

PHARMA PRICING PRACTICES AND THE CASE FOR MARKET SELF-CORRECTION

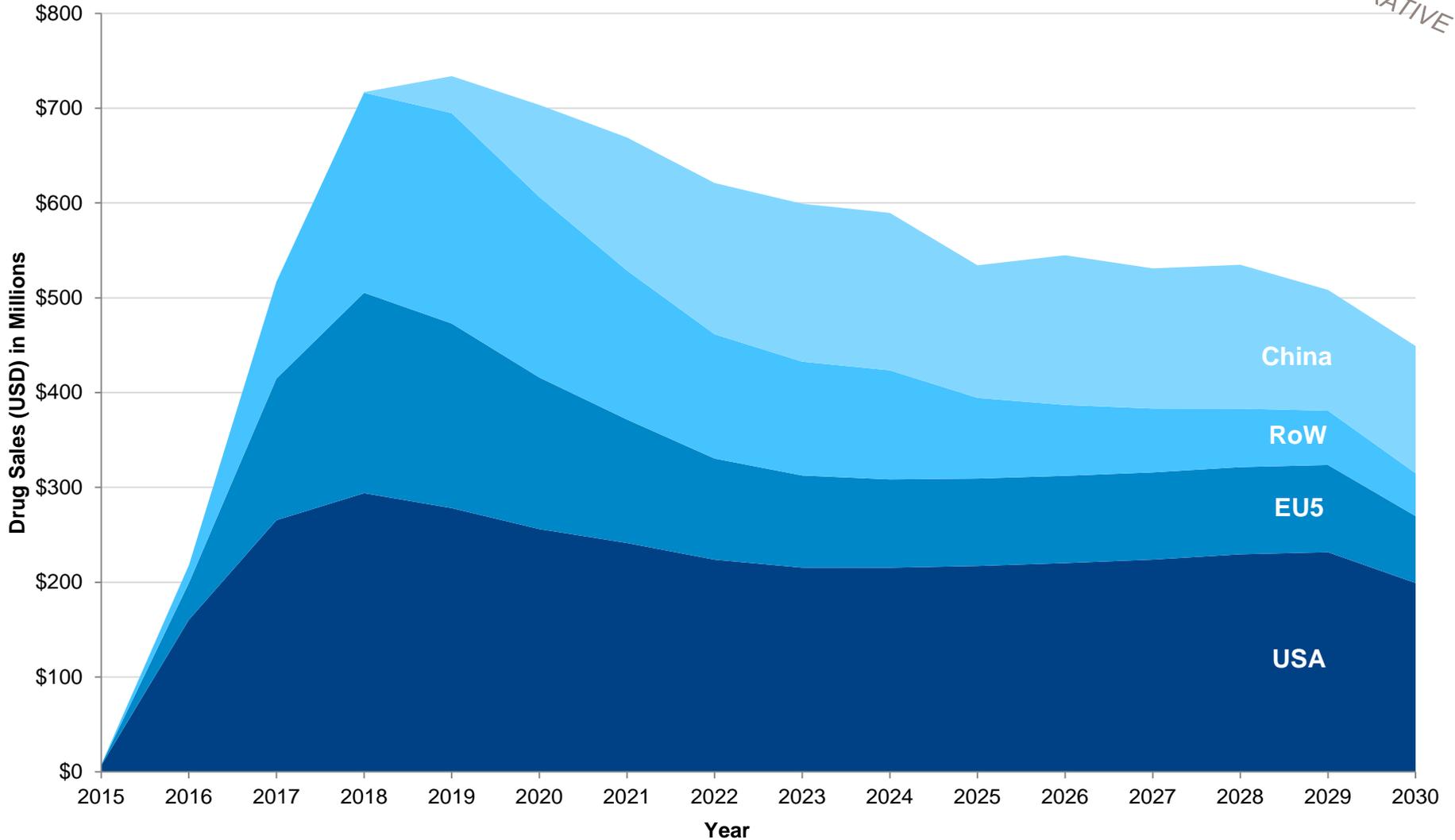
Ensuring Patient Access to Cancer Drugs

June 9, 2014

“Value” of an oncology drug



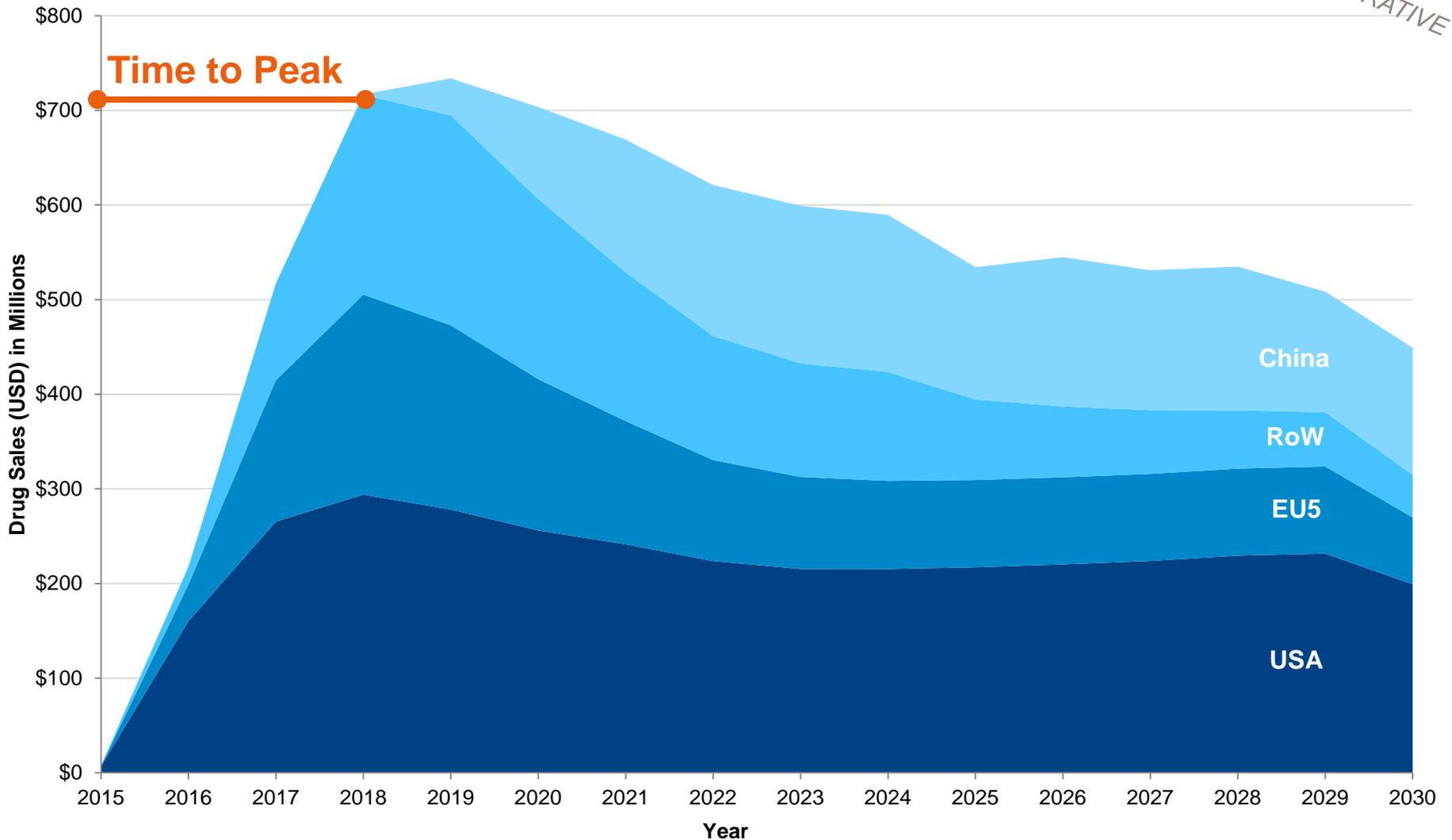
ILLUSTRATIVE



How fast they “grow up”



