

4.44: Cost Of Cancer Drugs - Basics In Cancer Drug Policy

⌵ Season	4
⌵ Type	Plenary Session
☰ Status	Complete

We Discuss:

- Introduction [0:00]
 - Sales (in billions) [6:30]
 - R&D [9:00]
 - Value [18:46]
 - Innovation [27:00]
 - Closing thoughts [39:00]
 - R&D pt. 2 [35:29]
 - Closing thoughts [39:00]
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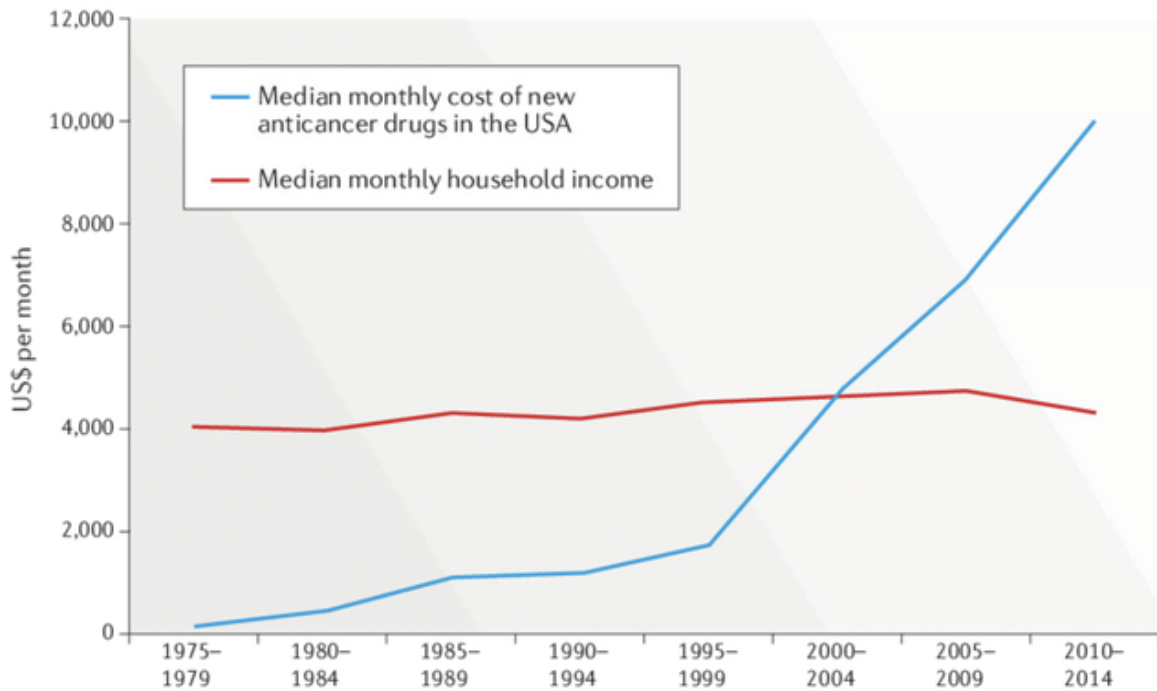
Plenary Session 4.44 Show Notes

Overview

Lecture

- **Introduction [0:00]**
 - The rise in costs – a representative depiction
 - These prices are rising much faster than inflation

- It's also worth noting that this statistic is out of date and that the situation has almost certainly become worse



Source

- Price examples

- Cole AL, Dusetzina SB. Generic Price Competition For Specialty Drugs: Too Little, Too Late?. *Health Aff*

- Novartis first introduced Imatinib for about \$4,000 per month, but they offered a little reduction the next year since it was widely publicized as being too expensive

- Then, gradually, the price continued to rise

- Then the patent expired, and the generic manufacturer began producing the medicine.

- People usually claim that when a medicine becomes generic, it will no longer be highly costly.

