



Memorial Sloan Kettering
Cancer Center™

New Cancer Drugs: Rising Prices & Diminishing Yield

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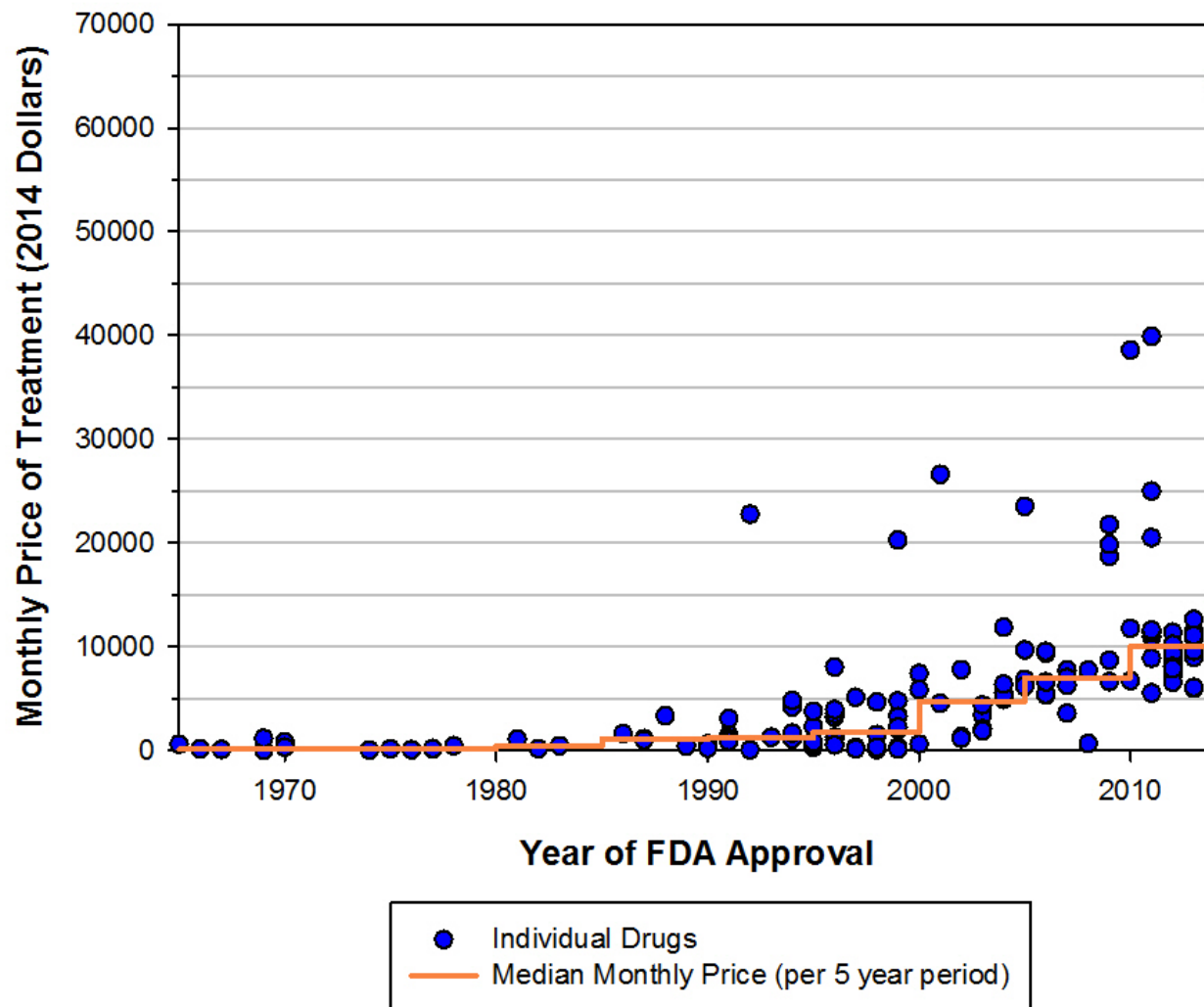
April 9, 2015



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Rising prices of cancer drugs