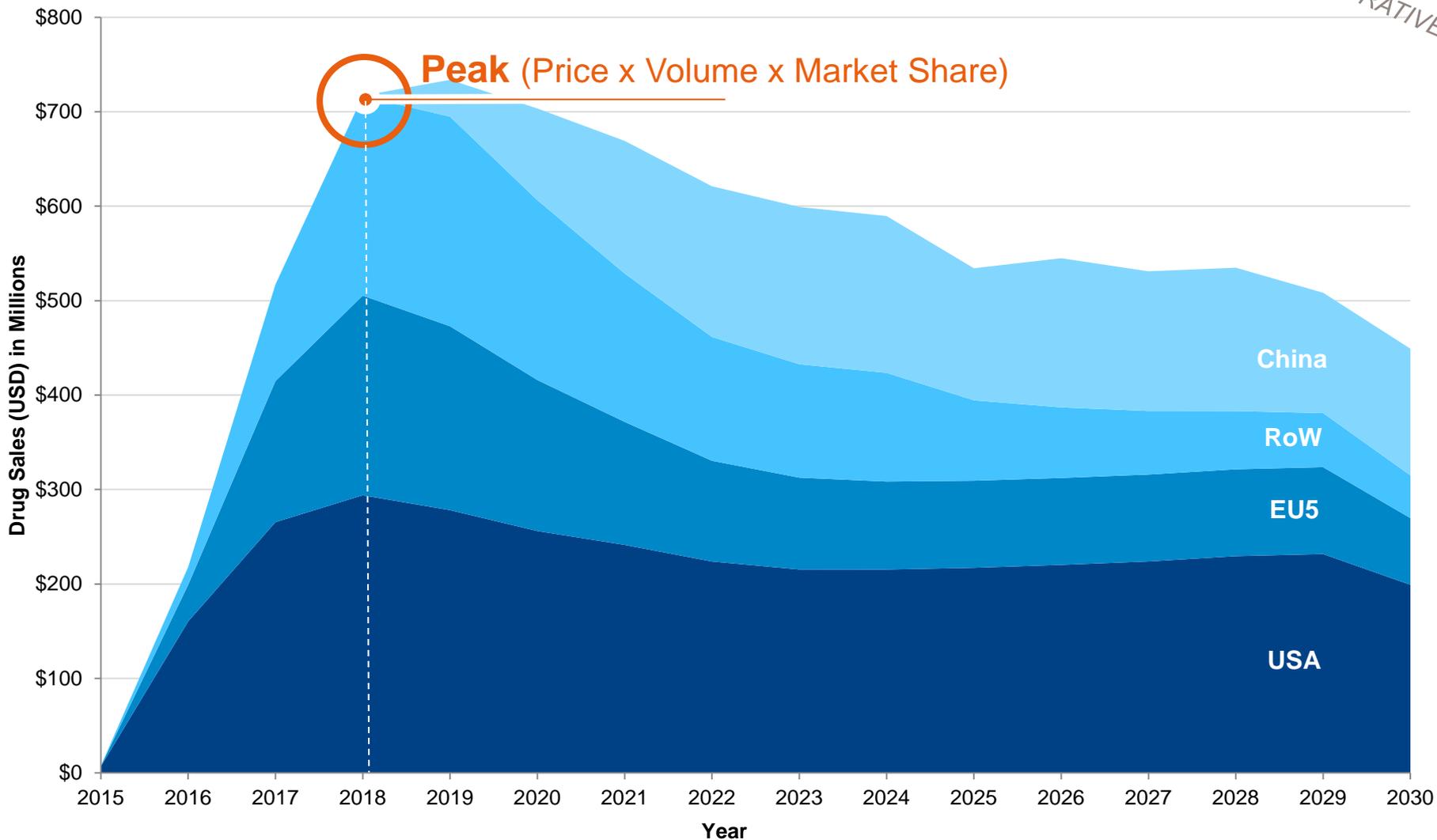
ILLUSTRATIVE



How tall they become



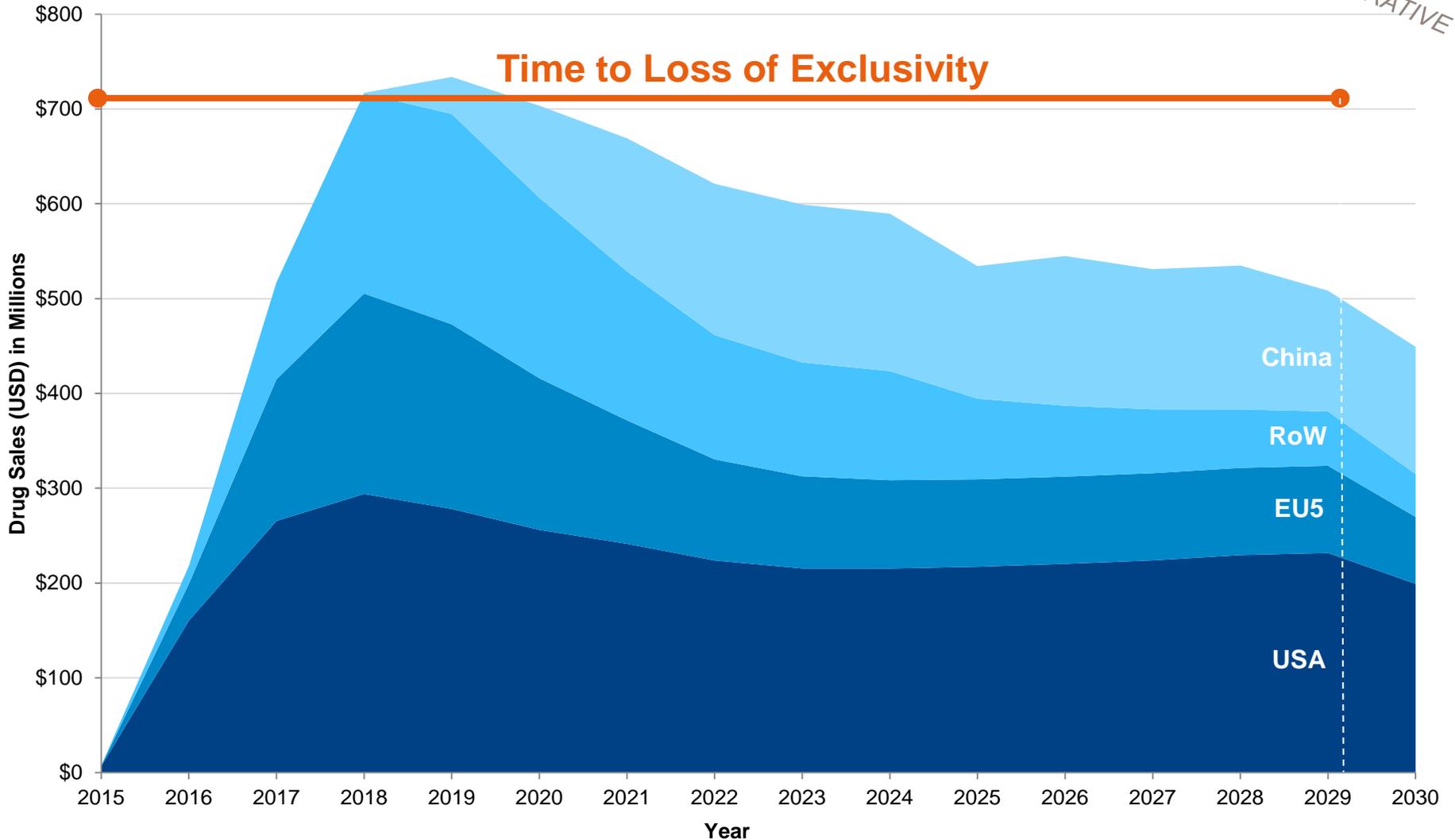
ILLUSTRATIVE



The *lifespan* of a commercial product

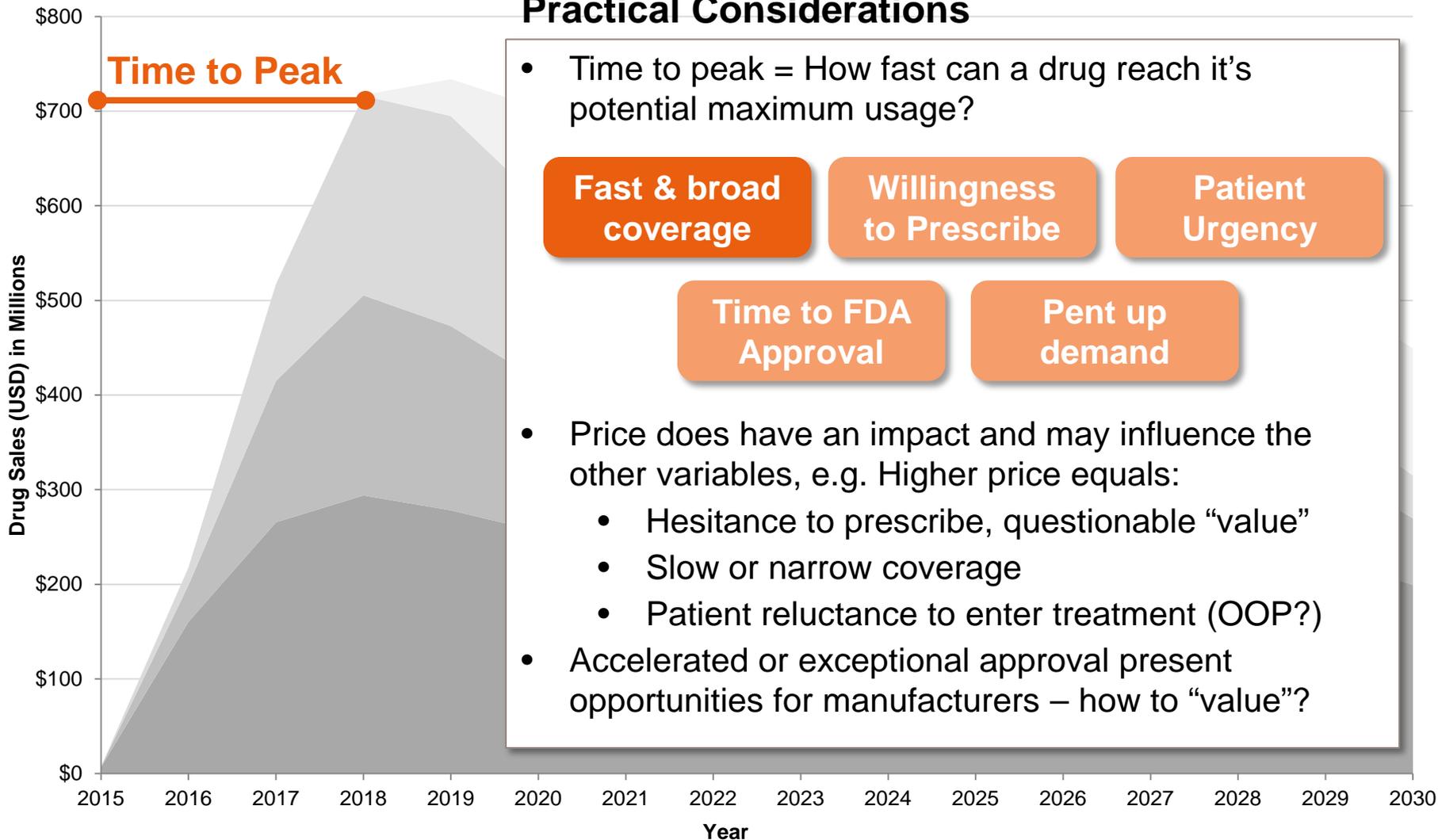


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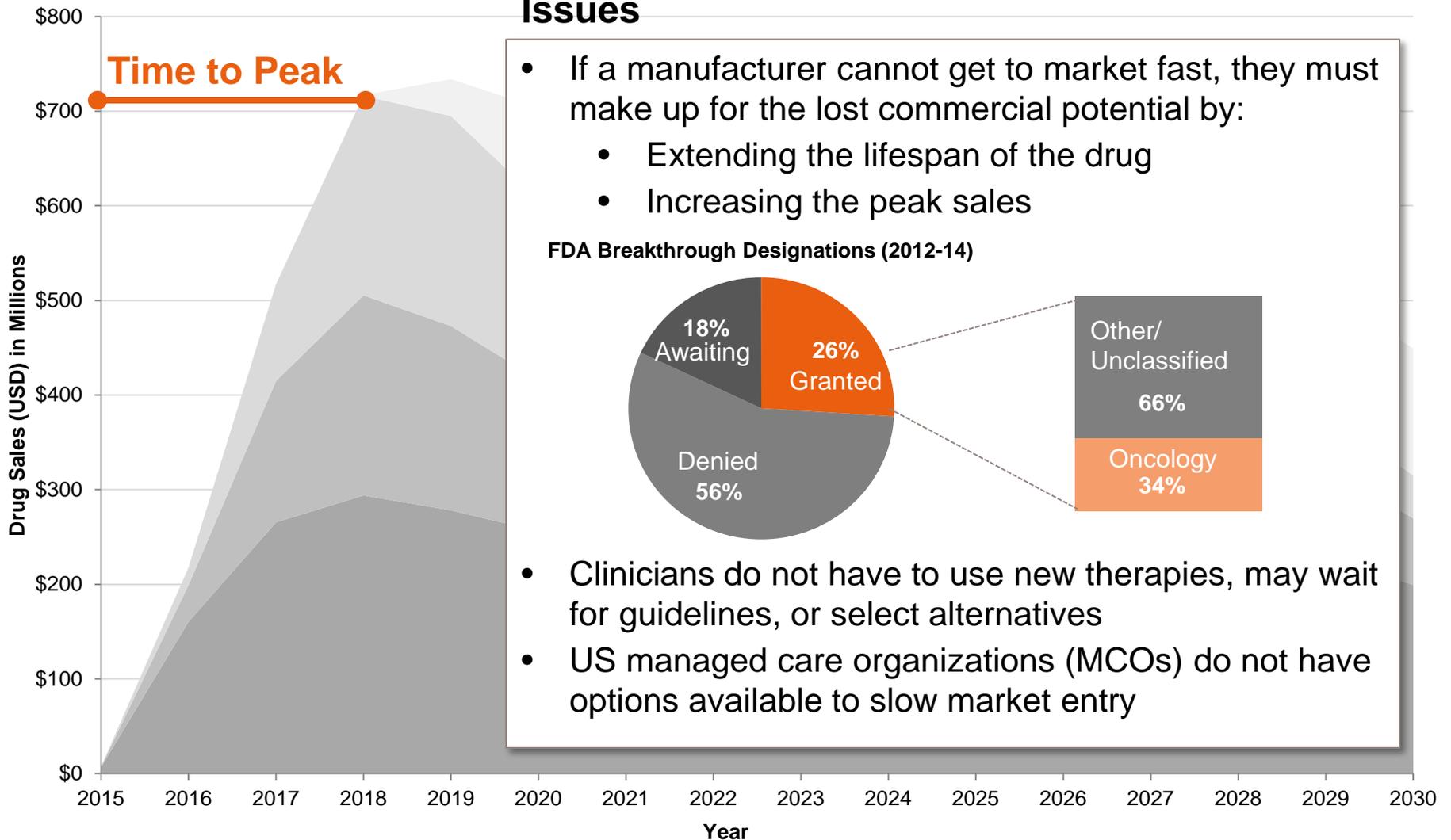