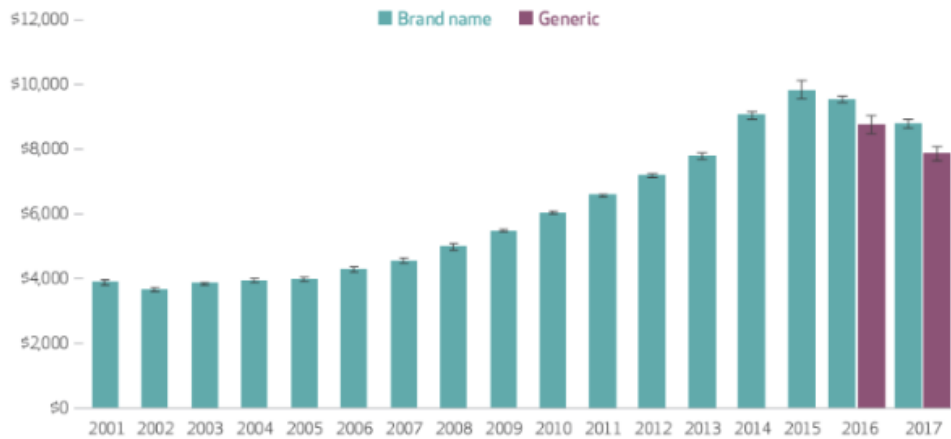
- However, as you can see right here, the generic pricing, although lower than the original price, is still roughly twice

as expensive as the initial launch price

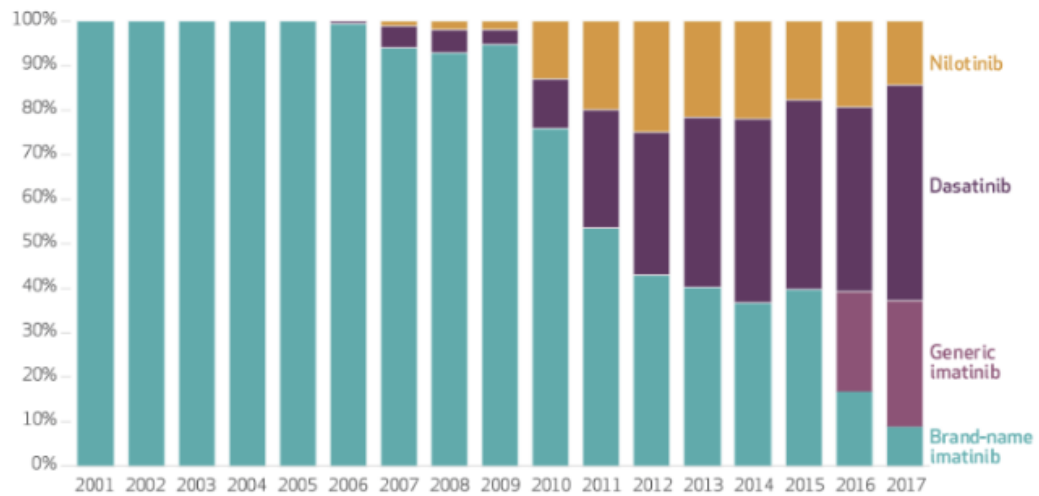
“Even though we're having discounts with generic drugs, we're still paying more than what we paid when the product initially came out” - VP

EXHIBIT 1

List prices of brand-name and generic imatinib for commercially insured patients with chronic myeloid leukemia



Percentages of patients diagnosed with chronic myeloid leukemia newly treated with brand-name nilotinib (Tasigna), dasatinib (Sprycel), or imatinib (Gleevec) or generic imatinib, 2001-17



Cole et al.

- o Additionally, the me-too drugs have never been shown to increase overall quality of life or survival

- They do, however, enhance the proportion of patients who attain molecular remission – a surrogate endpoint – leading to preferred prescription patterns