Monthly and Median Costs of Cancer Drugs at the Time of FDA Approval
1965 - 2014

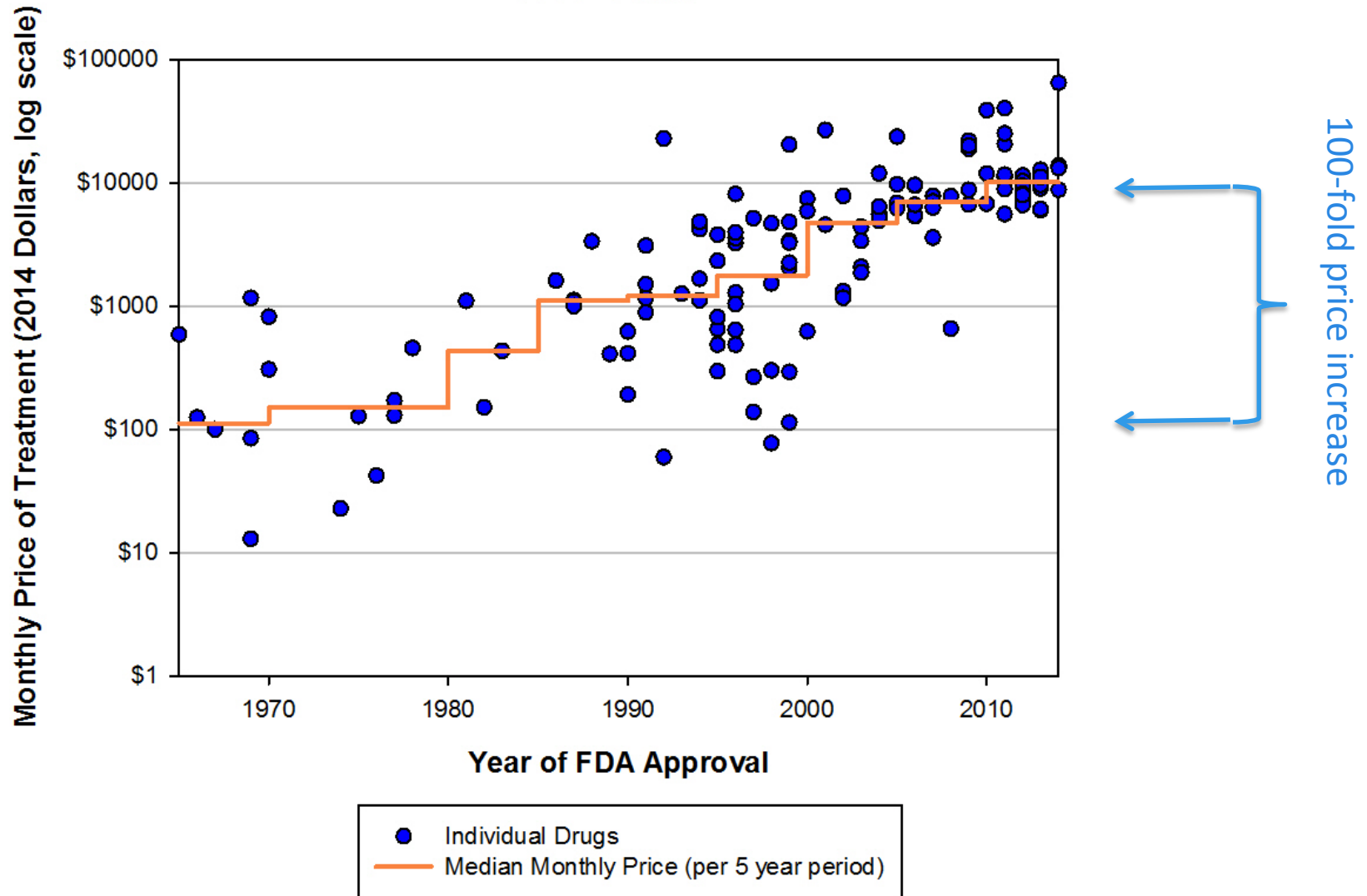


Source: Peter B. Bach, MD, Memorial Sloan-Kettering Cancer Center

Are rising prices logical?

- Maybe:
 - We're willing to pay more to get more
- But maybe not
 - We're probably not willing to pay more each time for benefits that are smaller each time
 - When prices rise faster than gains:
 - “Diminishing Returns”
 - Each additional \$ from patient/insurer buys less health than the one before it.

