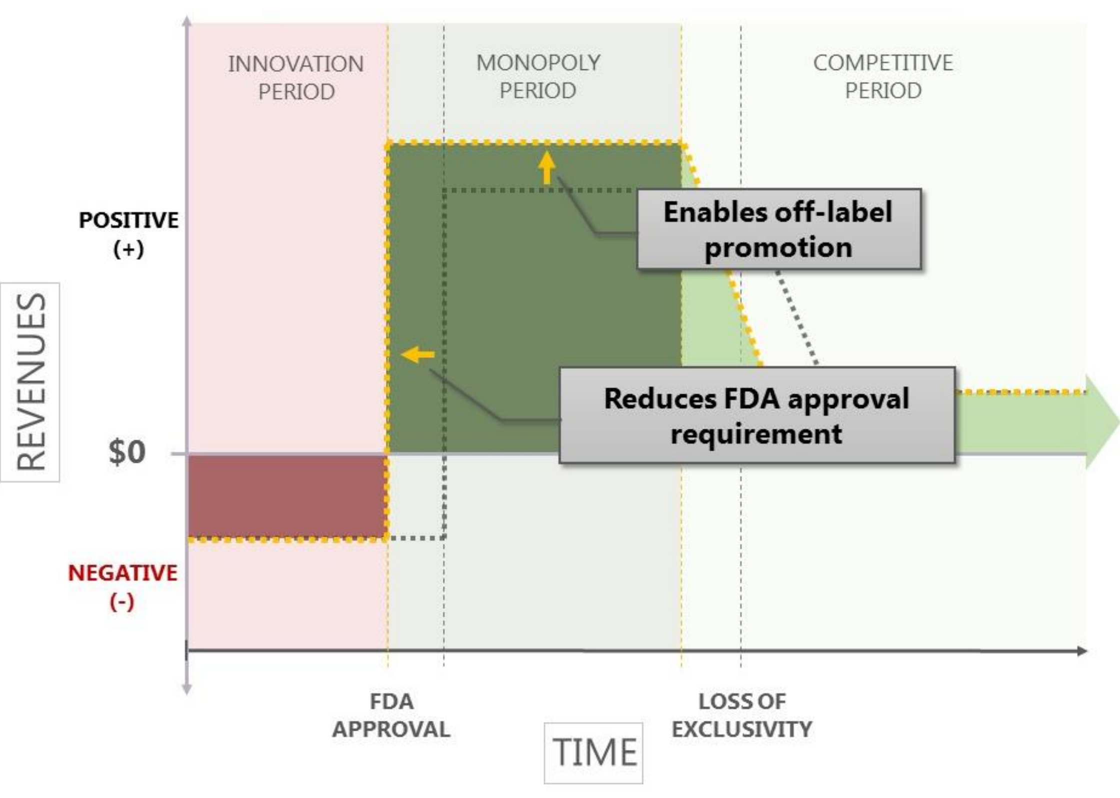
TIME

Reward Box is routinely changed by Policy

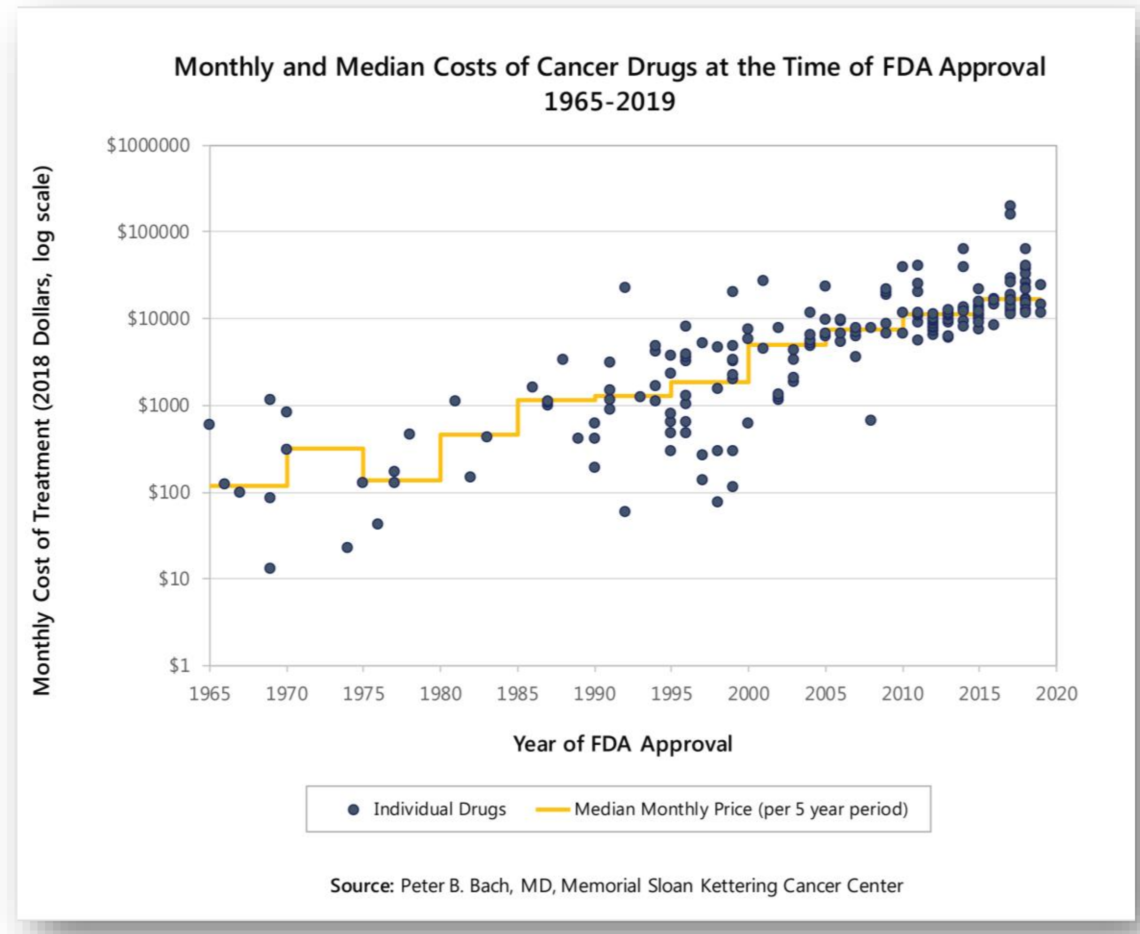
Policy: Orphan Drug Act



Policy: 21st Century Cures Act



But while monopoly duration addressed in policy, prices during monopoly are not



Prices rising more than 'value'

Figure 2: Price per life year gained versus approval date

Source of survival benefit:
- ● Trial, overall survival
- ▲ Trial, progression-free survival
- □ Modelling study

Price per life year gained ($1,000s of 2013 USD)

400, 350, 300, 250, 200, 150, 100, 50, 0

↑802

1996, 1998, 2000, 2002, 2004, 2006, 2008, 2010, 2012, 2014

Approval date

Cost (2018 Dollars)

The best fit line is: Price per life year gained = $54,100 + $8,500 x Approval year.
Approval Year = 0 for 1995, 1 for 1996, etc. For purposes of display, we re-coded one value from $802,000 to $400,000.
Source: Authors

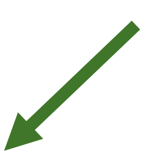
How does ‘value’ connect with drug prices?

- Basic principles, and a tough needle to thread
  - Drug innovation matters
    - So incentives for it are desirable
  - Access to innovative drugs matters
    - So a system in which restricting access or giving ‘skin in the game’ is the go-to check on prices undermines its own purpose
  - Money is not infinite – there are always productive alternative uses (like letting people keep it)
- Determining fair prices, or ‘value based prices’, is a means to balance these objectives

This thing about other uses of money

- Remember, we are trying to thread a tough needle
  - Allocate enough to encourage innovation
  - But not so much we cannot afford other priorities