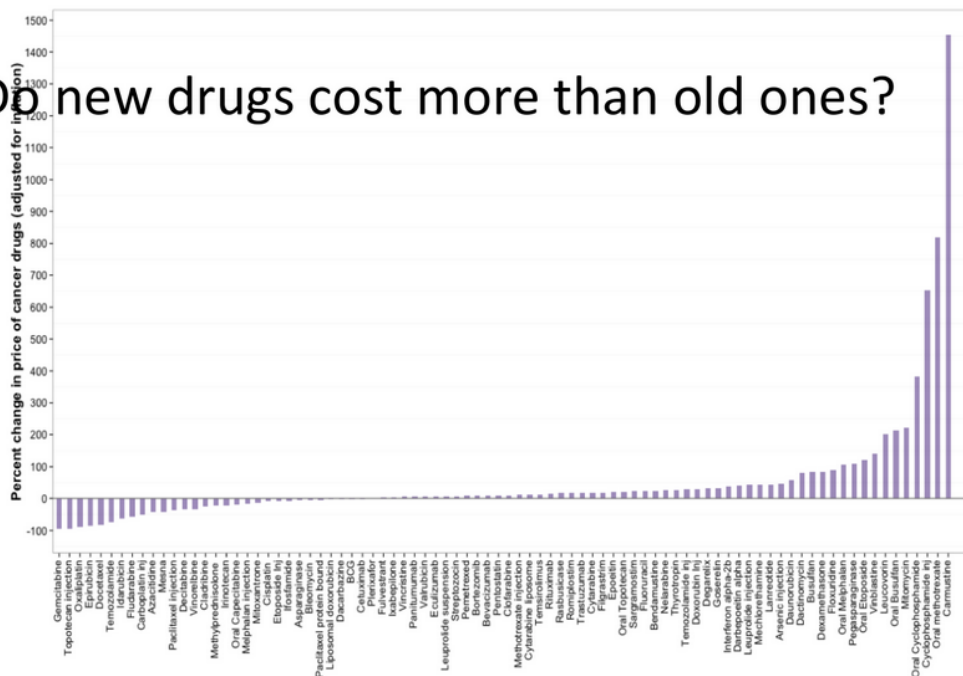
“By the time the generic comes around, only about a third of people are even taking the parent drug, two thirds of people have moved on to the next generation alternatives and there ain't no generic for that” - VP

- **Sales (in billions) and competition [6:30]**

Drug	Sales (in billions)	Cancer Indications
Rituximab (<i>Rituxan/MabThera</i> , Genentech/Roche)	\$7.78	non-Hodgkin's lymphoma, chronic lymphocytic leukemia
Bevacizumab (<i>Avastin</i> , Genentech/Roche)	\$6.75	colorectal, lung, kidney, and glioblastoma
Trastuzumab (<i>Herceptin</i> , Genentech/Roche)	\$6.56	breast, esophageal, and gastric
Imatinib (<i>Gleevec</i> , Novartis)	\$4.69	variety of leukemias and gastrointestinal stromal tumors
Pegfilgrastim (<i>Neulasta</i> , Amgen)	\$4.39	febrile neutropenia
Lenalidomide (<i>Revlimid</i> , Celgene)	\$4.28	multiple myeloma, mantle cell lymphoma, myelodysplastic syndromes
Pemetrexed (<i>Alimta</i> , Eli Lilly)	\$2.70	lung
Bortezomib (<i>Velcade</i> , Takeda and Johnson & Johnson)	\$2.61	multiple myeloma, mantle cell lymphoma
Cetuximab (<i>Erbix</i> , ImClone and Merck)	\$1.87	colorectal, head and neck
Abiraterone (<i>Zytiga</i> , Johnson & Johnson)	\$1.70	prostate

- Cancer medications have witnessed phenomenal sales; they are highly profitable.
 - Do the new drugs cost more than the old ones?

Do new drugs cost more than old ones?



- What are the drugs on the right with the greatest price increase? Are those the newest drugs?
 - The X axis are the drugs based on year of approval and the Y axis is the change in price over those five years
 - As you can see, it wasn't the newer treatments that had the highest price rises; **it was the older pharmaceuticals** that, due to market perversity, finally had some form of exclusivity that enabled the producer to raise the price

- **R&D [9:00]**

“Although the companies wish to portray what they do is very risky. If you consistently make a double-digit profit margin, then you you may have a risk with individual drug development programs, but your portfolio level risk is actually rather buffered”- VP

