PHARMA PRICING PRACTICES AND THE CASE FOR MARKET SELF-CORRECTION

Ensuring Patient Access to Cancer Drugs
June 9, 2014
“Value” of an oncology drug
How fast they “grow up”
How tall they become

Peak (Price x Volume x Market Share)

Drug Sales (USD) in Millions

USA
EU5
RoW
China

Year
The *lifespan* of a commercial product

![Graph showing the time to loss of exclusivity for drug sales in millions across USA, EU5, RoW, and China from 2015 to 2030.](image-url)
Pricing Levers: Time to Peak
How fast they “grow up”

Practical Considerations

- **Time to peak** = How fast can a drug reach its potential maximum usage?

- **Fast & broad coverage**
- **Willingness to Prescribe**
- **Patient Urgency**
- **Time to FDA Approval**
- **Pent up demand**

- Price does have an impact and may influence the other variables, e.g. Higher price equals:
  - Hesitance to prescribe, questionable “value”
  - Slow or narrow coverage
  - Patient reluctance to enter treatment (OOP?)

- Accelerated or exceptional approval present opportunities for manufacturers – how to “value”?
How fast they “grow up”

**Issues**

- If a manufacturer cannot get to market fast, they must make up for the lost commercial potential by:
  - Extending the lifespan of the drug
  - Increasing the peak sales

**FDA Breakthrough Designations (2012-14)**

- 18% Awaiting
- 26% Granted
- 56% Denied
- 66% Other/ Unclassified
- 34% Oncology

- Clinicians do not have to use new therapies, may wait for guidelines, or select alternatives
- US managed care organizations (MCOs) do not have options available to slow market entry

Breakthrough designation is a fast track process allowing drugs to receive approval ahead of schedule
Source: US FDA, Data as of March 31, 2014
Pricing Levers: Peak
How tall they become

**Practical Considerations**

- Peak represents the maximum potential utilization, at the optimal price, in a given market

**Price**
- ✓ Strategy
- ✓ Quality of Access
- ✓ Laws & Regulations

**Volume**
- ✓ Number of patients
- ✓ Line of Tx
- ✓ Biomarkers

**Market share**
- ✓ Alternatives
- ✓ CE*
- ✓ WTP** OOP
- ✓ WTRx***

*CE=Comparative Effectiveness  
**WTP=Willingness to Pay  
***WTRx=Willingness to Prescribe
How tall they become

**Peak**

Peak represents the maximum potential utilization, at the optimal price, in a given market.

### Practical Considerations

- **Price**
  - Strategy
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---

*CE=Comparative Effectiveness  
**WTP=Willingness to Pay
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Pricing strategy considers lifecycle and portfolio considerations

**Profit Maximization**
- Priced at the equilibrium price where price and volume provide the maximum possible profit, trading off volume with price

**Population Maximization**
- The price at which the largest number (volume) of consumers will have access to a medication

**Price Maximization**
- The maximum price achievable in a given setting, focusing on a small population
A variety of state laws protect, define coverage boundaries, or limit payer ability to manage oncology.

CMS rules: Plans offering Medicare drug coverage must provide access to at least two medications from each therapeutic category and class.
Practical Considerations

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**Price**
- ✓ Strategy
- ✓ Quality of Access
- ✓ Laws & Regulations

**Volume**
- ✓ Number of patients
- ✓ Line of Tx
- ✓ Biomarkers

**Market share**
- ✓ Alternatives
- ✓ CE*
- ✓ WTP** OOP
- ✓ WTRx***
Not all cancers are the same, with varying mortality and prevalence rates in the United States.

The number of oncology drugs intended for use as 1st line therapy options decreased over the past 13 years. Manufacturers have targeted earlier, first-line therapy positioning half as often as for drug launches in 2001 have been targeted later lines of therapy (second-line or later) – more than three times as often was the case in the year 2001.

