High Cancer Drug Prices in the US- Causes, Consequences and Solutions

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High Cancer Drug Prices. The Trigger

- 3 CML drugs (ponatinib, bosutinib, omacetaxine) FDA approved in 2012--all priced > $100,000/year
- Price of Gleevec increased from $28,000 in 2001 to $92,000 in 2012, $132,000 in 2014, and $144,000 in 2016
- 12/13 drugs approved by FDA in 2012 for cancer indications priced at $100,000 +/yr
- All drugs approved in 2014 are priced at $120,000+/yr; 2015--$140,000

REDBOOK Online-updated periodically. Vasella. Magic Cancer Bullet, 2003
Light, Kantarjian. Cancer 119: 3902; 2013. Fojo. JNCI 101: 1044; 2009

High Cancer Drug Prices. Perspective

- Average cancer drug prices $5-10,000/yr before 2000; ↑ to > $140,000+/yr by 2015
- Older cancer drugs prices ↑ by 10-20% annually--Explanation: “charge what the market bears”
- Cancer drug prices ↑ about 10-fold over a decade; average household income ↓ by 8%

High Cancer Drug Prices. Recent Trends

- 58 cancer drugs approved from 1995-2013 reviewed
- Since 1995, cancer drug prices increased by 10% annually, an average of $8,900/year
- No correlation between price and survival benefit
- Price per life-year gained increased from $54,000 in 1995 to $207,000 in 2013 (adjusted for inflation, in 2013 dollars value)

Howard. Journal of Economic Perspectives 29: 139-162; 2015

High Drug Prices. Relevant Questions

- Are Cancer Drug Prices too high? -- yes
- Are these prices harming our patients?--yes
- Can we do something about it?--we must

Hippocratic Oath emphasis on 2 tenets: protection of patients from harm and injustice

High Cancer Drug Prices. The Harm

- 20-30% out-of-pocket expenses ≈ $20-30,000/year or about 1/2 of average annual household income ($52,000)
- High rate of personal bankruptcies
- Emotional and socio-economic adverse effects on patient and families
- 10% of patients do not take the treatment; 20% poorly compliant
- In CML, adverse effect of survival
  - —Sweden: 8-10 yr relative survival 80%
  - —US SEER: 5-yr survival 60%

Bjorkholm. JCO 29: 2514; 2011. Chen. Leukemia Lymphoma 54: 1411; 2013. Zafar. Oncologist 18:381;2013
Dusetzina. JCO Dec 23: (epub ahead of print); 2013

Cancer Drug Prices and Having "Skin in the Game"

- Out-of-pocket expenses (skin in the game) can help reduce cost (e.g. choice between a $10 generic vs $1,000 patented drug)
- In oncology, key question is "life in the game"– For insurers it is " Deterrence-in-the-game"
- With cancer drugs: out-of-pocket costs not affordable--$20-30,000 for each

Kantarjian. JAMA Oncol, July 2 (epub ahead of print) 2015.

What Justifies High Cancer Drug Prices?

- High cost of research
- Cost-benefit of new drugs
- Market forces will settle prices at reasonable levels
- Controlling drug prices will inhibit innovation

➢ None of the 4 arguments are convincing

$1 billion to Develop a Cancer Drug to Market—a Myth

- 50% is estimate of profit if money invested in pharma stocks at annual 11% profit compounded over 15 years
- 50% tax subsidies through credits deductions
- Estimate made of most costly fifth of new drugs
- Mean rather than median cost
- Revised estimates 5-20% of original estimate = $60-170 million
- Andrew Witty (GSK CEO): $1 billion cost is “one of the great myths of the industry”

DiMasi. Journal of Health Economics 22: 151; 2003. http://csdd.tufts.edu. Light. BMJ 331: 958;2005. Light. Cancer 119: 3900; 2013. Harper. Forbes-Pharma and Health 8.11.2013. Silverman. Pharmalot-posted 3.18.2013. Light, Kantarjian. AARP Your Health: 22; 05.2014.