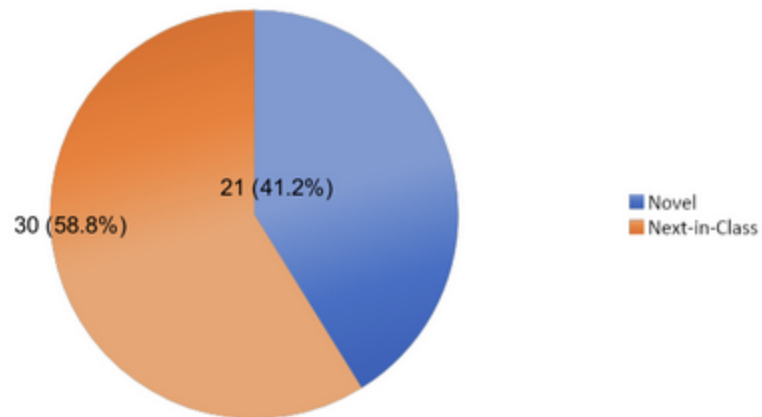
World's largest pharmaceutical firms

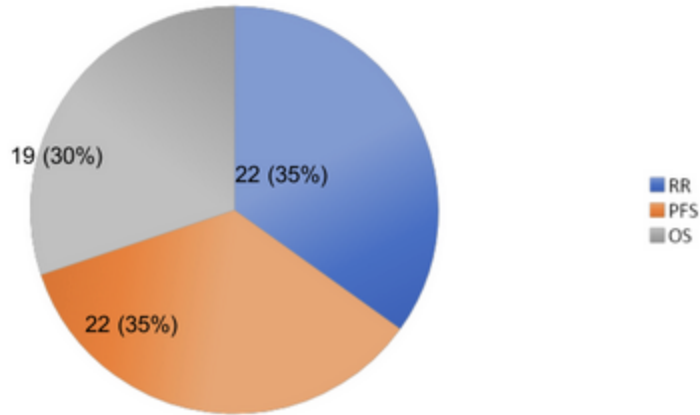
Company	Total revenue (\$bn)	R&D spend (\$bn)	Sales and marketing spend(\$bn)	Profit (\$bn)	Profit margin (%)
Johnson & Johnson (US)	71.3	8.2	17.5	13.8	19
Novartis (Swiss)	58.8	9.9	14.6	9.2	16
Pfizer (US)	51.6	6.6	11.4	22.0	43
Hoffmann-La Roche (Swiss)	50.3	9.3	9.0	12.0	24
Sanofi (France)	44.4	6.3	9.1	8.5	11
Merck (US)	44.0	7.5	9.5	4.4	10
GSK (UK)	41.4	5.3	9.9	8.5	21
AstraZeneca (UK)	25.7	4.3	7.3	2.6	10
Eli Lilly (US)	23.1	5.5	5.7	4.7	20
AbbVie (US)	18.8	2.9	4.3	4.1	22

Source:
GlobalData

o Me-too drugs

- Mailankody S, Prasad V. Five Years of Cancer Drug Approvals: Innovation, Efficacy, and Costs. *JAMA Oncol*

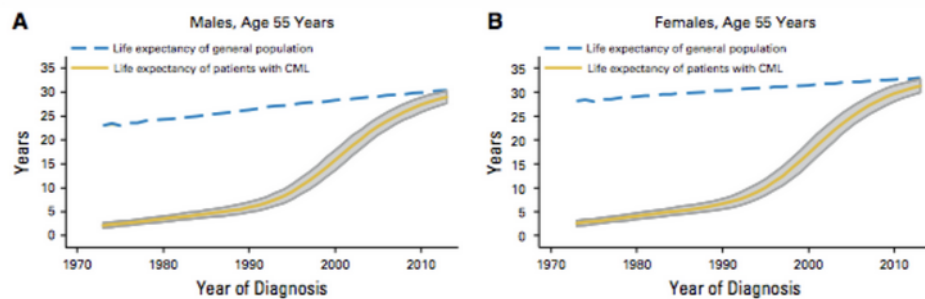




- We would anticipate that medications proved to extend life expectancy would be the most expensive, while the other two groups will be the least expensive
 - However, we discovered that medications that shrink tumor size are the most expensive, while the other two groups are the same price
 - The weakest evidence shouldn't have the highest drug price