Percent of oncology drugs targeting first-line position

<table>
<thead>
<tr>
<th>Year</th>
<th>1L</th>
<th>2L</th>
</tr>
</thead>
<tbody>
<tr>
<td>2001</td>
<td>80%</td>
<td>20%</td>
</tr>
<tr>
<td>2013</td>
<td>40%</td>
<td>60%</td>
</tr>
</tbody>
</table>

1L = First Line  /  2L = Second Line

Additionally, cancers have been parsed more finely and indications have become more precise, creating smaller, more targeted patient pools.

### The changing landscape of Hematology

<table>
<thead>
<tr>
<th>60 Years Ago</th>
<th>&quot;Disease of the Blood&quot;</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 Years Ago</td>
<td>Leukemia or Lymphoma</td>
</tr>
<tr>
<td>40 Years Ago</td>
<td>Chronic Leukemia</td>
</tr>
<tr>
<td></td>
<td>Acute Leukemia</td>
</tr>
<tr>
<td></td>
<td>Preleukemia</td>
</tr>
<tr>
<td>Today</td>
<td>~38 Leukemia types identified:</td>
</tr>
<tr>
<td></td>
<td>Acute myeloid leukemia (~12 types)</td>
</tr>
<tr>
<td></td>
<td>Acute lymphoblastic leukemia (2 types)</td>
</tr>
<tr>
<td></td>
<td>Acute promyelocytic leukemia (2 types)</td>
</tr>
<tr>
<td></td>
<td>Acute monocytic leukemia (2 types)</td>
</tr>
<tr>
<td></td>
<td>Acute erythroid leukemia (2 types)</td>
</tr>
<tr>
<td></td>
<td>Acute megakaryoblastic leukemia</td>
</tr>
<tr>
<td></td>
<td>Acute myelomonocytic leukemia (2 types)</td>
</tr>
<tr>
<td></td>
<td>Chronic myeloid leukemia</td>
</tr>
<tr>
<td></td>
<td>Chronic myeloproliferative disorders (5 types)</td>
</tr>
<tr>
<td></td>
<td>Myelodysplastic syndromes (6 types)</td>
</tr>
<tr>
<td></td>
<td>Mixed myeloproliferative/myelodysplastic syndromes (3 types)</td>
</tr>
<tr>
<td></td>
<td>Indolent Lymphoma</td>
</tr>
<tr>
<td></td>
<td>Aggressive Lymphoma</td>
</tr>
<tr>
<td></td>
<td>~51 Lymphomas identified:</td>
</tr>
<tr>
<td></td>
<td>Mature B-cell lymphomas (~14 types)</td>
</tr>
<tr>
<td></td>
<td>Mature T-cell lymphomas (15 types)</td>
</tr>
<tr>
<td></td>
<td>Plasma cell neoplasm (3 types)</td>
</tr>
<tr>
<td></td>
<td>Immature (precursor) lymphomas (2 types)</td>
</tr>
<tr>
<td></td>
<td>Hodgkin's lymphoma (5 types)</td>
</tr>
<tr>
<td></td>
<td>Immunodeficiency associated lymphomas (~5 types)</td>
</tr>
<tr>
<td></td>
<td>Other hematolymphoid neoplasms (~7 types)</td>
</tr>
</tbody>
</table>

Lung cancer has evolved rapidly, defining smaller patient populations.

The changing landscape of Lung Cancer

- **Tx by Ability to take Platinum Doublet**
  - Before 2006: 
    - PS 2/3: Ineligible
    - PS 01: Eligible
  - 2006: 
    - PS 2/3: Ineligible
    - PS 01: Eligible
  - 2008: 
    - PS 2/3: Ineligible
    - PS 01: Eligible
  - Today: 
    - PS 2/3: Ineligible
    - PS 01: Eligible

- **Tx by Comorbidities**

- **Tx by histology**
  - Before 2006: 
    - SCC: Ineligible
    - Non-SCC: Eligible
  - 2006: 
    - SCC: Ineligible
    - Non-SCC: Eligible
  - 2008: 
    - SCC: Ineligible
    - Non-SCC: Eligible
  - Today: 
    - SCC: Ineligible
    - Non-SCC: Eligible

- **Tx by histology and molecular profile**

The number of oncology drugs that have specific companion biomarkers doubled over the past 13 years.