Monthly and Median Costs of Cancer Drugs at the Time of FDA Approval 1965 - 2014



Source: Peter B. Bach, MD, Memorial Sloan-Kettering Cancer Center

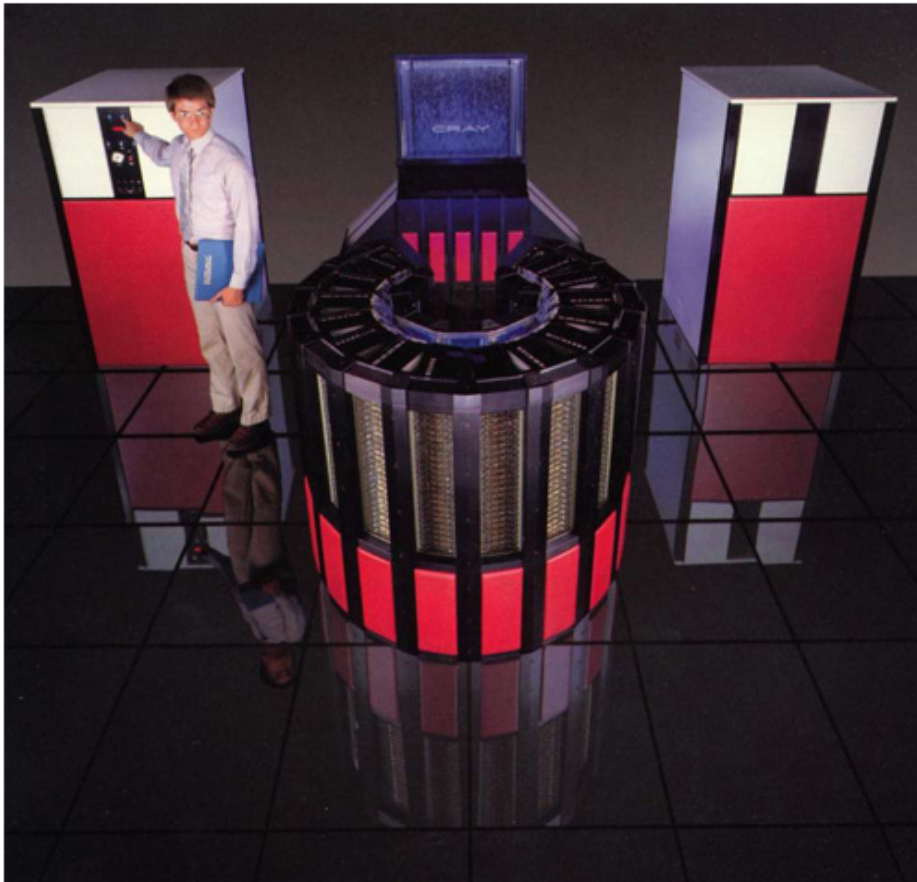


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What diminishing returns DON'T look like:

By Kirstin B.
SMITHSONIAN

iPad 2 as fast as Cray 2 supercomputer, fraction of the size



for Motorola, had an audacious idea: He wanted
m anywhere. Sure enough, in April 1973, Cooper



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The Price Tag on Progress — Chemotherapy for Colorectal Cancer

Deborah Schrag, M.D., M.P.H.

Table. Estimated Drug Costs for Eight Weeks of Treatment for Metastatic Colorectal Cancer.			Gain
Regimen	Drugs and Schedule of Administration	Drug Costs*	
		\$	
Regimens containing fluorouracil (1960s)			
Mayo Clinic	Monthly bolus of fluorouracil plus leucovorin	63	4 months
Roswell Park	Weekly bolus of fluorouracil plus leucovorin	304	
LV5FU2	Biweekly fluorouracil plus leucovorin in a 48-hr infusion	263	
Regimens containing irinotecan or oxaliplatin (2002)			
Irinotecan alone	Weekly bolus	9,497	9 months
IFL	Weekly bolus of fluorouracil plus irinotecan	9,539	
FOLFIRI	LV5FU2 with biweekly irinotecan	9,381	
FOLFOX	LV5FU2 with biweekly oxaliplatin	11,889	
Regimens containing bevacizumab or cetuximab (2004)			
FOLFIRI with bevacizumab	FOLFIRI with fortnightly bevacizumab	21,399	2 months
FOLFOX with bevacizumab	FOLFOX with biweekly bevacizumab	21,033	
Irinotecan with cetuximab	Weekly irinotecan plus cetuximab	30,790	
FOLFIRI with cetuximab	FOLFIRI and weekly cetuximab	30,675	

* Costs represent 95 percent of the average wholesale price in May 2004.