- **Value [18:46]**

- What is value?
 - Value = Benefits/Cost & Toxicities
 - An example:



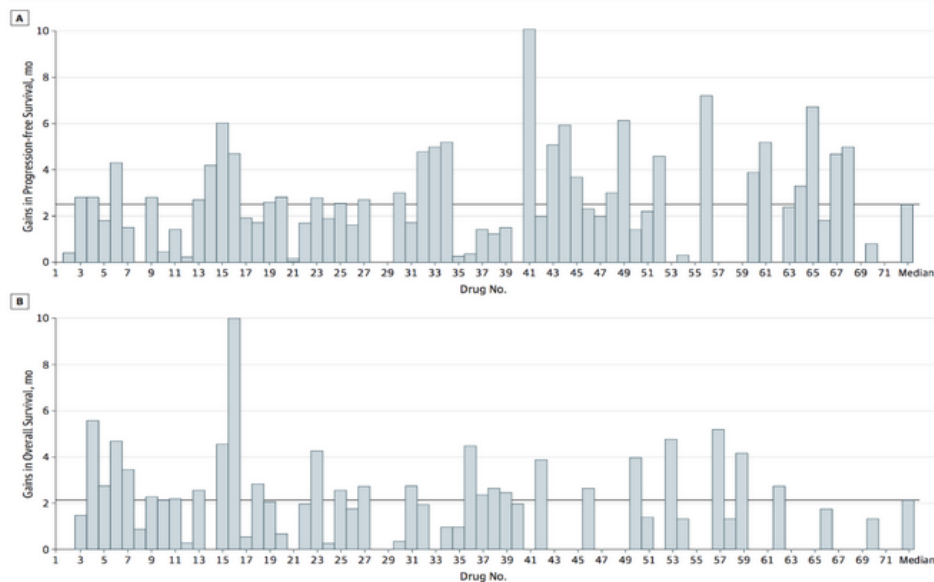
- Cost-effectiveness of Tyrosine Kinase Inhibitor Treatment Strategies for Chronic Myeloid Leukemia in Chronic Phase After Generic Entry of Imatinib in the United States
 - Padula et al., *JNCI*

- %/QALY for imatinib in CML is \$72,000
 - This begs the question → If someone tells you that a cancer therapy has a QALY less than this value, you should be skeptical
 - You have to question them, since how could their QALY be improved when the most effective medicine on the market was ~ \$70,000?

- The average cancer drug

- Fojo T, Mailankody S, Lo A. Unintended Consequences of Expensive Cancer Therapeutics—The Pursuit of Marginal Indications and a Me-Too Mentality That Stifles Innovation and Creativity: The John Conley Lecture
JAMA Otolaryngol Head Neck Surg

Figure 1. Graphical Representation of the Results in Table 1: Gains in Progression-Free Survival (PFS) and Overall Survival (OS) for the 71 Drugs Approved by the FDA From 2002 to 2014 for Metastatic and/or Advanced and/or Refractory Solid Tumors



- **Innovation [27:00]**

Value of innovation in hematologic malignancies: a systematic review of published cost-effectiveness analyses

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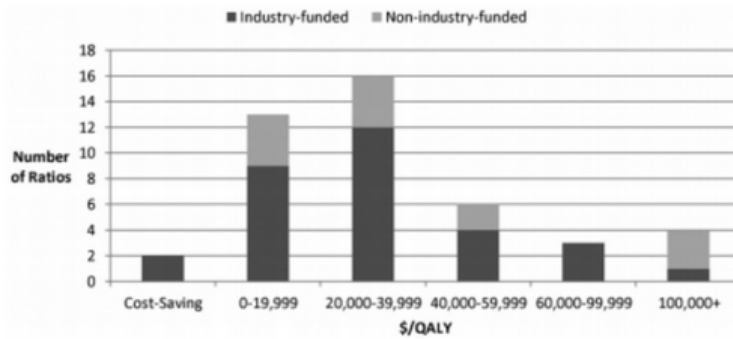


Figure 1. Ratios by ICER (\$/QALY) and funding source. Note: ratios were inflated to 2012 United States dollars using the general Consumer Price Index.