Manufacturers have launched twice the amount of drugs with associated biomarkers compared to those launched in the year 2001.

Percent of oncology drugs with a companion biomarker:

- 2001: 20%
- 2013: 40%

CDx = Companion Diagnostic

As a result, the average size of the eligible patient population for oncology drugs has been declining.

Between 2001 and 2013, the average addressable treatment population for oncology manufacturers decreased by almost 242 patients per year.

How tall they become

Practical Considerations

- Peak represents the maximum potential utilization, at the optimal price, in a given market

<table>
<thead>
<tr>
<th>Price</th>
<th>Volume</th>
<th>Market share</th>
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<tr>
<td>✓ Strategy</td>
<td>✓ Number of patients</td>
<td>✓ Alternatives</td>
</tr>
<tr>
<td>✓ Quality of Access</td>
<td>✓ Line of Tx</td>
<td>✓ CE*</td>
</tr>
<tr>
<td>✓ Unmet need</td>
<td>✓ Biomarkers</td>
<td>✓ WTRx***</td>
</tr>
</tbody>
</table>

*CE=Comparative Effectiveness
**WTP=Willingness to Pay
***WTRx=Willingness to Prescribe
The availability of treatment options for various cancers ranges, with few treatments for some of the most burdensome tumors.

Treatments are scarce, often focusing on very different stages, settings, and cadences within the treatment paradigm – lack of substitutability is an important feature of oncology pricing.

Competitive crowding is already impacting the way manufacturers approach various tumor types.

Treatment pathway for metastatic prostate cancer

More treatment options increase complexity, decrease addressable populations, and add pressure to price competitively and/or contract to secure broad access.
Oncology drugs are seldom brought to market with comparative effectiveness data.

Comparative data is difficult due niche label indications for current therapies and the rapidly evolving marketplace – what is standard of care today, may not be in 5 years.

Among awards with a therapeutic focus, oncology research accounted for the 2nd highest number of awards, totaling $124 million.

ARRA CER Investment by Therapeutic Area (Avalere EBM Navigator)

- Although it is not yet clear whether the ARRA investment will lead to the creation of meaningful tools and resources for CER, the considerable focus on infrastructure is cause for optimism.
- The material question now is how well PCORI can build on the progress made under ARRA as it identifies, funds, and pursues its own CER priorities.
Practices & hospitals are fraught with perverse and conflicting incentives, encouraging a high willingness to prescribe

- Site of care has an inflating impact on the perceptions of oncology drug costs (see right)

- Buy-and-bill presented clinicians with profit-seeking incentive

- 340B Drug Pricing Program enables organizations to purchase outpatient drugs at discounted prices
  - The program has grown rapidly, with the number of participating facilities doubling between 2001 and 2011. One third of all hospitals now participate

- Contracting with payers is done privately, not impacting the patient, nor lowering their OOP

Source: Innovations in cancer care and implications for health systems, M. Aitken, IMS Institute for Health Informatics, May 2014
...however, change is afoot

- The majority of academic physicians believe that cost should not factor into their clinical recommendations, nor should cost limit a patient’s access to “effective” treatment.

- 78% of physicians would prescribe effective therapy regardless of cost.

- Oncologists’ cost-effectiveness thresholds are significantly higher than those values previously held to be standard for clinical interventions.

- Physicians express that costs would likely become a more important factor in their practice.

“We are pleased that the community of stakeholders is willing and ready to deal with the tough questions around cancer care costs, and that this group has taken a critically important first step to partner with ASCO to address this problem… We want to ensure that patients receive high-quality care, but that care must provide better outcomes and value to each and every patient.”

- ASCO President Clifford A. Hudis, MD, FACP
Patients feel vested in the treatment decision process with physicians, while insurers are expected to pay.

Q: Who should decide whether treatment is offered? Who should pay?

- **Who decides?**
  - Patients and their families: 83%
  - Physicians: 32%
  - Local Insurer: 10%
  - Government: 5%
  - DK/NA: 0%

- **Who pays?**
  - Local Insurer: 74%
  - Government: 25%
  - DK/NA: 0%

Patients desire to have a major influence on the type of treatment offered. Patients also expect insurers to pay for the medication, realizing they have a financial responsibility as well.