Do High Cancer Drug Prices Reflect Cost Benefit? - No

- Little correlation between actual efficacy/benefit of a new drug and its price as measured by
  - Cost-efficacy (CE) ratios
  - Prolongation of patient life in years
  - Quality-adjusted life-years (QALY)
- Drug A may prolong life by days and Drug B by years; yet both are priced at > $100,000/year

Kantarjian. JCO 31: 3487; 2013. Hillner. JCO 27: 2111; 2009

The Market Forces Do Not work

- No market forces; only monopolies/oligopolies
- Companies compete on everything except drug prices
- No differential price sensitivities that produce competitive marketing
  - —6 drugs for CML; all priced at $132-170,000
  - —8 drugs for renal cancer; all priced at $80-120,000
- High prices over extended periods, despite competitive market = "collective monopoly". Appearance of tacit collusive behavior or oligopolies
- Recent suit against generic companies for alleged collusion on prices

Stiglitz. The Price of Inequality; 2012; pp45.
Scherer. Oligopoly and Shared Monopoly; 2013: https://research.hks.harvard.edu/publications/getFile.aspx?Id=978

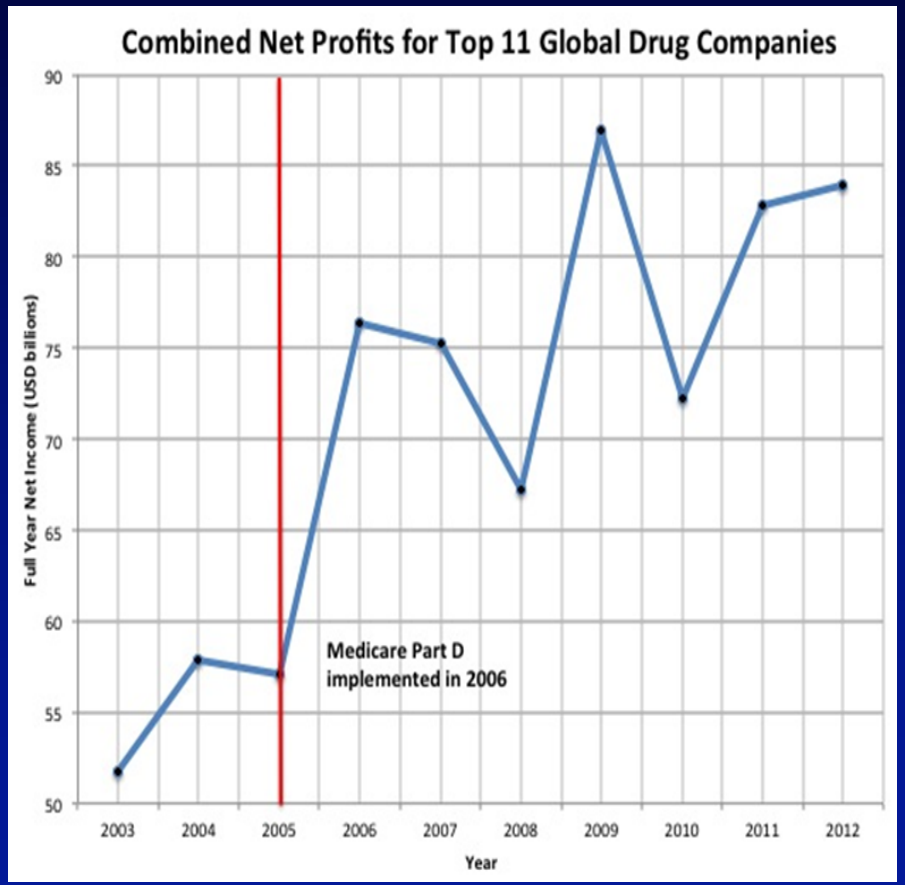
Why The Failure of Free Market Forces?