Pricing Levers: Time to Peak

How fast they “grow up”



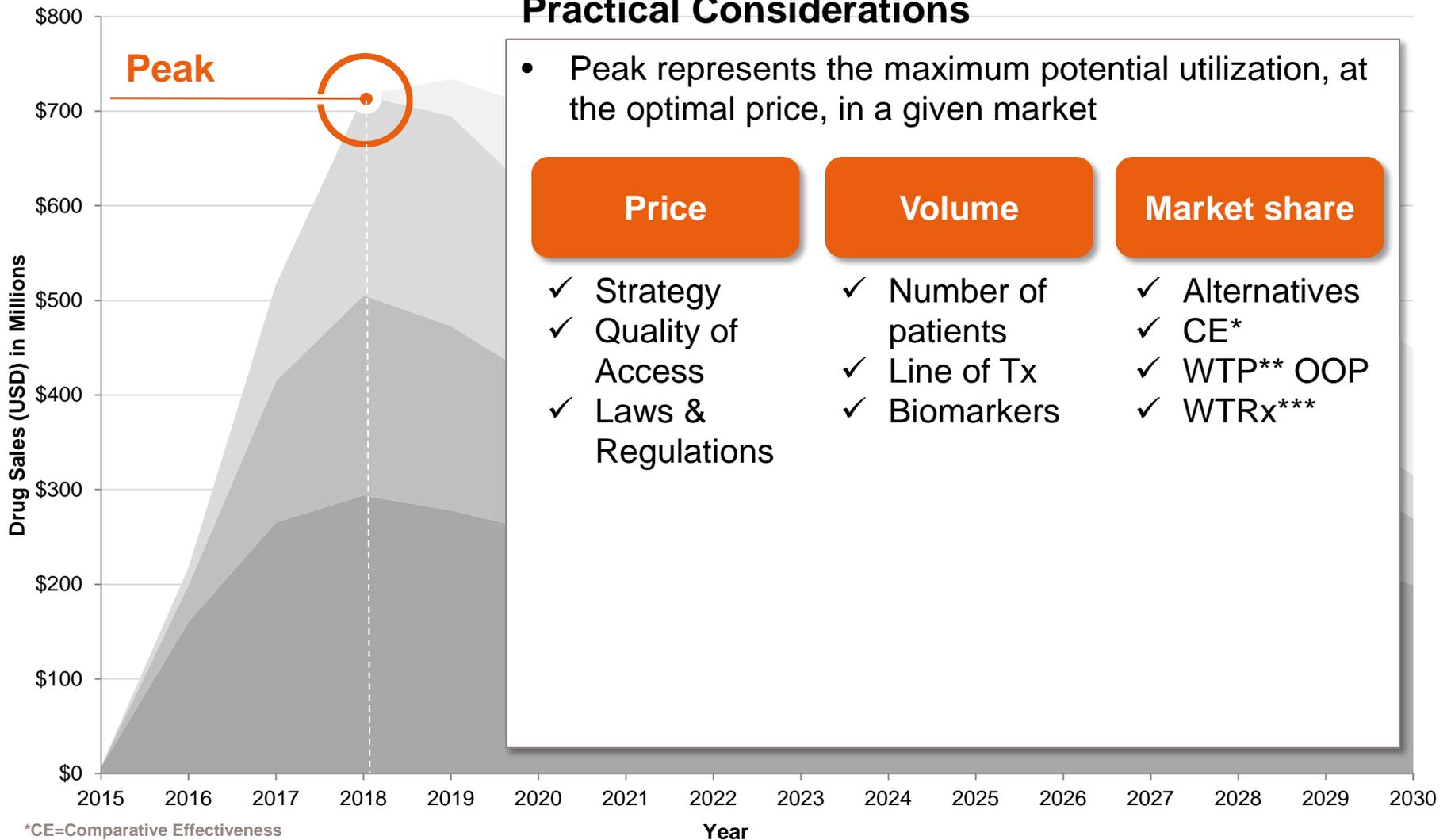
How fast they “grow up”

Fast & Broad
Coverage



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



*CE=Comparative Effectiveness
 **WTP=Willingness to Pay
 ***WTRx=Willingness to Prescribe