[Saret et al.](#)

- Effectiveness [31:31]

- Do cancer drugs work as well in the real world?
 - Are the trials representative of the real world cancer patient population?

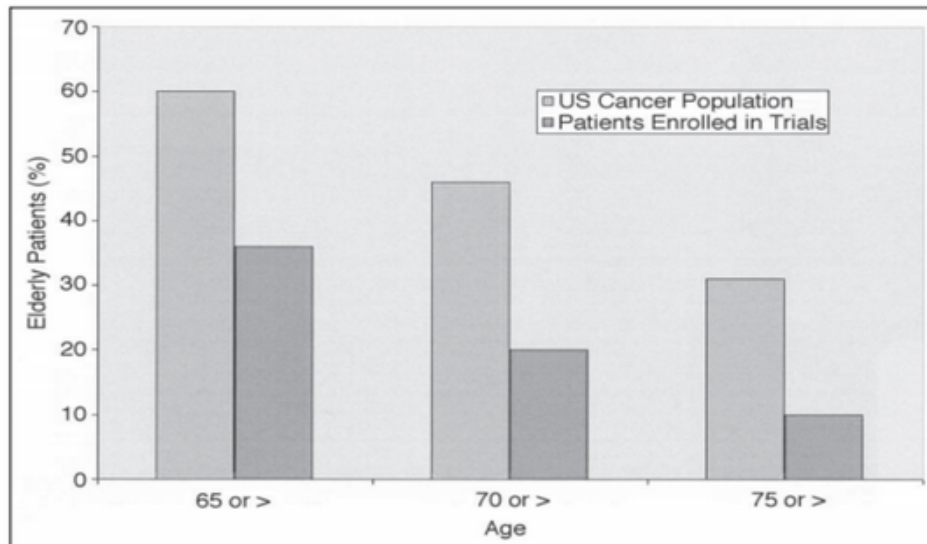
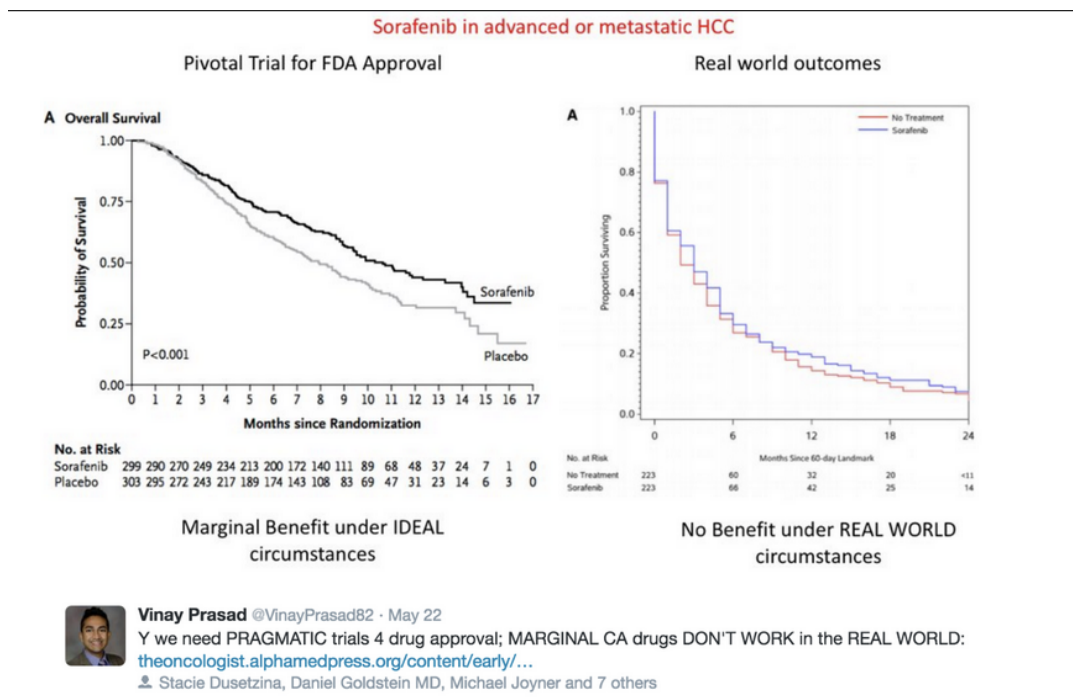