- Medicare Reform Act 2003-legislation forbids Medicare to negotiate drug prices
- Oligopolies—only drug companies and distributors decide prices
- "Pay-for-delay" and "approved generics"
- Patient-Centered Outcomes Research Institute (PCORI) not allowed to consider cost in its recommendations
- Importation of drugs from abroad illegal
- For profit = no real patient advocates (pharma, insurance, hospitals, pharmacy outlets, elected officials)

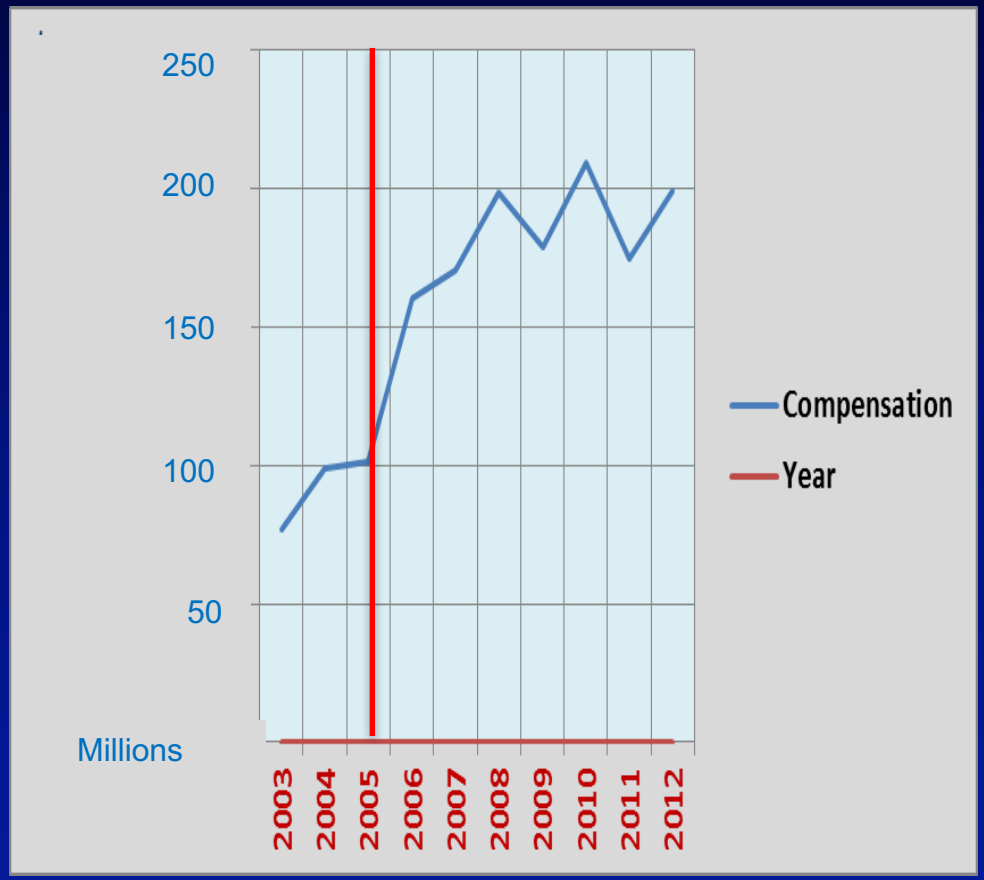
Rosenthal E. NYT-Sunday October 13, 2013;pp 1,18-19. Jones. Blood 127: 1398; 2016

An Interesting Observation

- Medicare Reform Act 2003 prohibits negotiation of drug prices + inclusion of drug coverage under Medicare Part D (2006) = skyrocketing profits to Pharma



Revenues



CEO Salaries

Rome E. Huffington Post Politics;4/2013.