How tall they become



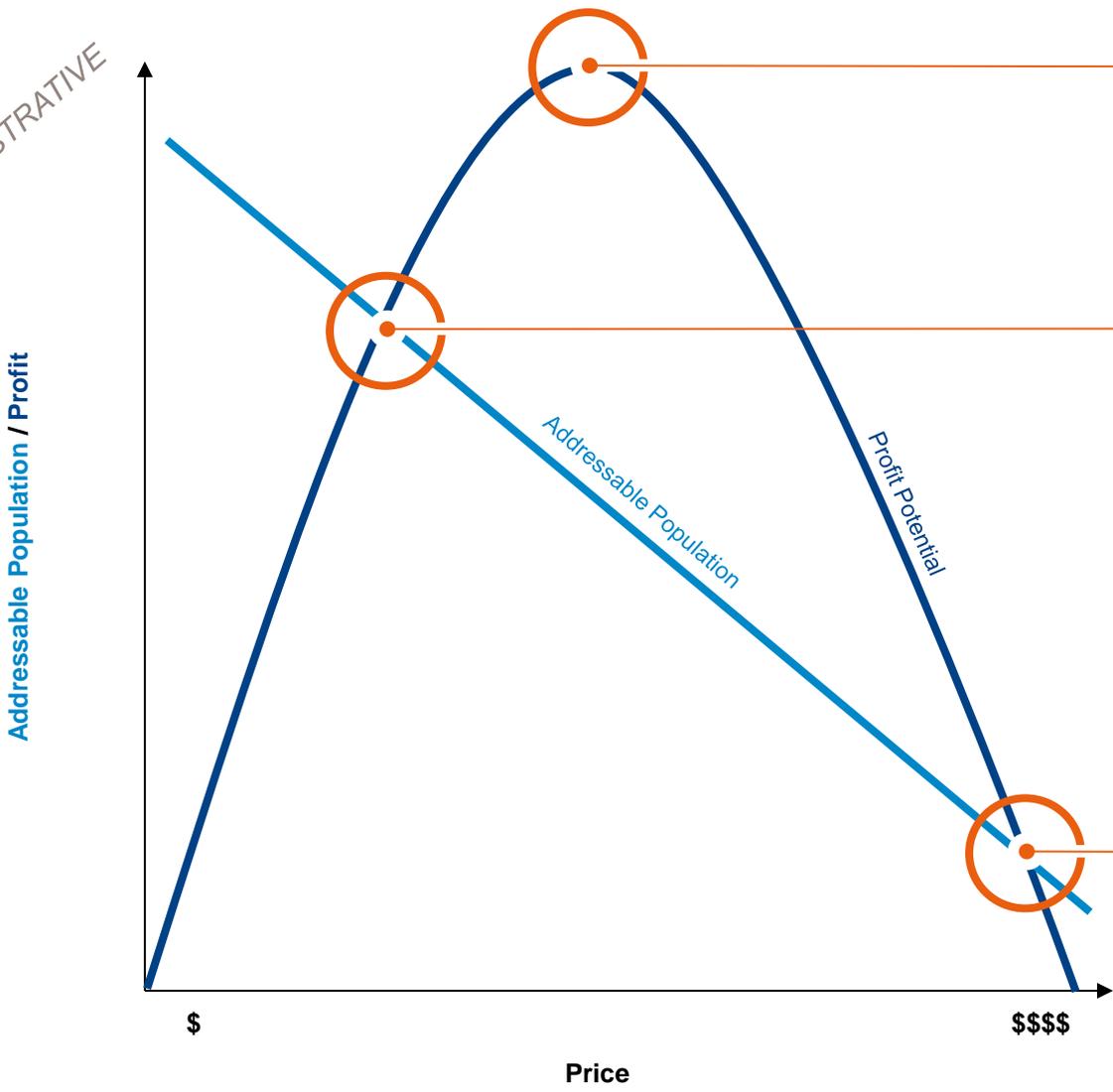
*CE=Comparative Effectiveness
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Pricing strategy considers lifecycle and portfolio considerations

Price



ILLUSTRATIVE



Profit Maximization

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

Population Maximization

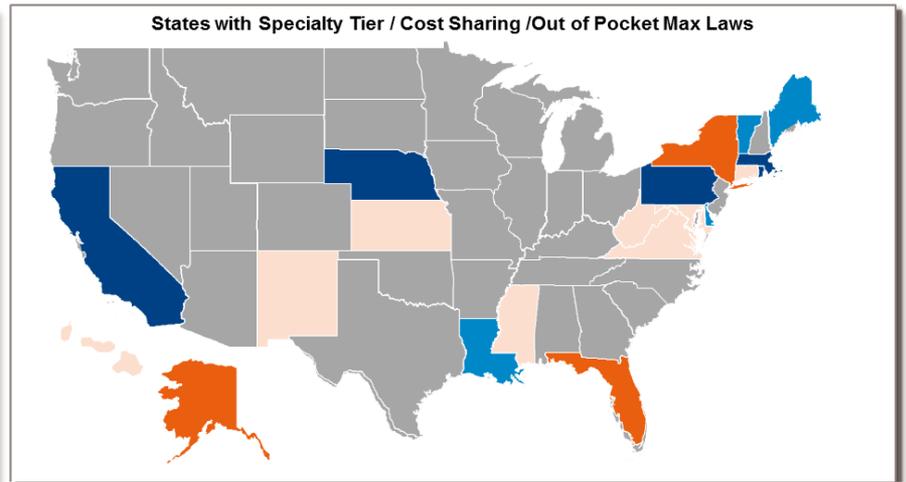
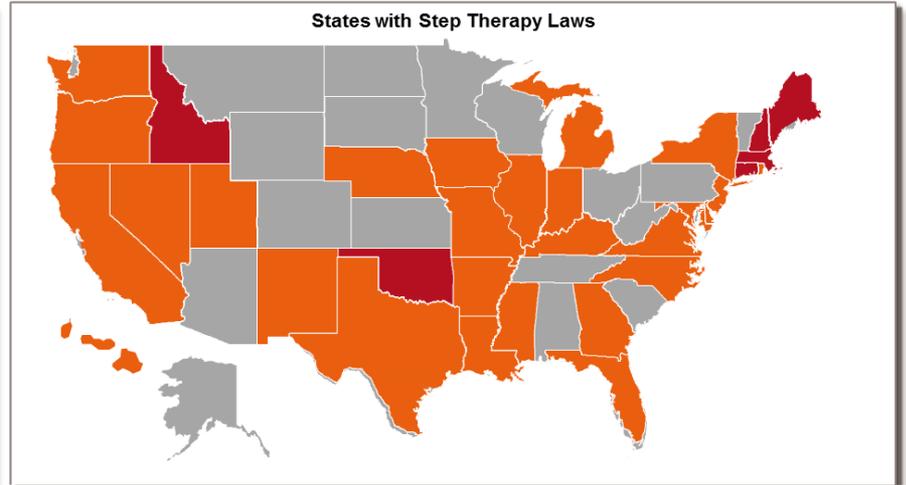
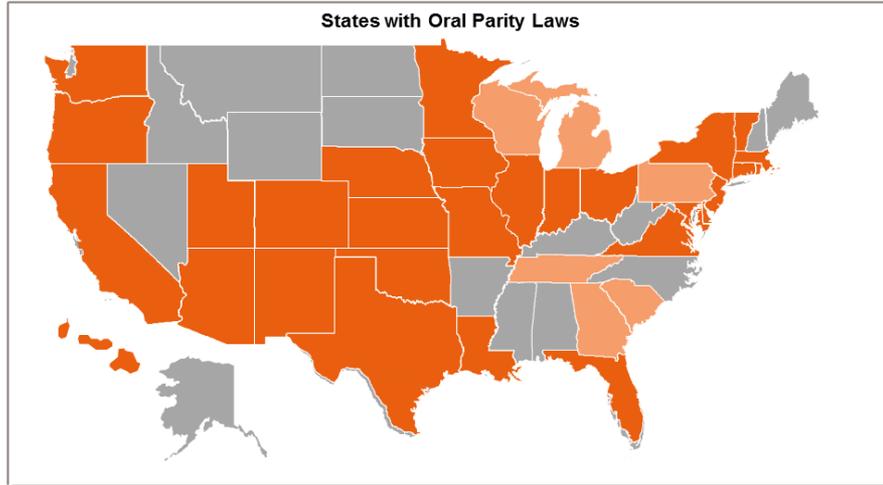
- The price at which the largest number (volume) of consumers will have access to a medication