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Progress in Hepatitis C?

It costs more to get less

Table 3. Cost-Effectiveness of Treatment of Patients With HCV Infection: Genotype 2*

Treatment Strategy	SVR, %	Cost, \$	Incremental Cost, \$	QALYs	Incremental QALYs	ICER, \$/QALY
No cirrhosis						
Naive						
No treatment	-	169 000	-	13.9	-	-
24 wk of PEG-RBV	82	173 000	4300	15.5	1.5	3000
12 wk of SOF-RBV	98	261 000	87 900	15.8	0.4	238 000
Cirrhosis						
Naive						
No treatment	-	94 000	-	5.1	-	-
24 wk of PEG-RBV	62	150 000	54 000	11.3	6.2	8700
12 wk of SOF-RBV	90	253 000	103 000	14.2	2.9	35 500

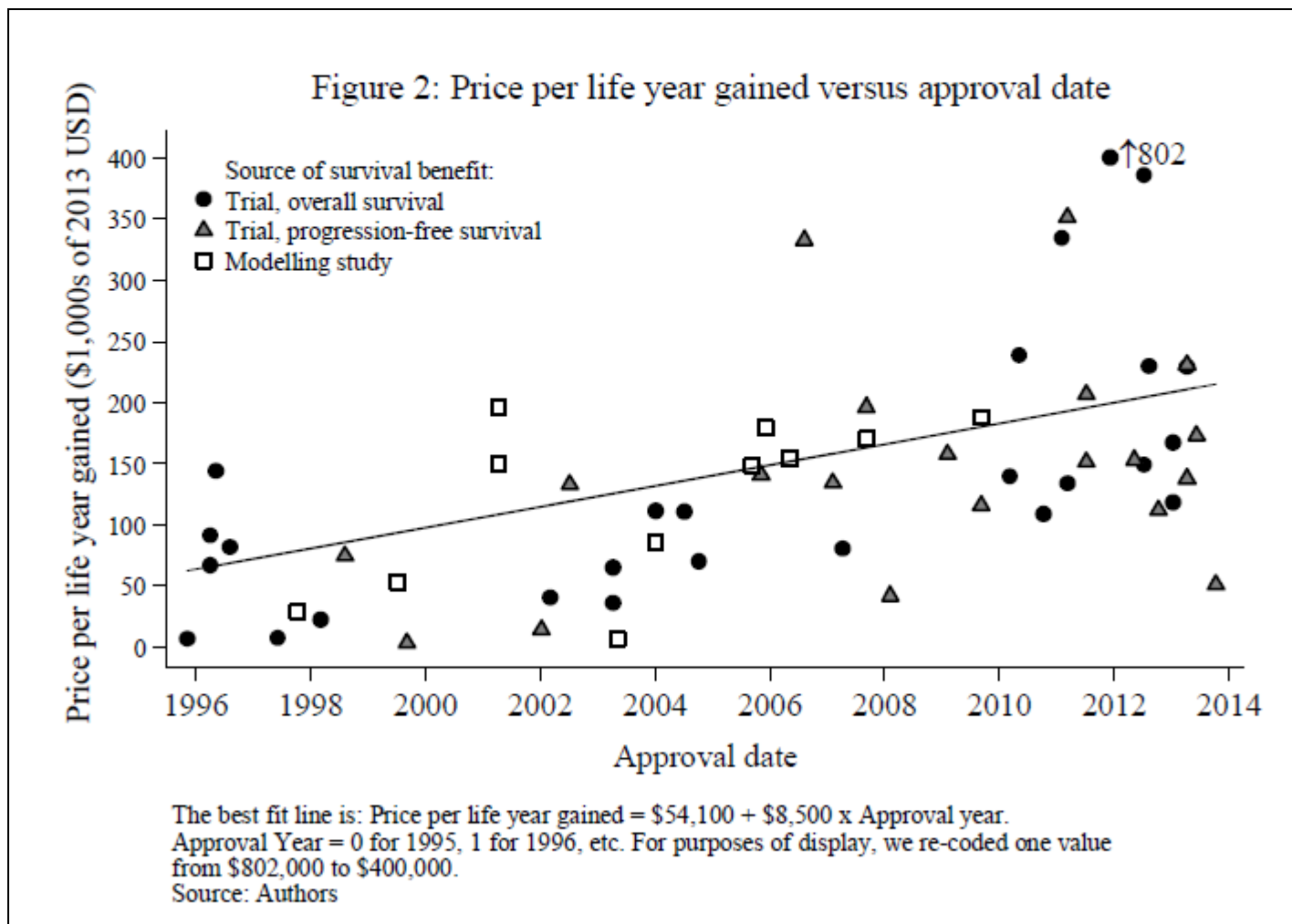
HCV = hepatitis C virus; ICER = incremental cost-effectiveness ratio; PEG = pegylated interferon; QALY = quality-adjusted life-year; RBV = ribavirin; SOF = sofosbuvir; SVR = sustained virologic response.