Controlling Drug Prices Stifles Innovation

- Innovation continues regardless of profit
- 50% of discoveries from academic institutions
- 85% of basic research funded by taxpayers' money (NCI, NIH, philanthropy)
- Drug companies invest 20% of revenues in advertisement; only 1.3% invested in basic research– recent trend to forgo in-house R&D and buy in 3/4 of pipeline
- Most profits benefit CEOs, bonuses, salaries, investors--little returns to discoverers or to basic research reinvestment
- High drug prices bad for innovation

Bach, P. Forbes 10-23-2014
http://ww.forbes.com/sites/matthewherper/2014/10/23/could-high-drug-prices-be-bad-f

High Cancer Drug Prices Stifle Innovation

- Gilead paid 89% premium for Pharmasset ($11 billion) because they knew they could charge an astronomic price for new hepatitis C drug—recouped in Yr1(10.3 billion)
- Pharmasset forecasted price $36,000—what was needed to drive innovation
- Gilead price $80-160,000
- Same recent scenario with CART– Gilead bought Kite for $12 billion= money diverted from R&D

Bach, P. Forbes 10-23-2014
http://ww.forbes.com/sites/matthewherper/2014/10/23/could-high-drug-prices-be-bad-f

Drug Prices in US vs the World

- US taxpayers subsidize most of the research and discoveries in cancer
- Ironically, when drugs approved, US patients and healthcare system pay 50-500% more on comparable drugs
- Regulated profit margins outside US remain highly profitable
- Why does the US pay more?
  - Medicare prohibition from negotiating drug prices
  - Pharma lobbies: 2500 lobbyists, $310 million spent in 2012
  - Free-market policies

Kantarjian. JAMA Oncology 1: 729; 2015

How Do We Justify Not Allowing Medicare Not to Negotiate Drug Prices?

- Pharma and PhRMA driven messages—Allowing Medicare to negotiate will increase costs
- Grassley—"Government does not negotiate well"
- But :
  1) Veterans Administration (VA) and Medicaid obtain drugs at 50-70% of Medicare prices
  2) Other governments obtain cancer drugs at 20-50% of US prices
- Dean Baker--Allowing Medicare to negotiate would save $600 billion between 2006 and 2013

Baker Dean. Center for Economic and Policy Research, *The Savings from an Efficient Medicare Prescription Drug Plan* Washington, D.C.: January 2006.

Cancer Drug Prices in US vs Canada/England

Drug	% Price Abroad vs US
Bevacizumab	50
Brentuximab	60
Cetuximab	47
Ipilimumab	67
Obinutuzumab	79
Trastuzumab	45
Afatinib	34
Bosutinib	40
Imatinib	26
Nilotinib	31
Erlotinib	30
Erlotinib	29
Ibrutinib	63
Sorafenib	33
Pazopanib	37
Sunitinib	37
Vemurafenib	40

Kantarjian. JAMA Oncology 1: 729; 2015

Imatinib Prices - 2016

Imatinib Source	Price ($ US /year)
• Patented imatinib -- US 2016	146,000
• Generic imatinib -- US 2016	140,000
• Patented imatinib -- Canada 2016	38,000
• Generic imatinib -- Canada 2016	5,000-8,000
• Generic imatinib -- India	400
• Imatinib -- cost of production	< 150

Debunking the 10% Myth

- "Drug costs are only 10% of health care costs"
- Drugs used in hospitals (inpatient chemoRx) or given in doctors' offices not counted
- IMS estimates drugs account for 22% of healthcare spending; most recent estimate 2017—34%!!
- MEDPAC reports drug costs are 19% of Medicare spending

Peter Bach. Morning Consult. "Debunking the 10% Myth". 11.20.2015 (http://morningconsult.com/author/peter-bach/). Kaiser Health News September 2017

How Are Cancer Drug Prices Decided?

- **Official answer:** based on 1) cost benefit, 2) competition, 3) population at risk, and 4) company profits projections

- **Reality:** look at the price of similar drugs, and price new one about 20% higher (considering older drugs are increasing in prices by 10-20% annually)—**launch price (paid by Medicare) determines all downstream negotiations and future cancer drug launch prices**

High Cancer Drug Prices--What Happened 4 Years Later?