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

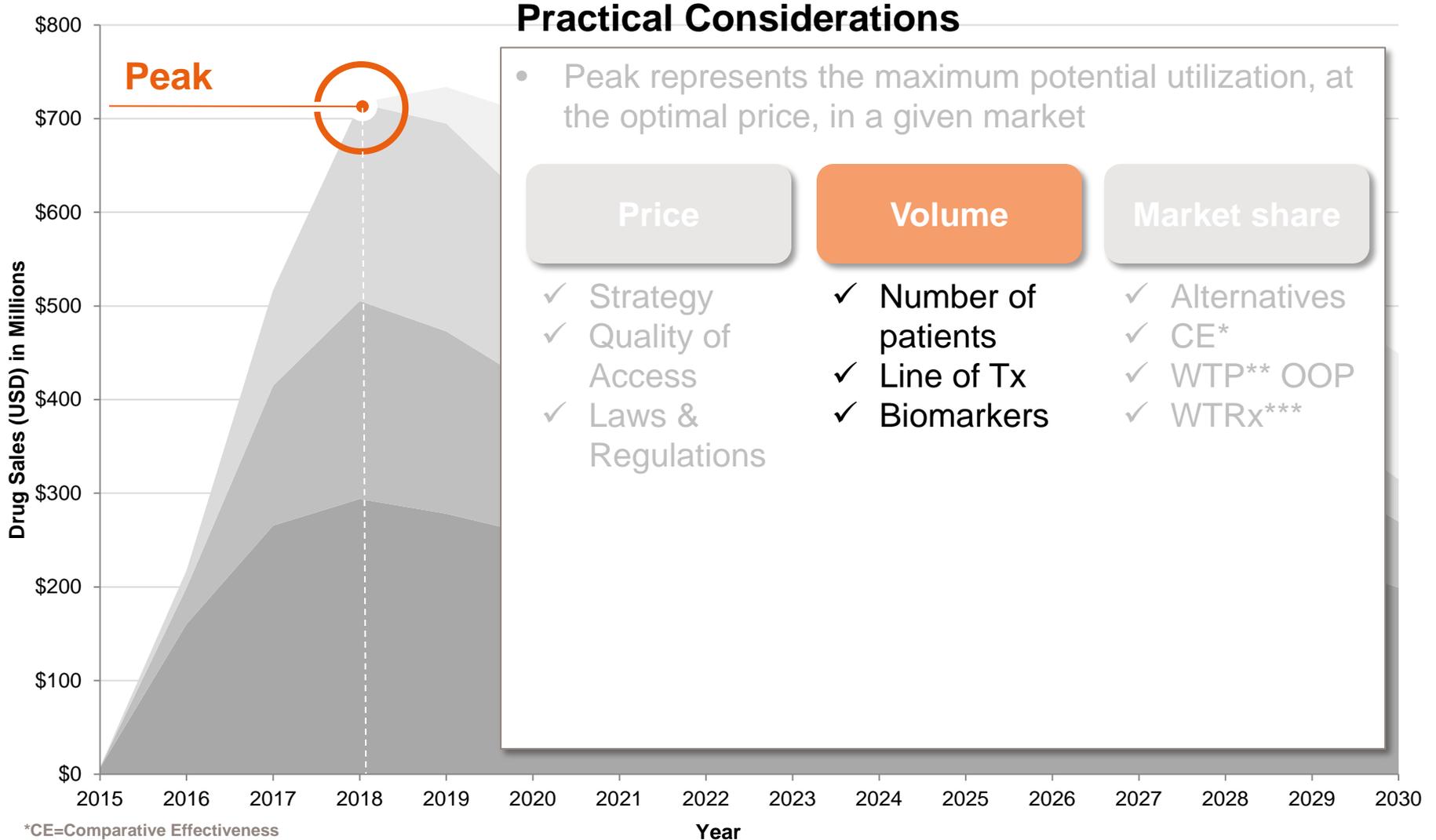
Fast & Broad
Coverage



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

Refer to Appendix for details

How tall they become



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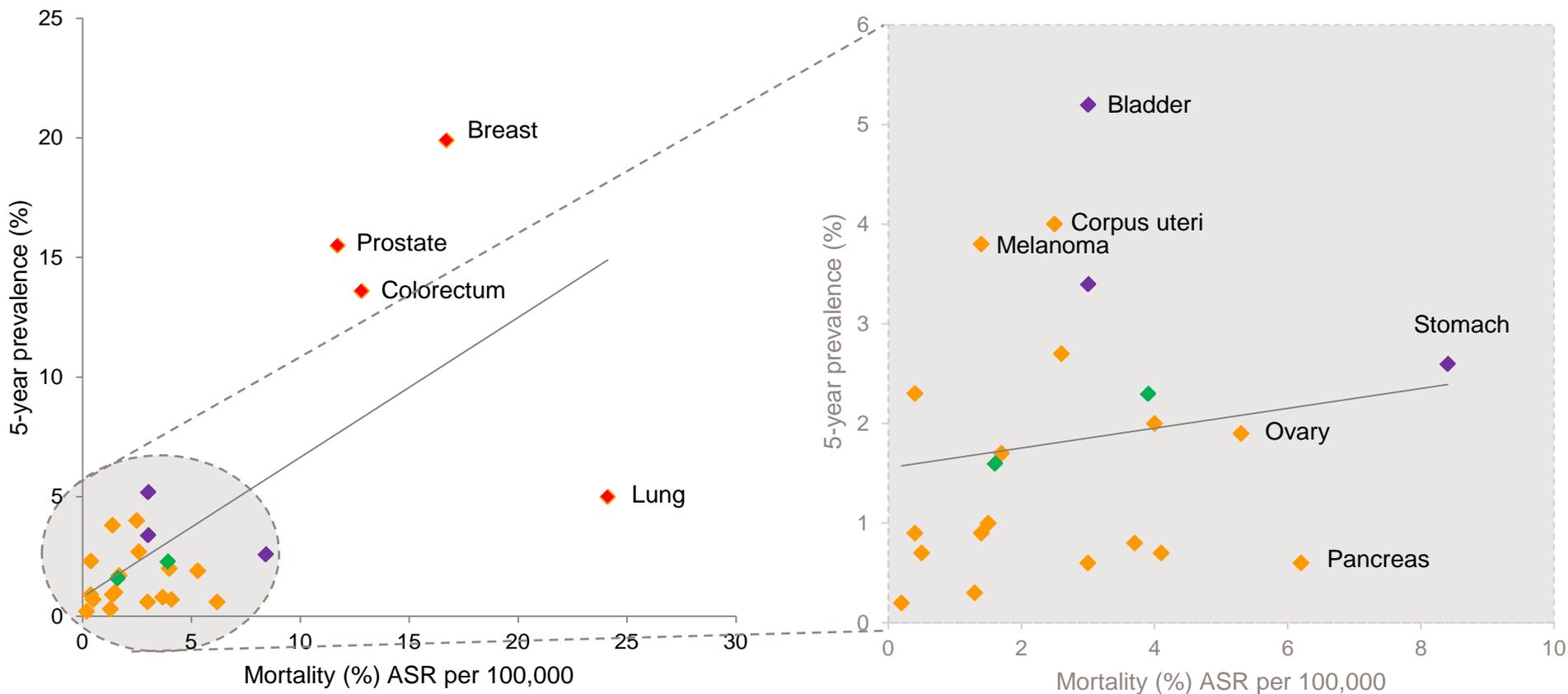
Not all cancers are the same, with varying mortality and prevalence rates in the United States

Volume



Number of Patients

Worldwide prevalence and mortality rates of various cancers



Source: GLOBOCAN 2008: Cancer Incidence and Mortality Worldwide. *International Agency for Research on Cancer*. Retrieved from <http://www.iarc.fr/en/media-centre/iarcnews/2010/globocan2008.php>

The number of oncology drugs intended for use as 1st line therapy options decreased over the past 13 years

Volume



Later Lines of Therapy

2001

2013

*Percent of
oncology drugs
targeting first-line
position*

1L

80%



40%

2L

20%



60%



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

1L = First Line / 2L = Second Line

Source: Haute Autorité de Santé. Opinion on Drugs. Retrieved from <http://www.has-sante.fr/>

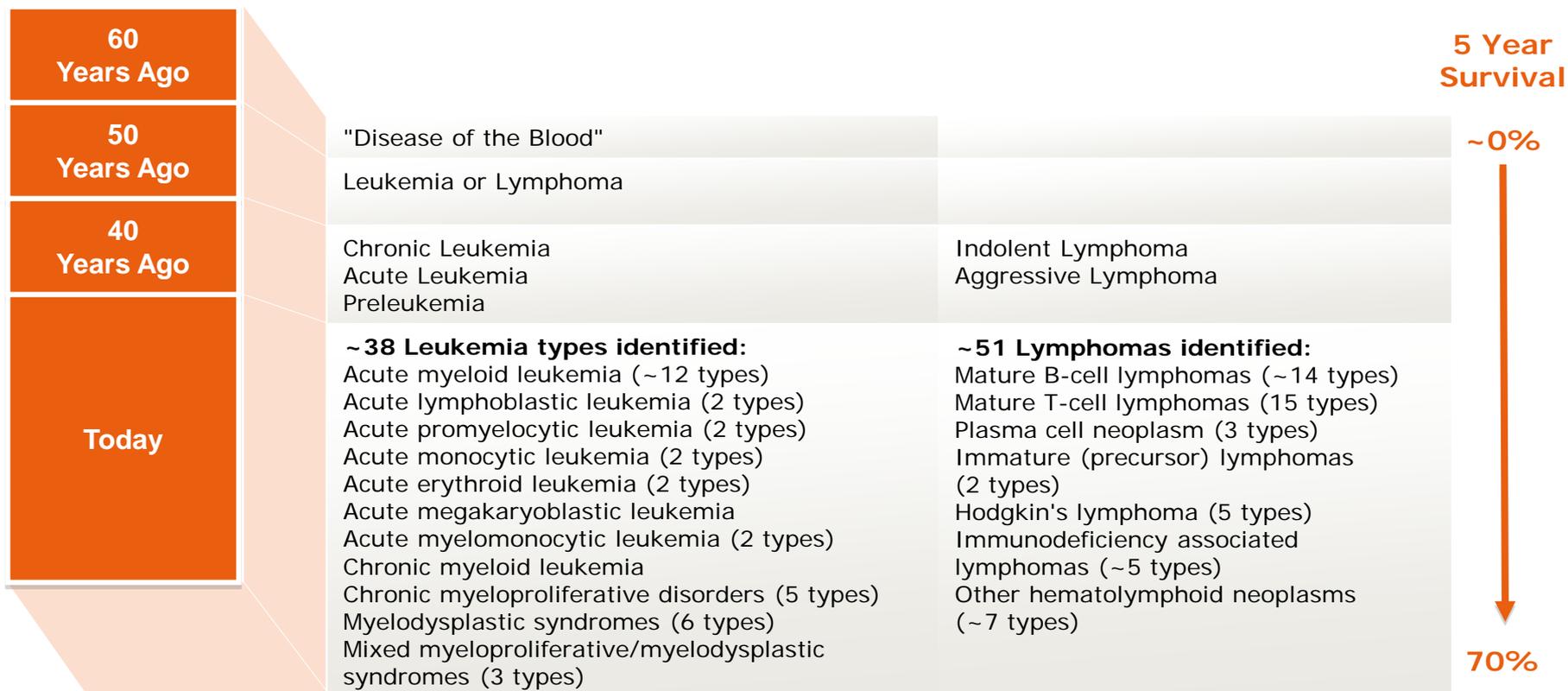


Additionally, cancers have been parsed more finely and indications have become more precise, creating smaller, more targeted patient pools