* All costs are in 2013 U.S. dollars.

† More costly and less effective than a competing strategy or had an ICER greater than that of a more effective strategy.



Cost for an additional year of life goes up each year in cancer





**Explanations:
It's just getting harder to get
through the FDA!**

But FDA making it faster and easier

Recently Approved Cancer Drugs: costs for a month of treatment at initial FDA approval

Brand name	Year of FDA approval	FDA Approval Pathway	Approval Trial Size	Monthly cost (2014 \$'s)
Kadcyla	2013	Priority Review	495	\$10,791
Pomalyst	2013	Accelerated Approval	108	\$11,502
Mekinist	2013	Accelerated Approval	214	\$8,942
Tafinlar	2013	Accelerated Approval	187	\$9,549
Xofigo	2013	Priority Review	541	\$12,638
Gilotrif	2013	Priority Review	230	\$11,060
Imbruvica	2013	Accelerated Approval	111	\$5,964
Gazyva	2013	Breakthrough Therapy	356*	\$6,071
Zykadia	2014	Accelerated Approval	163	\$13,672
Cyramza	2014	Priority Review	355	\$13,256
Keytruda	2014	Breakthrough Therapy	173	\$8,725
Blinicyto	2014	Breakthrough Therapy	185	\$64,260
Opdivo	2014	Breakthrough Therapy	120*	\$12,500

Sources: <http://www.mskcc.org/research/health-policy-outcomes/cost-drugs> & drugs@FDA database