- Essentially nothing
- Current drug prices continue to increase at a rate of 10-15% annually
- Example: Pfizer increased prices on 131 of its prescription drugs in 2015; median increase 10%
- Drug companies did 2 additional things: 1) kick the "public relations" machine into high gear; 2) prepare new "talking points"

FDA News. Drug Daily Bulletin

High Cancer Drug Prices 3 years later—What Did Pharma Do? "Playbook Fundamentals" or "Spin Business"

- Hire large and well-connected PR firms
- Set up and operate coalition and front groups (e.g. PhRMA) with titles that include "American", "freedom", "choice", "honesty", "public", "concerned", etc…
- Write letters to the editor and op-eds in local and national publications; develop newsletter (e.g. "Morning Consult")
- Influence the tone and content of articles
- Conduct bogus surveys or "slice-and-dice" data
- Feed "talking points" to contributors to op-ed pages
- Develop and carry out a duplicitous communications campaign ("part of the solution")

Wendell Potter. Deadly Spin.pp222-224

New Pharma "Talking Points" in 2016--The "Spin Business"

- High cancer drug prices needed to support "future" (not past) R&D costs
- "Do a better job of defining and dimensionalizing value"
- Our message must be rooted in the old saying that "value is in the eye of the beholder"
- "Need new intensely human ways to show who we are"
- "Companies must gently remind---race for cures for cancer, Alzheimer and Parkinson's"
- "Any marketer who continues to use cost of innovation to defend price must be ready to disclose the dollars invested—or the argument is empty. The days of unchallenged pricing are clearly drawing to a close"

Meg Alexander. Navigating post-Turing: Defining Value in Today's Landscape. PharmExec.com 11.20.2015

Progress in Lowering Drug Prices in 2017? None

- Very aggressive lobby to thwart any such efforts
- President Trump: drug companies are "getting away with murder"; but executive orders on drug costs focused on things the drug industry wants
- Pharma spent $145 million in lobbying in the first half of 2017— 2017 estimate $300 million
- PhARMA "Go Boldly" campaign--$28 million so far in 2017 on 6 ads shown in 4,600 national TV channels (quotes poet Dylan Thomas)
- Top 10 publicly traded US drug companies profit after taxes in 2016=$68 billion. 83.6 billion on revenues of $306 billion= 27% pretax profit margin ; even after spending billions on TV ads

Hancock. Kaiser Health News. September. 2017

High Cancer Drug Prices-Solutions

- Allow Medicare to negotiate drug prices
- Mechanisms to propose "just price" based on cost-benefit and Rx value--- role of PCORI and ASCO guidelines in including "value"
- Develop cancer drug Rx pathways that incorporate "value" (ASCO, ASH, NCCN, PCROI)—Patient advocacy groups remain silent (e.g. Leukemia-Lymphoma Society)
- Allow importation of drugs from abroad
- Eliminate "pay-for-delay" and strategies that delay generics
- Hold oncologists/societies to higher standards in publicizing benefits of new drugs
- Simplify and shorten FDA process to approve multiple generics; reduce cost of filing (past $1million;now $5 million/drug– timeline 4 yrs down to 18 mos) – need 4-5 generics in market to have "generic prices"—Also pursue the new real issue of possible collusion of generic companies (geographic agreements to keep generics prices high)
- Patient-based grass-root movements

Gottlieb. WSJ; August 20, 2016. Kantarjian. Cancer 119: 3902; 2013. Tefferi. Mayo Clinic Proceedings 90: 996; 2015

Patient Advocacy Organizations and Drug Industry

- Study of 104 organizations; 37% focus on cancer; annual revenues $7.5-25 million
- 86/104 (83%) received financial support from industry
- 39% received $1+million/year; 39% did not allow assessment
- This is the reason why patient advocacy organizations are silent about high cancer drug prices, and mostly support pharma arguments

McCoy. NEJM 376: 880; 2017

George W. Merck - 1929

Quote: “We try never to forget that **medicine is for the people**. It is **not for the profits**. The **profits will follow**, and if we remember that, they never fail to appear. The better we remember it, the larger they have been.”

DISCUSSION??

For additional questions , please connect:

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