$475,000



OR?

- One year of commercial insurance for 17 families of four
- One year of salary for 6 US nurses
- A dozen full treatment course for Hep C
- > 500,000 doses of pentavalent vaccine (DPT, HAV, Haemophilus)

How may ‘value’ affect drug prices?

- Tech assessment produces a threshold price –
  - The treatment at that price might deliver one quality adjusted life year per $100,000 (for instance)
  - Using $100,000 per QALY means a decision that health is worth that much for society
- These prices are not what is needed to incentivize innovation
  - That number is not known, but it is almost certainly higher for rare diseases than common ones
- When people say ‘fair’ prices, they mean (or should mean) fair to society, not to drug companies

The approach is called “Value-based pricing”

- Two prongs:
  1) Determines price based on treatment’s benefit (i.e. manage the height of the box along with standards for its commencement, termination and downward slope)
  2) With price managed, require payers (including Medicare and Medicaid) to cover with reduced copayments
     1) Those are there to manage price (which they do poorly)
- Value based pricing is not:
  - Perfect, but it is meaningfully better than current
  - Recognizes that ensuring access to new innovation is not something markets do well
  - Outcomes based contracting

Value-based pricing concepts and approaches

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Fair Price, Fair Access, Future Innovation

WATCH THIS SHORT VIDEO TO LEARN MORE ABOUT ICER'S WORK ASSESSING THE CLINICAL EFFECTIVENESS AND VALUE OF DRUGS.