Patient Estimations of costs of treatment midjudge insurance coverage but are often less than $10,000

80% of patients reported spending less than $10,000 on treatment and medical care and 16% of patients stated their own medical benefit plan had contributed less money than they had expected for cancer treatment

Q: How much money would you estimate you have spent (out of pocket, not money spent by your insurance company) treating your cancer, including medications to help prevent recurrence? ($)

Source: Impact of the Cost of Cancer Treatment: An Internet-Based Survey, M. Markman, JOP March 2010 vol. 6 no. 2 69-73
Patients are willing to pay more for generous specialty drug coverage – 50% would pay more than $25 / mo.

50% of patients are willing to pay more than $25 extra per month for generous specialty drug coverage and ~40% of cancer patients are willing to pay for “hope”.

Pricing Levers: Time to Loss of Exclusivity
The lifespan of a commercial product

**Practical Considerations**

- In a normal pharmaceutical market, the loss of patent exclusivity signals an important end of a product’s traditional “lifecycle”
- Competitors are allowed to enter the marker to produce a generic alternative, at significant reduced cost
- Biologics have not faced this pressure due to challenges entering the US marketplace
  - Price differentials for biosimilars range and are generally nowhere near the price differences seen with small molecules and generics
The number of firms competing post-LOE drive the price down.

**Relationship between LN inflation adjusted estimated supplier prices ($USD 2012) and manufacturer count after LOE**

- **Oral**
- **Physician-administered**


**Competition drives down price in order for a manufacturer to secure access.**
Biosimilar prices in Europe demonstrate savings of 8 to 32% off the prices of originator prices.

Mean biosimilar - reference product discount (2007-2010)

Biosimilars enter the European market at an average discount of 20% of the original product.

The ACA introduced an approval pathway for biosimilar therapy, however the requirements needed to substitute was left up to the states to decide.

The FDA has not yet determined what standards will be required to meet the threshold of “interchangeability” and as a result most states have not developed formal laws.

Biologic oncology drugs dominate the clinic expenditures

### Top 20 Antineoplastic Drug Expenditures in Clinics 2013

<table>
<thead>
<tr>
<th>Rank</th>
<th>Drug</th>
<th>Biologic or Nonbiologic</th>
<th>2013 Total Expenditure ($ million)</th>
<th>Top 20 Total %</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Rituxan</td>
<td>Biologic</td>
<td>1,718,862</td>
<td>18%</td>
</tr>
<tr>
<td>2</td>
<td>Avastin</td>
<td>Biologic</td>
<td>1,563,678</td>
<td>16%</td>
</tr>
<tr>
<td>3</td>
<td>Herceptin</td>
<td>Biologic</td>
<td>1,145,344</td>
<td>12%</td>
</tr>
<tr>
<td>4</td>
<td>Alimta</td>
<td>Nonbiologic</td>
<td>680,696</td>
<td>7%</td>
</tr>
<tr>
<td>5</td>
<td>Treanda</td>
<td>Nonbiologic</td>
<td>392,984</td>
<td>4%</td>
</tr>
<tr>
<td>6</td>
<td>Erbitux</td>
<td>Biologic</td>
<td>369,257</td>
<td>4%</td>
</tr>
<tr>
<td>7</td>
<td>Velcade</td>
<td>Nonbiologic</td>
<td>317,828</td>
<td>3%</td>
</tr>
<tr>
<td>8</td>
<td>Abraxane</td>
<td>Nonbiologic</td>
<td>309,832</td>
<td>3%</td>
</tr>
<tr>
<td>9</td>
<td>Yervoy</td>
<td>Biologic</td>
<td>288,838</td>
<td>3%</td>
</tr>
<tr>
<td>10</td>
<td>Leuprolide acetate</td>
<td>Nonbiologic</td>
<td>222,088</td>
<td>2%</td>
</tr>
<tr>
<td>11</td>
<td>Vidaza</td>
<td>Nonbiologic</td>
<td>197,439</td>
<td>2%</td>
</tr>
<tr>
<td>12</td>
<td>Faslodex</td>
<td>Nonbiologic</td>
<td>197,156</td>
<td>2%</td>
</tr>
<tr>
<td>13</td>
<td>Taxotere</td>
<td>Nonbiologic</td>
<td>175,598</td>
<td>2%</td>
</tr>
<tr>
<td>14</td>
<td>Cyclophosphamide</td>
<td>Nonbiologic</td>
<td>166,459</td>
<td>2%</td>
</tr>
<tr>
<td>15</td>
<td>Kyprolis</td>
<td>Nonbiologic</td>
<td>159,733</td>
<td>2%</td>
</tr>
<tr>
<td>16</td>
<td>Liposomal doxorubicin</td>
<td>Nonbiologic</td>
<td>128,797</td>
<td>1%</td>
</tr>
<tr>
<td>17</td>
<td>Dacogen</td>
<td>Nonbiologic</td>
<td>124,372</td>
<td>1%</td>
</tr>
<tr>
<td>18</td>
<td>Kadcyla</td>
<td>Biologic</td>
<td>109,817</td>
<td>1%</td>
</tr>
<tr>
<td>19</td>
<td>Perjeta</td>
<td>Biologic</td>
<td>96,152</td>
<td>1%</td>
</tr>
<tr>
<td>20</td>
<td>Eloxatin</td>
<td>Nonbiologic</td>
<td>78,242</td>
<td>1%</td>
</tr>
<tr>
<td></td>
<td>All Other Antineoplastics</td>
<td>Various</td>
<td>1,102,529</td>
<td>12%</td>
</tr>
</tbody>
</table>