Volume
Slicing of Indications



The changing landscape of Hematology



Lung cancer has evolved rapidly, defining smaller patient populations

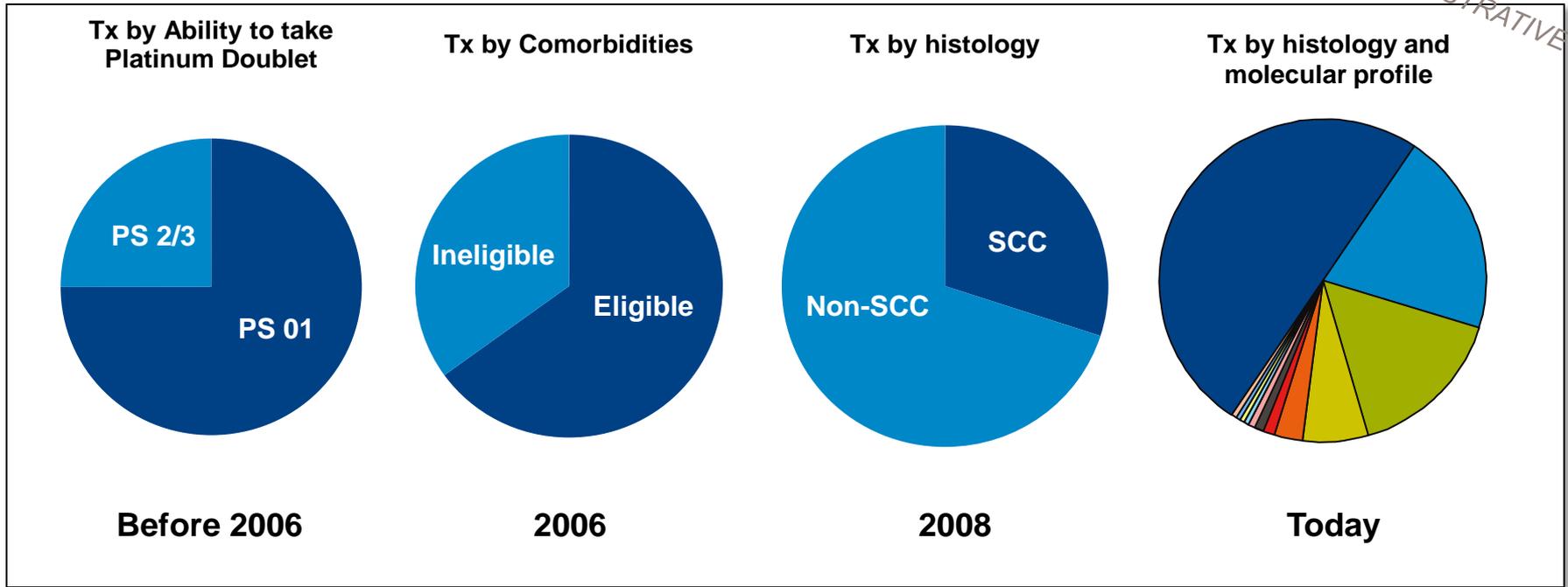
Volume



Biomarkers

The changing landscape of Lung Cancer

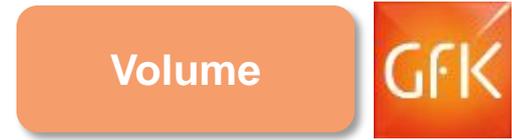
ILLUSTRATIVE



- No mutation detected
- KRAS 22%
- EGFR 17%
- EML4-ALK 7%
- Double mutants 3%
- BRAF 2%
- PIK3CA
- HER2
- MET AMP
- MEK1
- NRAS
- AKT1

Source: Kris MG, et al. ASCO 2011. Abstract CRA7506.

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



2001

2013

Percent of oncology drugs with a companion biomarker

CDx

20% ↑ 40%



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

CDx = Companion Diagnostic

Source: Haute Autorite de Santé. Opinion on Drugs. Retrieved from <http://www.has-sante.fr>

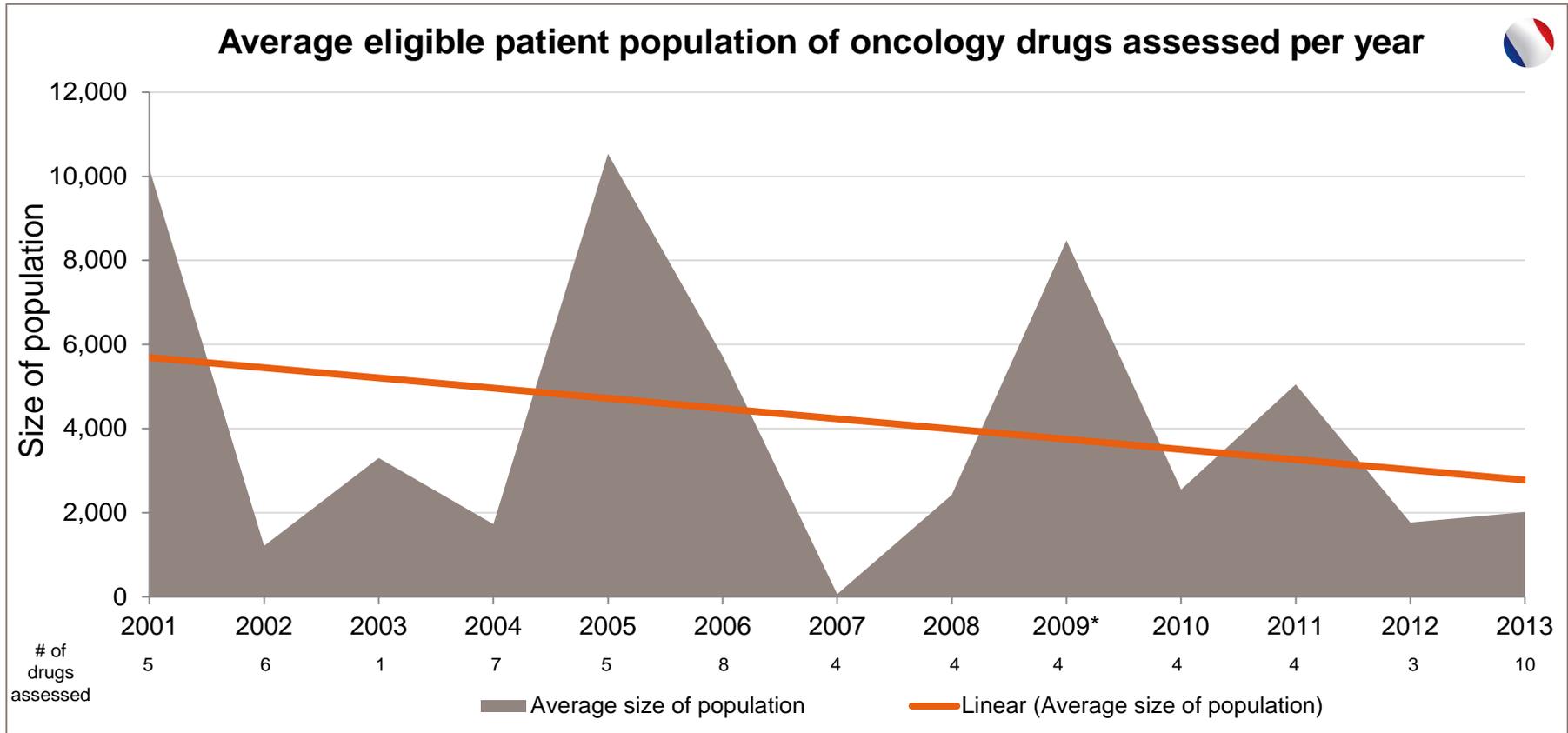


As a result, the average size of the eligible patient population for oncology drugs has been declining