What's New

08/09/2019 ICER to Assess Treatments for Sickle Cell Disease

08/07/2019 ICER Issues Statement Regarding Manufacturer's Manipulation of Data from Animal Testing of Zolgensma

These analyses reveal how misaligned prices can be

Bloomberg

OPINION | POLITICS & POLICY

Medicaid Is Right to Demand Lower Drug Prices

New York State can't afford $250,000 a year for one cystic fibrosis medicine.

By Peter B. Bach

Table ES5. Incremental Cost-Effectiveness Ratios Compared to Best Supportive Care (BSC) for the Base Case

Treatment vs. BSC	Cost Per LY Gained	Cost Per QALY Gained	Cost Per PEx Averted
CF Individuals with a Gating Mutation			
Kalydeco Plus BSC	$1,476,543	$956,762	$463,571
CF Individuals Homozygous for *F508del* Mutation			
Orkambi Plus BSC	$1,280,892	$890,739	$334,495
Symdeko Plus BSC	$1,367,400	$974,348	$424,212
CF Individuals Heterozygous for *F508del* Mutation and Residual Function Mutation			
Kalydeco Plus BSC	$1,340,171	$941,110	$373,541
Symdeko Plus BSC	$1,174,508	$840,568	$390,600

BSC: best supportive care; LY: life year; QALY: quality adjusted life years; PEx: pulmonary exacerbation

And sometimes show that prices are probably not far off

Table ES3. Estimated Event-Free Survival at Six Months in Therapies for Relapsed or Refractory Childhood B-ALL

Trial	Therapy	Event-free Survival at 6 Months*	Overall Survival at 12 Months
B2101J[18]	Tisagenlecleucel	58%	81%
B2205J[18]	Tisagenlecleucel	46%	62%
B2202 / ELIANA[19]	Tisagenlecleucel	60%	62%
Jeha 2006[20]	Clofarabine	11%	20%
Hijiya 2011[21]	Clofarabine/etoposide/ cyclophosphamide	35%	35%
Von Stackelberg 2016[22]	Blinatumomab	16%	38%
Locatelli 2017[23]	Blinatumomab	NR	NR

*Based on the number enrolled, not the number receiving the infusion with CAR-T cells or the number responding to treatment

Table ES8. Objective Response Rates Reported for Tisagenlecleucel for Relapsed or Refractory Adult B-Cell Lymphoma Compared with SCHOLAR-1

Trial	Therapy	ORR	CR
JULIET[29]	Tisagenlecleucel	53%	40%
NCT00924326[30]	Tisagenlecleucel	64%	57%
SCHOLAR-1[17]	Mix of salvage therapies	26%	7%

CR: complete remission, ORR: objective response rate

Table ES19. Value-Based Price Benchmarks for Tisagenlecleucel and Axicabtagene Ciloleucel

	WAC	Net Price (with Mark-Up)	Price* to Achieve $100,000 per QALY	Price* to Achieve $150,000 per QALY	Discount from WAC with Mark-Up to Reach Threshold Prices
Tisagenlecleucel (B-ALL)	$475,000	$575,000	$1,162,563	$1,688,232	+102% to +194%
Axicabtagene Ciloleucel (B-cell Lymphoma)	$373,000	$473,000	$340,797	$524,015	28% to +11%

Payment assumed for tisagenlecleucel was payment for responders at one month. Payment assumed for axicabtagene ciloleucel was payment at infusion.
*Price needed to achieve the thresholds includes both the acquisition cost and associated mark-up.
B-ALL: B-cell acute lymphoblastic leukemia, QALY: quality-adjusted life year
+Indicates premium

That word ‘value’, it’s getting around

That word ‘value’, it’s getting around

- Once analysts started talking about value based pricing, everyone started calling every pricing agreement value based
  - Mortgages, outcomes arrangements, the Netflix model, out of pocket caps
  - Nope – value pricing is when the benefits of a treatment are mathematically aligned with its price