55% of all oncology drug utilization within the clinic setting comes from biologic agents

Crisis! (?)
US healthcare spending has been growing

A global phenomenon: Rising healthcare spending is not isolated to the USA

Healthcare spending, wage and real GDP growth in the US and 7 major markets

Cancer still remains a small piece of total health spending

Yet spending on cancer, as a percent of total health spending, has remained constant over the past half a century.

Cancer spending accounts for approximately 6% of all healthcare spending – lower in the USA than in Europe


Top 10 costly conditions from 2008-2011

“The sky is falling!”


Other Media Sources Displayed Above
...but it started a long time ago

February 9, 1988

The Troubling Cost of Drugs That Offer Hope

By ANDREW POLLACK, Special to the New York Times

SAN FRANCISCO, Feb. 8— The Armour Pharmaceutical Company introduced a major drug in October - the first blood-clotting factor for hemophiliacs made using the tools of biotechnology. This purer version of Factor VIII virtually eliminated any chance that hemophiliacs would contract AIDS, hepatitis or other diseases from treatment.

There was one catch: This high-tech drug costs five to eight times as much as older versions, bringing the cost of a year's supply to more than $25,000. That puts the drug out of the reach of many patients for whom it is a matter of life and death.
...but it started a long, long time ago

Dilemma in Health Care: Rising Cost and Demand

By RICHARD D. LYONS
Special to The New York Times

WASHINGTON, Sept. 12—A decade ago, one medical group in Manhattan charged $35 for a basic physical checkup; today it charges $65. In those same years the going rate for an appendectomy in New York rose from $485 to $1,175 and the cost of an average hospital stay, costs, at a time when accumulated inflation has swollen most economic indicators, are staggering. This year Americans—through their own pocketbooks, their Federal, state and local governments, and their health insurance companies — will spend almost $80-billion for

…but it started a long, long, long time ago

Long Plans Inquiry on Pricing of Drugs

WASHINGTON, July 23 (AP) — Senator Russell B. Long said today he was planning an investigation of drug prices and Federal health programs.

When it comes to the Louisiana Democrat said, "people are going to be finding out that they're paying 400 times too much for some of their drugs."

The forum will be the Senate Finance committee; the topic, prescription practices under Medicare and federally aided health programs.
…but it started a long, long, long, long time ago

…but it started a long, long, long, super long time ago

Kefauver Seeking Anew To Reduce Drug Prices

Special to The New York Times

WASHINGTON, April 9—Senator Estes Kefauver opened a new campaign today for lower drug prices.