Volume



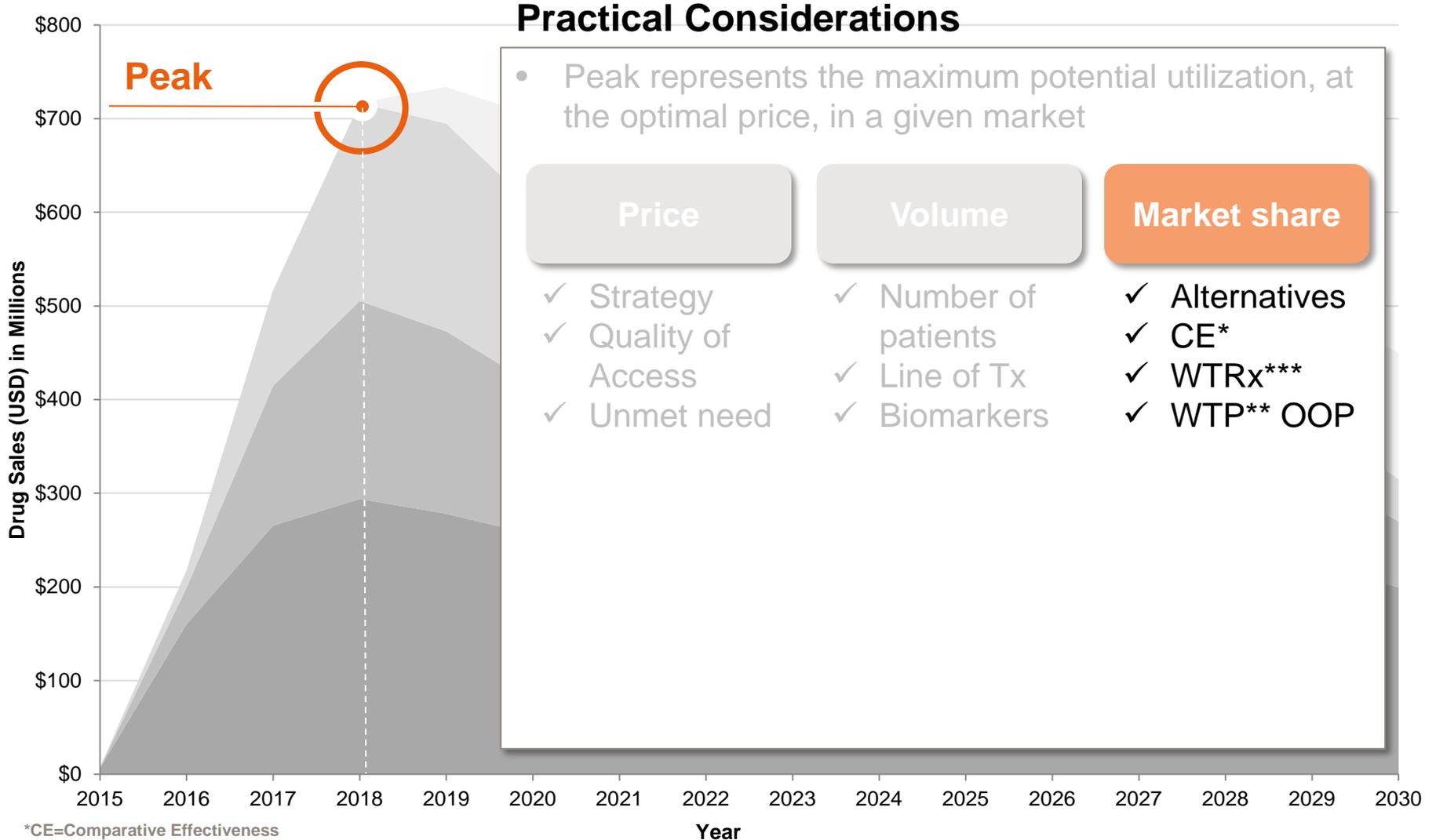
Smaller Populations



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

Source: Haute Autorité de Santé. Opinion on Drugs. Retrieved from <http://www.has-sante.fr/>

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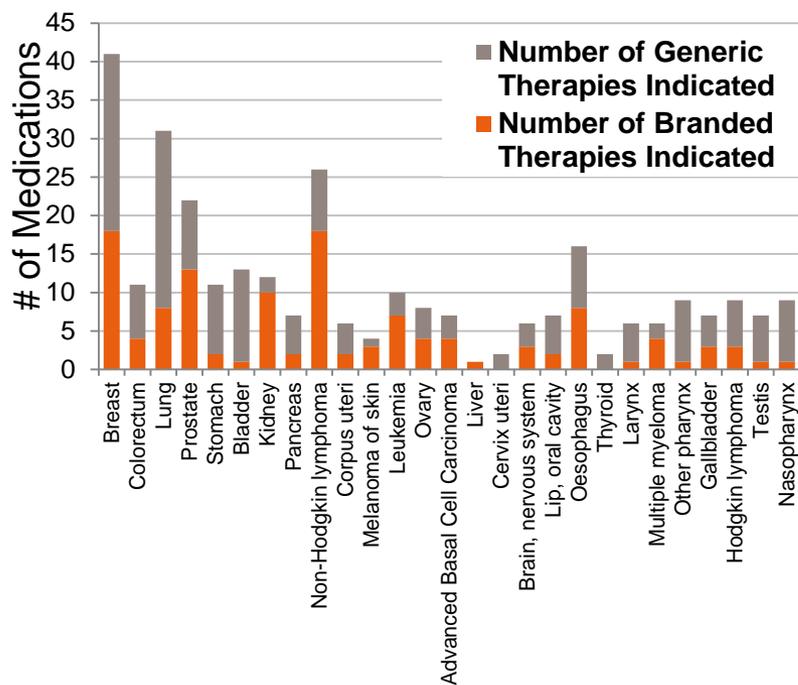
The availability of treatment options for various cancers ranges, with few treatments for some of the most burdensome tumors

Market share

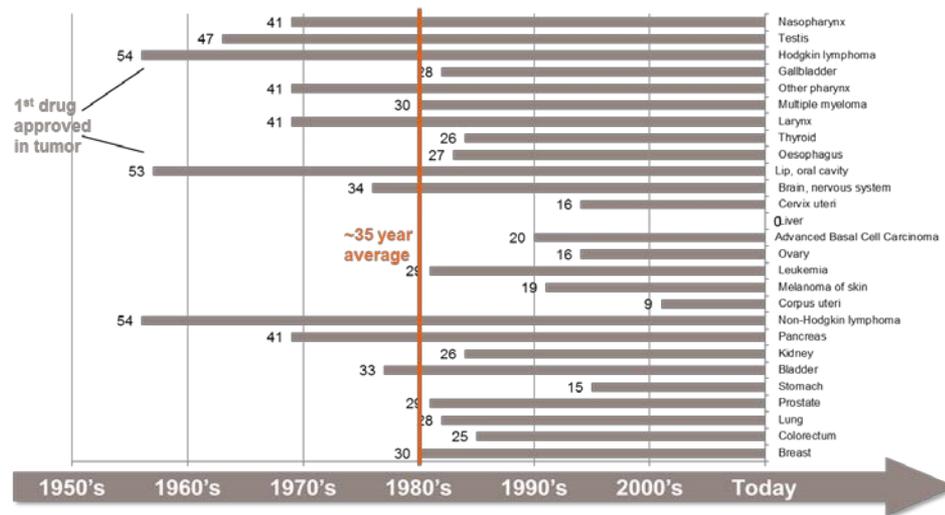


Alternatives

Medications Indicated to Treat Various Cancer Types (Branded & Generic)



Market Maturity: Time between first drug to today (Years from today)



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

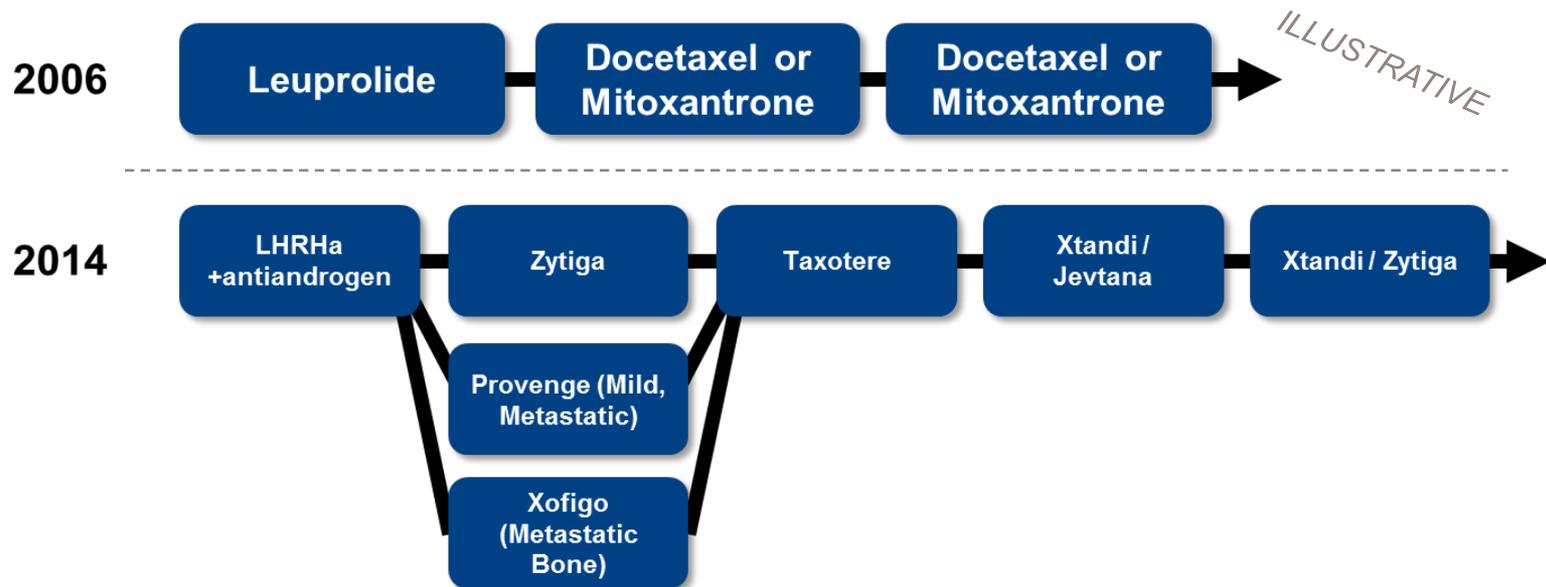
Competitive crowding is already impacting the way manufacturers approach various tumor types