Pricing is not the only needed fix – prescriber incentives

Relation between Medicare Part B mark-ups and prescribing for oncology drugs

Article (Year)	Population studied	Comparison	Findings
Elliott et al. (2009)[1]	Medicare beneficiaries with low risk and metastatic prostate cancer	Use of 'androgen suppression therapy' before and after a reimbursement change due to a law change that decreased the margin, compared between low risk and metastatic patients	Reduction in reimbursement of 64% associated with an OR of 0.61-0.70 reduction of use in low risk with no change in metastatic patients.
Jacobson et al. (2010)[2]	Medicare beneficiaries with lung cancer	Use of five different drugs for lung cancer that all experienced shifts in margin due to a law change in 2005	Use of drugs with the largest decline in margin fell the most after the rule change. Use of drugs with unchanged margins increased.
Colla et al. (2012)[3]	Medicare decedents who had any cancer, treated in physician offices or hospital outpatient department	Utilization of chemotherapy in the months preceding death before and after a law change that decreased margins and comparing impact on two settings, where physician offices presumed to be more affected by incentives	Use of chemotherapy prior to death declined in physician offices following a reduction in margins, but did not decline in the hospital outpatient departments.
Epstein et al. (2012)[4]	Medicare beneficiaries with breast cancer (1992-2002)	Within treated population evaluation of prescribing frequency in relation to 'margin' (reimbursement – acquisition cost)	Increase margin of +10% led to an increase in prescribing likelihood of +10% - +177%.
Conti et al. (2012)[5]	Medicare beneficiaries with metastatic colorectal cancer	Use of two alternative drugs for colorectal cancer, one which went generic and as a result had a decline in margin compared to the other that did not	Use of the drug that went generic declined once the margin on the drug was reduced. Use of the alternative drug was maintained.

[1] Elliott et al. "Reduction in Physician Reimbursement and Use of Hormone Therapy in Prostate Cancer" J Natl Cancer Inst. 2010; 102(24):1826-1834.
[2] Jacobson et al. "How Medicare's Payment Cuts for Cancer Chemotherapy Drugs Changed Patterns of Treatment". Health Affairs. 2010; 1391-1399.
[3] Colla et al. "Impact of Payment Reform on Chemotherapy at the End of Life. Journal of Oncology Practice. 2012; e6s-e13s
[4] Epstein and Johnson. "Physician response to financial incentives when choosing drugs to treat breast cancer". Int J Health Care Finance Econ. 2012; 285-302.
[5] Conti et al. Journal of Oncology Practice. 2012 8:3S, e18s-e23s

Pricing is not the only needed fix – supply chain mark-ups

- Manufacturers – $323b
- Wholesalers – $18b
- Pharmacies – $73b
- PBMs – $23b
- Providers – $35b
- Insurers – $9b

HealthAffairs DrugPricing Lab Memorial Sloan Kettering

Pricing is not the only needed fix – monopoly period has to end and doesn't for biologics

HEALTH AFFAIRS BLOG

Biologics Are Natural Monopolies (Part 1): Why Biosimilars Do Not Create Effective Competition

Preston Atteberry, Peter B. Bach, Jennifer A. Ohn, Mark Trusheim

Biologics Are Natural Monopolies (Part 2): A Proposal For Post- Exclusivity Price Regulation Of Biologics

Mark Trusheim, Preston Atteberry, Jennifer A. Ohn, Peter B. Bach

OPINION | COMMENTARY

Time to Throw In the Towel on Biosimilars

Biologic drugs don't face strong competition, and Washington's preferred solution slows innovation.

By Peter B. Bach and Mark Trusheim
Aug. 21, 2019 6:58 pm ET

BUSINESS

STAT+

Peter Bach's latest crazy idea: Give up on biosimilars. Regulate drug prices instead

By MATTHEW HERPER @matthewherper *and* ED SILVERMAN @Pharmalot / APRIL 15, 2019

Dr. Peter Bach
FORTUNE BRAINSTORM HEALTH 2016

Significant savings through regulated pricing

Proposal for post-exclusivity price regulations estimated to generate savings exceeding $200 billion.

EXHIBIT 1: Five-Year Savings (2018-22) Based On Various Estimates Of Post-Exclusivity Prices, Calculated From Projected US Revenue

SAVINGS FROM 2018-2022 (BILLIONS OF US$)						
	Assuming current 12-year exclusivity period is maintained			*Assuming exclusivity period is extended to 15 years*		
Percent of current price	Total savings	Savings to Medicare	Savings to Medicaid	Total savings	Savings to Medicare	Savings to Medicaid
30%	258.1	63.7	23.7	213.5	52.7	19.6
20%	295.0	72.9	27.1	244.0	60.3	22.4
10%	331.8	82.0	30.5	274.5	67.8	25.3

Source: Authors' analysis.

THANK YOU