Fig 1. Proportion of elderly patients enrolled onto registration trials compared with the proportion of elderly patients in the US cancer population. The differences between the two groups were significant for all age groups ($P < .001$).

- Data shows that we recruit in clinical trials participants who are younger and healthier than the typical cancer patient in the United States
- Sorafenib in advanced or metastatic HCC



- Mailankody S, Prasad V. Overall Survival in Cancer Drug Trials as a New Surrogate End Point for Overall Survival in the Real World. *JAMA Oncol*
 - Overall survival in trials should be a surrogate for overall survival in the real-world population to the difference between efficacy and effectiveness
 - A marginal drug in an ideal population likely has little to no benefit in the US population
- **R&D pt. 2 [35:29]**

Drug/Manufacturer	R&D start date	Number of drugs in development	FDA approval date	Basis of FDA approval	Time to approval (years)	Total R&D costs ^c (millions \$)	R&D costs including 7% per year cost of capital ^f (millions \$)	Time since approval (years)	Revenue since approval ^f (millions \$)	Return on Investment (%)
Ponatinib/Ariad Pharmaceuticals	January 2007	3	December 2012	Accelerated (RR)	5.9	477.1	545.0	4.1	5419.6 ^b	1035.9
Ibrutinib/Pharmacylics	April 2006 ^a	4	November 2013	Accelerated (RR)	7.6	334.0	399.2	1.3	22039.3 ^b	6498.6
Enzalutamide/Medivation	August 2005 ^a	2	August 2012	Regular (OS)	7.0	470.3	551.2	3.3	1627.7	246.1
Brentuximab Vedotin/Seattle Genetics	January 2001	3	August 2011	Accelerated (RR)	10.6	894.1	1113.0	5.3	1027.0	14.9
Cabozantinib/Exelixis	January 2004	11	November 2012	Regular (PFS)	8.8	1936.2	2583.6	4.1	340.4	-82.4
Liposomal Irinotecan/Merrimack Pharmaceuticals	December 2009 ^a	5	October 2015	Regular (OS)	5.8	809.7	953.0	1.3	1058.1	30.7
Liposomal Vincristine/Talon Therapeutics	May 2006 ^a	4	September 2012	Accelerated (RR)	6.3	155.3	201.1	0.8	203.3 ^b	30.9
Ruxolitinib/Incyte Corporation	January 2004	5	November 2011	Regular (other)	7.8	1091.9	1367.2	5.1	2236.8	104.9
Pralatrexate/Allos Therapeutics	December 2002 ^a	3	September 2009	Accelerated (RR)	6.8	177.1	216.1	3.0	303.1 ^b	71.1
Eculizumab/Alexion Pharmaceuticals	January 2002	3	March 2007	Regular (other)	15.2	816.6	1086.8	8.8	10051.9	1130.9

- Closing thoughts [39:00]

Medical student

- “I suspect the cost savings proposed here are grossly overstated due to the simple fact that the cost to manufacture the drugs is essentially unrelated to the cost of the drug. The drug companies are selling their intellectual property and pricing the drugs to provide a certain number of treatments based on what the market will bear. This is a cute paper, but the prices for the treatments would simply rise in the years it would take to establish systems to reduce waste. Waste should be reduced when possible but this article is hyperbole.”

- Other literature mentioned:

- [Malignant: How Bad Policy and Bad Evidence Harm People with Cancer](#)

- Other people mentioned:

- [Stacie B. Dusetzina](#)

- [Sham Mailankody, MBBS](#)
 - [Antonio Tito Fojo](#)
-

Plenary Session is a podcast on medicine, oncology, & health policy.

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