The Tennessee Democrat, introducing his bill, told the Senate it would require compulsory licensing “only for those drugs whose prices are clearly excessive, and as a rough measure of what constitutes a clearly excessive price I have taken the figure of 500 per cent.”

...but it started a long, long, long, super long time ago

10,000% Drug Mark-up Cited

By Patricia Wiggins
United Press International

Sen. Estes Kefauver (D-Tenn.) wound up hearings on what customers were paying for drugs yesterday, charging that some supermarkets were charging up to 10,000% more than the cost of the drug. Kefauver also charged that evidence "clearly shows" Americans are required to pay too much for drugs.

Union drug company head was asked why Upjohn sold drugs to another manufacturer at a price 14 times less than that charged drug stores for the finished product.

Sen. Estes Kefauver (D-Tenn.) wound up hearings on what customers were paying for drugs yesterday, charging that some supermarkets were charging up to 10,000% more than the cost of the drug. Kefauver also charged that evidence "clearly shows" Americans are required to pay too much for drugs.

1959

…but it started a long, long, long, super long time ago

…but it started a long, long, long, super long time ago

Drug Price Rises

The latest merry-go-round spiral of price rises in the drug field by the various manufacturers is going too far indeed.

The usual excuse for the rise which the mailman brings daily is by now common and stereotyped. The excuse given of “higher cost of raw materials and labor” sounds too silly by now in view of the fact that these same manufacturers show the greatest profit ever. The various promises given by NAM in “holding the line” were never sincere and by now the motives and greed are clearly visible.

We pharmacists are confronted with a very serious situation: We are to face the public in a guilty manner, offering apologies and explanations for the rise in price of

...but it started a long, long, long, super long time ago

**DRUG PRICES SOAR**

*Morphine Going Up $1 Per Ounce a Day and Quinine Follows*

In the last two weeks there has been a big jump in the price of drugs, and, as regards opiates, which are practically a necessity in medical practice, a shortage exists which seems critical.

Morphine and codeine, which are derived from opium, can be purchased only in small quantities, and the prices asked are almost fabulous. Quotations on these drugs in the last two weeks have increased at the rate almost of $1 per ounce a day, wholesale, and to the consumer, of course, the price is much higher. The quotations, good only for the day, are $50. Two weeks ago the drugs were selling at $14.

The reasons given for the phenomenal rise are the failure of the opium crop in India, and the great demand for these drugs, because of the war. No new opium is coming into the country, and there will soon be a shortage that will make the drug as precious as any jewel.

Quicksilver, which in normal times is quoted from $2 to $8, is now $150 per 15 pound flask. Permanganate of potash, a disinfectant, is now $1.50 a pound; before the war it was 12 cents a pound. As this comes principally from Germany, the high price is easily explained.

Quinine is 50 percent higher, and continues to go up. Camphor is 50 percent higher than two years ago.

...but it started a long, long, long, super long time ago

Source: Cut Prices on Drugs (1893) Chicago Daily Tribune Retrieved from https://secure.pqarchiver.com/chicagotribune
…but it started a long, long, long, long time ago
Pricing is a persistent issue in the press

Top ranking pharma issues that dominated the news, 2005 - 2013

- Others
- Healthcare Reform
- Medicare/Medicaid Coverage for Drugs
- Flu Vaccines
- Genomics and Biologics
- Bioterrorism
- Marketing/Sales Incentives
- DTC Advertising
- Developing Countries
- Generics
- Clinical Study Designs and Sponsorships
- Data Disclosure
- R&D for New Drugs
- Interaction with the FDA
- Drug Safety
- High Drug Prices in the US

Defeating Cancer: A gargantuan challenge
Cancer is the 2nd leading cause of death in the United States, almost 4-times higher than the next cause and nearly equal to heart disease.

Cancer is not just one disease, but in fact many conditions with varying prevalence and mortality rates.