* = subset of trial on which FDA approval was based, full trial size is larger



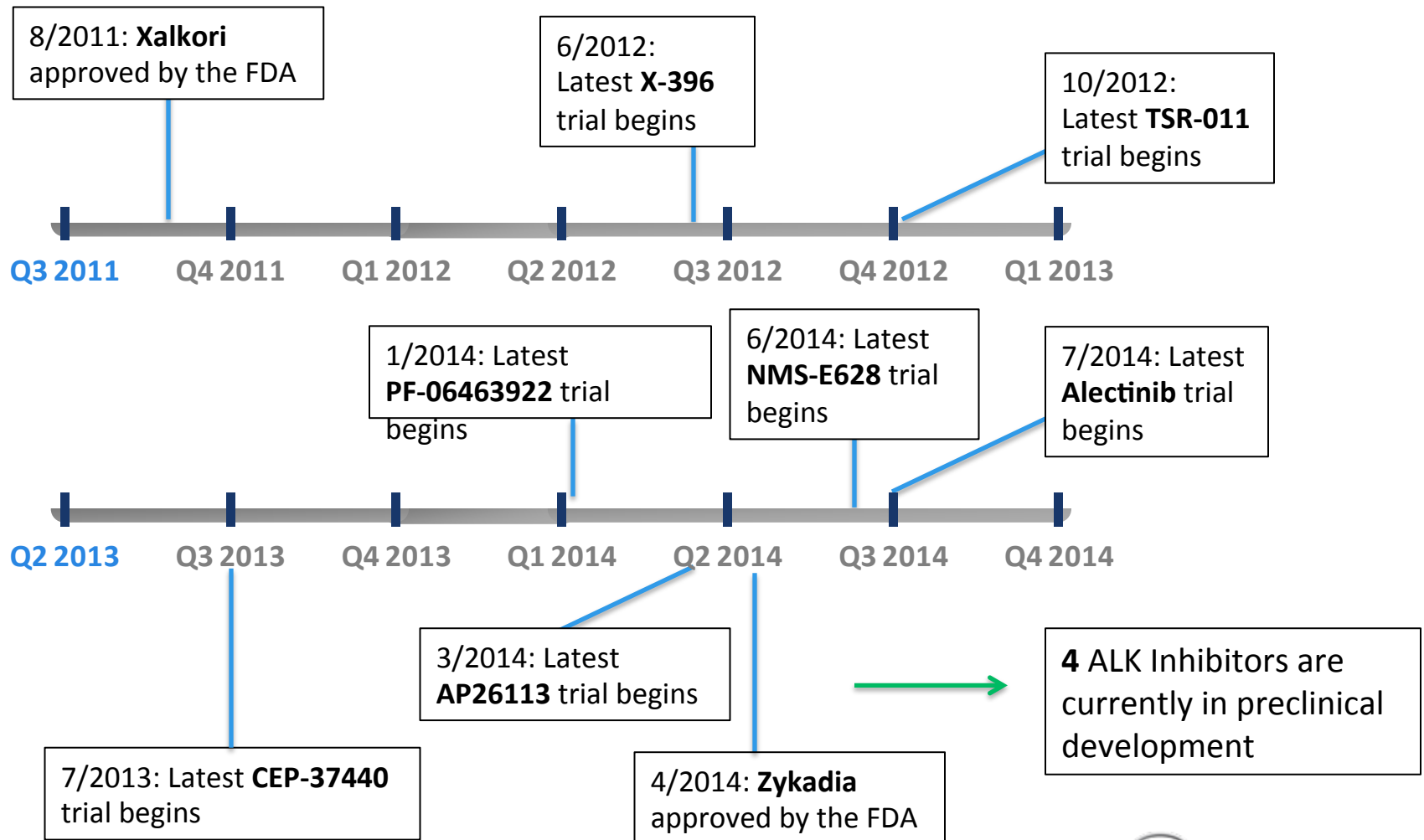
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**Prices are at the level
needed to drive any
innovation!**



The Market for ALK Inhibitors: Appropriately Priced? Or frothy?





**Okay, prices are high. But at
least they make sense!**

Two similar drugs? By their prices “yes”

Farydak (Feb 2015 approval)

Price: \$10,035 per month

- FDA path: Squeaked through (voted down by ODAC advisors 5 to 2).
- Use: 3rd line multiple myeloma
- Benefit: Increased PFS by 5 months, but not overall survival
- Tolerability: Severe side effects with a “Black Box”

Ibrance (Feb 2015 approval)

Price: \$9,978 per month

- FDA path: Accelerated approval from impressive Phase 2 data
- Use: 1st line metastatic breast cancer
- Benefit: Increased PFS by 10 months, survival data pending
- Tolerability: Moderate side effects





**Companies can't make
money unless they sell at
these high prices!**



International pricing of drugs for Chronic Myeloid Leukemia

blood

Table 1. Annual price estimates, by region, of drugs approved for the treatment of CML

Country	Price in thousands of US dollars (rounded to nearest \$0.5 thousand)		
	Imatinib	Nilotinib	Dasatinib
United States	92	115.5	123.5
Germany*	54	60	90
United Kingdom	33.5	33.5	48.5
Canada	46.5	48	62.5
Norway	50.5	61	82.5
France	40	51.5	71
Italy	31	43	54
South Korea	28.5	26	22
Mexico	29	39	49.5
Argentina	52	73.5	80
Australia	46.5	53.5	60
Japan	43	55	72
China	46.5	75	61.5
Russia	24	48.5	56.5
South Africa	43	28	54.5



Gilead (Sovaldi maker) survives near 50% discount

- Launched Sovaldi at \$1,000/pill or \$84,000 per treatment
- Competition led to about 40% price reduction in Feb 2014

GILEAD SCIENCES INC

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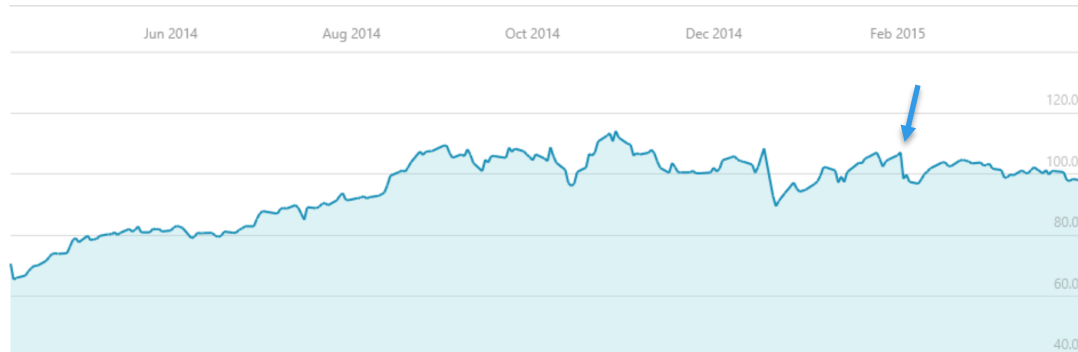
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**Or is it just that the pricing
environment places no
barriers on high prices?**

Limits on Medicare's Ability to Control Rising Spending on Cancer Drugs

Peter B. Bach, M.D., M.A.P.P.

Table 2. Laws, Regulations, and Court Rulings That Prevent Medicare from Using Strategies to Control the Prices or Utilization of Cancer

Least-costly-alternative reimbursement	"[T]he Secretary [of Health and Human Services] lacks authority under §1862(a)(1)(A) to apply the least costly alternative to DuoNeb." ¹⁴	Suggests that Medicare may not have the legal authority to implement least-costly-alternative reimbursement or reference pricing at the national level
Competitive bidding	"[T]he Secretary shall conduct such competition among entities for the acquisition of at least one competitively biddable drug and biological within each billing and payment code within each category." [§1847B(b)(1)]	Requires that competitive bidding for Part B drugs include effectively all new physician-administered drugs and biologics, thus limiting the negotiating leverage the bidders could hold over the drug manufacturers
Formulary flexibility	<p>Pertaining to Part D plans at inception (2006), CMS guidance reads: "CMS will check to see that beneficiaries who are being treated with these classes of medications have uninterrupted access to all drugs in that class." [(Listed classes include "antineoplastic" drugs and five other drug classes.)]</p> <p>Pertaining to Part D plans as of 2010: "PDP [prescription-drug plan] sponsors offering prescription drugs shall be required [by 2010] to include all covered Part D drugs . . . where restricted access would have major or life threatening clinical consequences . . . such as drugs used in the treatment of cancer." [§1860D-4(b)(3)(G)(ii)]</p>	Requires Part D plans to include essentially all cancer drugs on their formularies, which limits their negotiating leverage. Formulary managers can obtain lower prices only when they have the ability to forgo some drugs and include or preferentially treat others in the same clinically equivalent category.

* The listed quotations are from Title 18 of the Social Security Act, unless otherwise indicated.



Limits on Medicare's Ability to Control Rising Spending on Cancer Drugs

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Table 3. State Legislation Affecting the Coverage of Off-Label Uses of Cancer Drugs by Private Payers.*

Requirement	States Affected	Total Population of States Affected	Percentage of the U.S. Population Affected
Mandated coverage if use is listed in either recognized compendia or peer-reviewed medical literature	AL, AZ, AK, CA, FL, GA, IL, IN, KS, LA, ME, MD, MA, MN, MS, NE, NV, NJ, NY, OH, OR, RI, SC, SD, TN, VT	174,621,577	62
Mandated coverage if use is listed in recognized compendia only	CT, NC, OK, VA	21,984,047	8
Mandated coverage if use is supported in medical literature only	MI	9,938,444	4
Mandated coverage if use is "medically necessary" (but no other requirements) [†]	NH	1,235,786	<1
Total mandated coverage		207,779,854	74

* Data are from the National Cancer Institute's State Cancer Legislative Database Program. Population estimates are from the 2000 U.S. Census. The total U.S. population was 281,421,906 in 2000.