Cost isn’t the only concern cancer patients have to navigate

"Fear Factors" related to cancer care in the USA, 2013

While the general public fears the ability to pay the most, cancer patients and caregivers are more concerned with the health impact, quality of life and impact on their family & friends.

Is it worth it?

- The US invests about $60 billion annually in medical research, of which about 40% is federally funded
  - Non-federal sources support 60% of research funding
  - Oncology is the largest investment area for R&D

- A permanent 1% reduction in mortality from cancer has a present value to current and future generations of Americans of nearly $500 billion

- Quality of life may be an even more valuable dimension of recent health advances

“A war on cancer that would spend an additional $100 billion on cancer research and treatment would be worthwhile if it has a one in five chance of reducing mortality by 1 percent and a four in five chance of doing nothing at all.”
- Kevin Murphy & Robert H Topel, University of Chicago & National Bureau of Economic Research

“Even if we offset these gains by substantial increases in the cost of the treatments required to implement potential new technologies, potential net gains appear large.”
- Kevin Murphy & Robert H Topel, University of Chicago & National Bureau of Economic Research
## Summary on Pharma pricing practices and the case for market self-correction

<table>
<thead>
<tr>
<th><strong>System</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pricing underlies the investment framework for oncology</td>
</tr>
<tr>
<td>State laws and regulations limit the options payers have in oncology</td>
</tr>
<tr>
<td>Faster launches with limited data are likely to remain common</td>
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</tbody>
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<table>
<thead>
<tr>
<th><strong>Influence</strong></th>
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<td>Pricing strategy depends on competition, volume, and WTRx / WTP</td>
</tr>
<tr>
<td>Cancer drug labels have been getting smaller &amp; narrower for a decade</td>
</tr>
<tr>
<td>Competitive crowding and CE can add pressure to cancer drug pricing</td>
</tr>
<tr>
<td>Physicians &amp; hospitals are fraught with perverse and conflicting incentives, encouraging a high willingness to prescribe</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Agents of Change</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients face an OOP burden but demonstrate a high WTP</td>
</tr>
<tr>
<td>Biosimilars, like generics, present opportunities for conversion post-LOE</td>
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</table>

<table>
<thead>
<tr>
<th><strong>Trends</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Oncology spending as a % of total health spending has remained flat</td>
</tr>
<tr>
<td>Media sensationalism on drug pricing has existed for at least a century</td>
</tr>
</tbody>
</table>
While the US has the highest health expenditure share of GDP, many EU markets have a higher cancer share of total healthcare expenditures.

### Estimated direct costs of cancer, 2006 (US$, PPP-adjusted)

<table>
<thead>
<tr>
<th>Country</th>
<th>Total expenditures on health, MUS$</th>
<th>Health Expenditure share of GDP (%)</th>
<th>Total expenditure on health per capita</th>
<th>Cancer share of health expenditures (%)</th>
<th>Direct costs of cancer per capita</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>2,074,861</td>
<td>15</td>
<td>6,719</td>
<td>4.7</td>
<td>314</td>
</tr>
<tr>
<td>FR</td>
<td>223,830</td>
<td>11</td>
<td>3,420</td>
<td>6.6</td>
<td>226</td>
</tr>
<tr>
<td>DE</td>
<td>208,856</td>
<td>11</td>
<td>3,465</td>
<td>7.2</td>
<td>249</td>
</tr>
<tr>
<td>IT</td>
<td>155,346</td>
<td>9</td>
<td>2,631</td>
<td>6.4</td>
<td>168</td>
</tr>
<tr>
<td>ES</td>
<td>113,409</td>
<td>8</td>
<td>2,466</td>
<td>4.0</td>
<td>99</td>
</tr>
<tr>
<td>UK</td>
<td>174,647</td>
<td>8</td>
<td>2,815</td>
<td>5.6</td>
<td>158</td>
</tr>
<tr>
<td>SE</td>
<td>29,535</td>
<td>9</td>
<td>3,162</td>
<td>6.4</td>
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<tr>
<td>JP</td>
<td>328,897</td>
<td>8</td>
<td>2,581</td>
<td>7.3</td>
<td>188</td>
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</tbody>
</table>

Prostate cancer is the most expensive, followed closely by Lung and Breast cancer.

NCI spending in FY 2010 for the 10 most common types of cancer in the United States ($ millions)
Patients understand that innovations often come in the form of small, incremental improvements.

**Opinion regarding whether major breakthroughs vs. smaller advances is the driver of longer cancer patient survival**

- **A.** Major breakthroughs that dramatically improve how long patients survive
- **B.** Smaller but important advances that improve how long patients survive a little bit at a time
- **C.** Not sure

Most people realize that small advances drive longer cancer survival.

Cancer patients and the general public both feel that OOP should remain small while agencies/insurers should pay $100k or more.

One extra year of life-limit that public payers should pay vs. amount individual is willing to pay - patient perspective, 2013

Cancer patients feel that payers should pay up to $100,000 or more for one extra year of life.

Patients are willing to switch doctors to access the most innovative oncology drugs

61% of patients will leave their physician to access new treatments

States have enacted oral parity laws – protecting oral oncolytic medication access

Parity laws equalize the out of pocket spending for oncologic IVs and orals, which can result in increased access to oral chemotherapies

States have erected barriers to payer use of step-edit – also known as “fail first” – policies.

Step therapy laws have been put into place that define a timeframe and/or conditions under which a doctor may override insurer step therapy policies in specific instances.

Note: Step-edit or “fail first” laws are not specific to cancer but often cite oncology as a primary case study in support of legislation (along with Pain, amongst others).

States have required coverage of clinical trial costs – encouraging removing barriers to cancer care

Lack of insurance coverage for routine patient care is a barrier to enrollment of patients who might otherwise take part in a clinical trial

Some states have introduced laws to reduce the cost burden of cancer treatment from pharmaceuticals.

States have implemented cost-saving measures focused on the specialty tier of pharmaceuticals, reducing the amount of cost-sharing payers can require, and by putting a cap on pharmaceutical out-of-pocket spending.

### Key contacts

<table>
<thead>
<tr>
<th>Name</th>
<th>Title/Position</th>
<th>Contact Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alex Bastian</td>
<td>Vice President</td>
<td>Tel: 415-762-1052 Email: <a href="mailto:alex.bastian@gfk.com">alex.bastian@gfk.com</a></td>
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<td>Senior Consultant</td>
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<tr>
<td>Akwasi Asabere, PhD</td>
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</tr>
</tbody>
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#### USA

<table>
<thead>
<tr>
<th>Location</th>
<th>Address</th>
<th>Contact Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>New York</td>
<td>GfK Market Access</td>
<td>Tel: +1 212 240 5300</td>
</tr>
<tr>
<td></td>
<td>200 Liberty, 1 World Financial Center</td>
<td></td>
</tr>
<tr>
<td></td>
<td>New York</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NY 10011</td>
<td></td>
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<tr>
<td>USA</td>
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#### EUROPE

<table>
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<th>Address</th>
<th>Contact Information</th>
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</thead>
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<tr>
<td>Nuremberg</td>
<td>GfK Market Access</td>
<td>Tel: +49 911 395 3345</td>
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<tr>
<td></td>
<td>Nordwestring 101</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Nuremberg</td>
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<tr>
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<tr>
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<td>Germany</td>
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<tr>
<td></td>
<td>Tel:</td>
<td></td>
</tr>
<tr>
<td>London</td>
<td>GfK Market Access</td>
<td>Tel: +44 207 535 2920</td>
</tr>
<tr>
<td></td>
<td>Marble Arch Tower</td>
<td></td>
</tr>
<tr>
<td></td>
<td>55 Bryanston Street</td>
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</tr>
<tr>
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</tr>
<tr>
<td></td>
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</tr>
<tr>
<td>Melton</td>
<td>GfK Market Access</td>
<td>Tel: +44 1664 503 700</td>
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<tr>
<td></td>
<td>Pera Innovation Park</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Nottingham Road</td>
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</tr>
<tr>
<td></td>
<td>Melton Mowbray, LE13 0PB</td>
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<tr>
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