[†] A number of states include "medical necessity" as an additional standard for coverage beyond the compendia or medical-literature standards, including AL, AZ, AR, CA, FL, IL, LA, ME, MD, MA, MN, NE, NV, NJ, OH, OK, OR, RI, SD, TN, VT, and VA.



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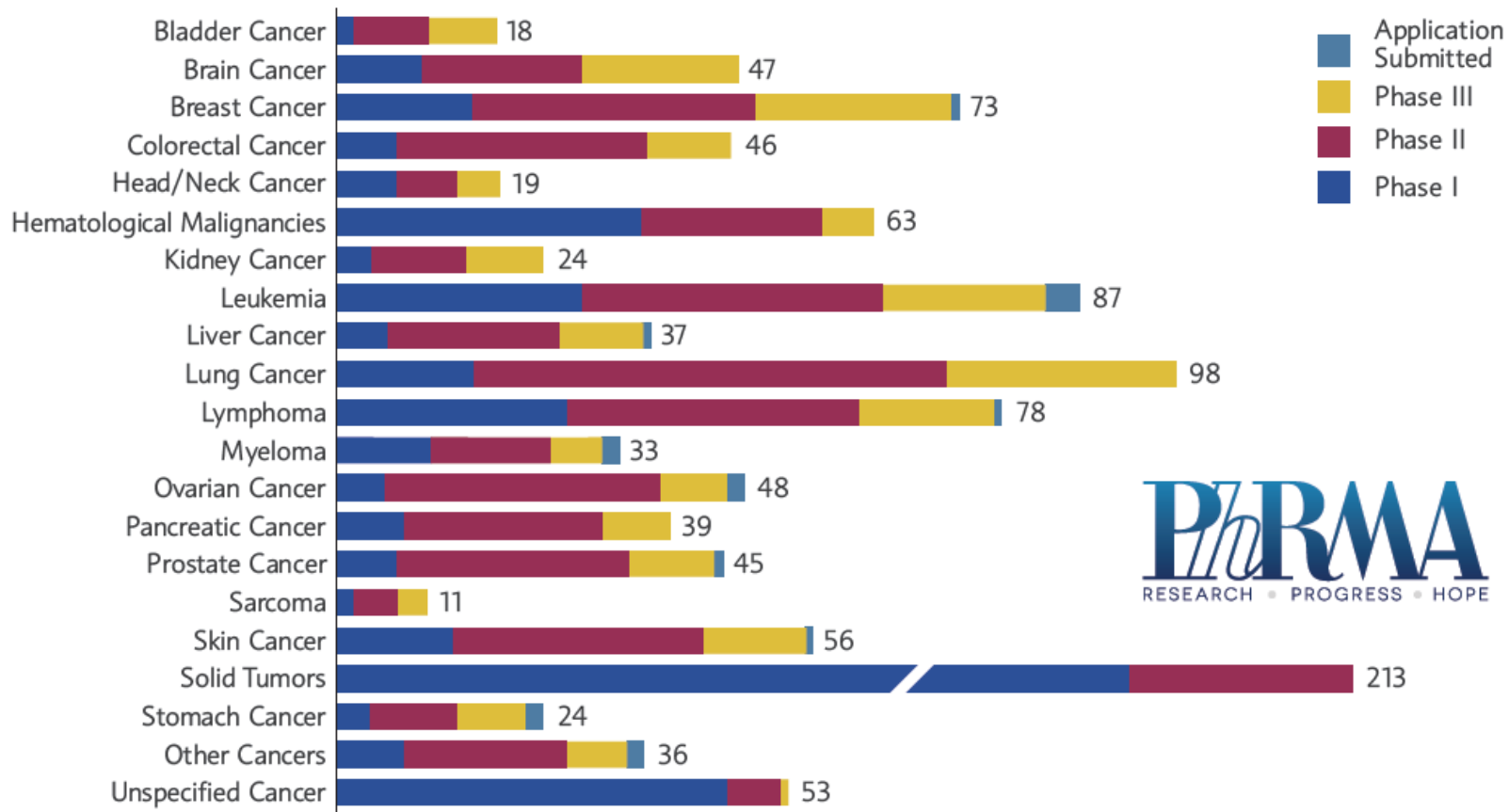


**Are we almost through this
problem?**

Not so much

Medicines in Development By Disease and Phase

Some medicines are listed in more than one category.



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Thank you



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