Market share



Alternatives

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

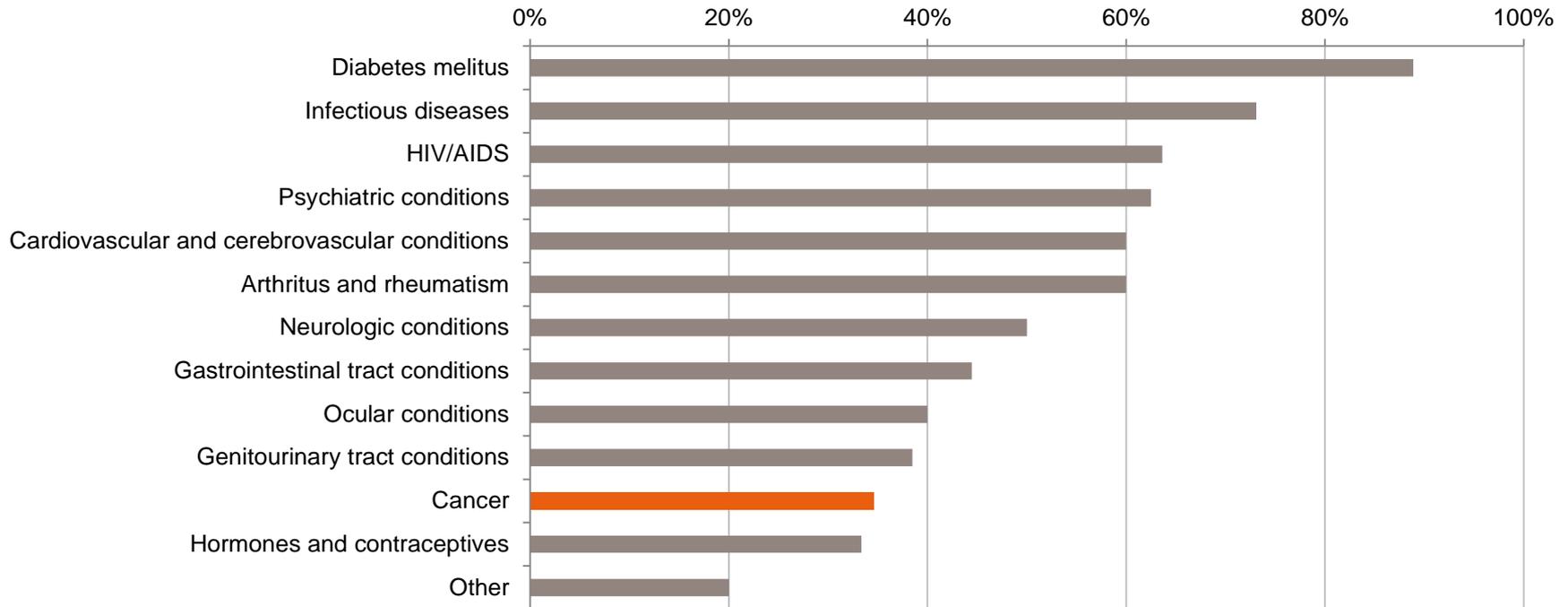
Oncology drugs are seldom brought to market with comparative effectiveness data

Market share



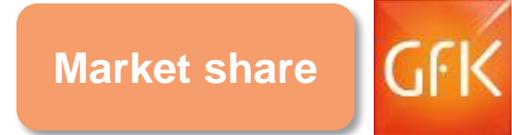
Comparative Effectiveness

Percentage of New Molecular Entities approved with Comparative Efficacy Data Available between 2000 and 2010



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

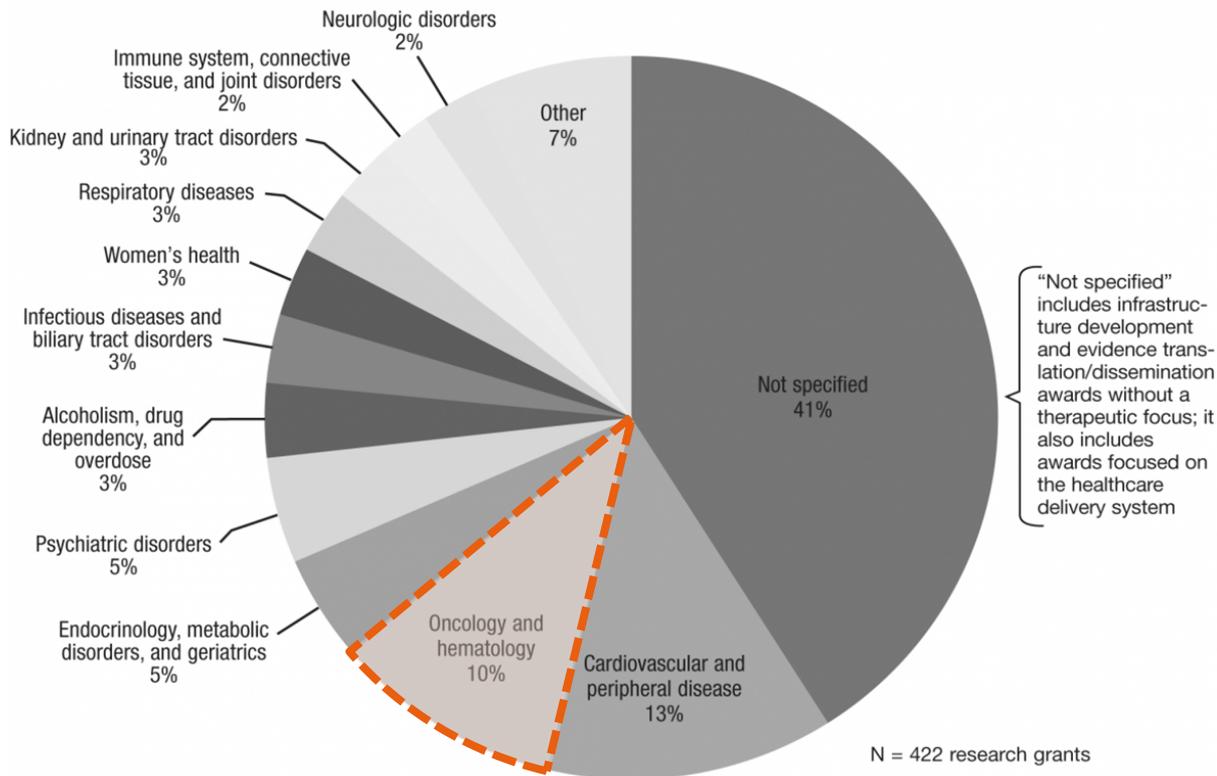
Among awards with a therapeutic focus, oncology research accounted for the 2nd highest number of awards, totaling \$124 million



Comparative Effectiveness



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

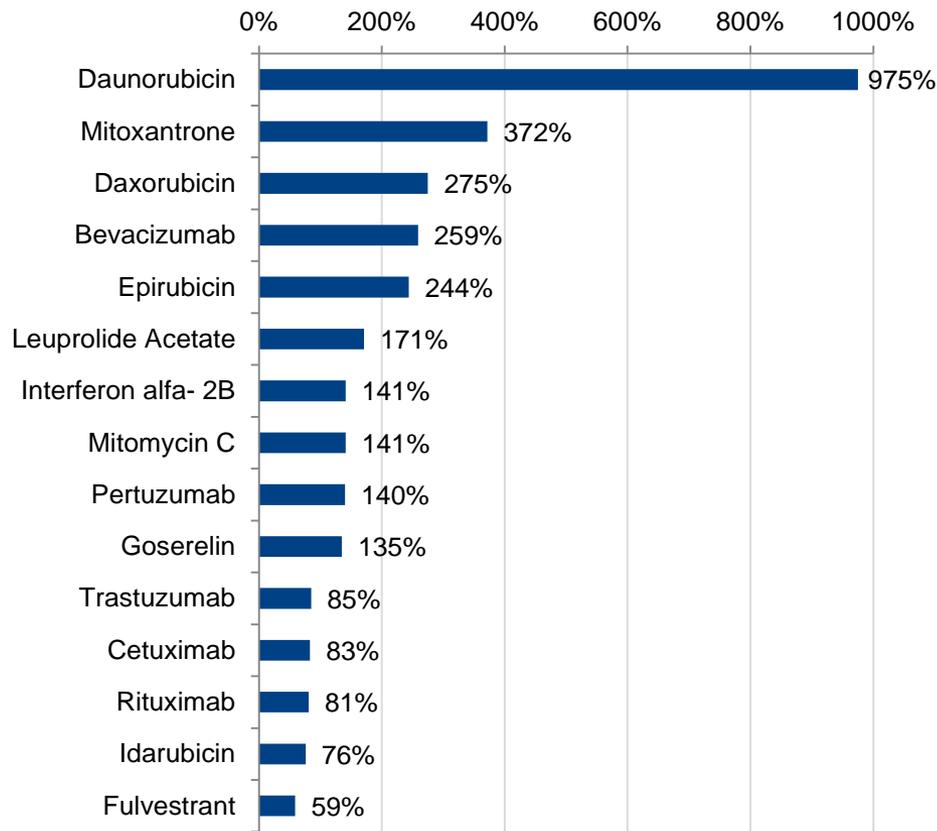
Practices & hospitals are fraught with perverse and conflicting incentives, encouraging a high willingness to prescribe



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

% Increase in Hospital Outpatient Costs over Physician Office Costs



...however, change is afoot

Market share

GfK

Willingness to Prescribe

- 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



The screenshot shows the ASCO website header with the logo and tagline "American Society of Clinical Oncology Making a world of difference in cancer care". Below the header is a navigation menu with links for HOME, ABOUT ASCO, MEMBERSHIP, MEETINGS, ADVOCACY, PRACTICE & RESEARCH, and PROFESSIONAL DEVELOPMENT. The main content area displays a news article titled "ASCO Holds Leadership Summit to Address Value in Cancer Care, Cost of Cancer Drugs and Technologies" posted on January 28, 2014. The article text begins with "The American Society of Clinical Oncology (ASCO) yesterday convened a leadership summit with pharmaceutical representatives, insurance payers, patient advocates, and physicians to initiate a dialogue on the challenge of defining value in cancer care. This meeting was held amid growing concerns about the sustainability of continued increases in the costs of new drugs and technologies used in the diagnosis and treatment of cancer."

"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

Source: ASCO website, www.asco.org

Do Oncologists Believe New Cancer Drugs Offer Good Value?, E.Nadler, *The Oncologist* February 2006 vol. 11 no. 2 90-95

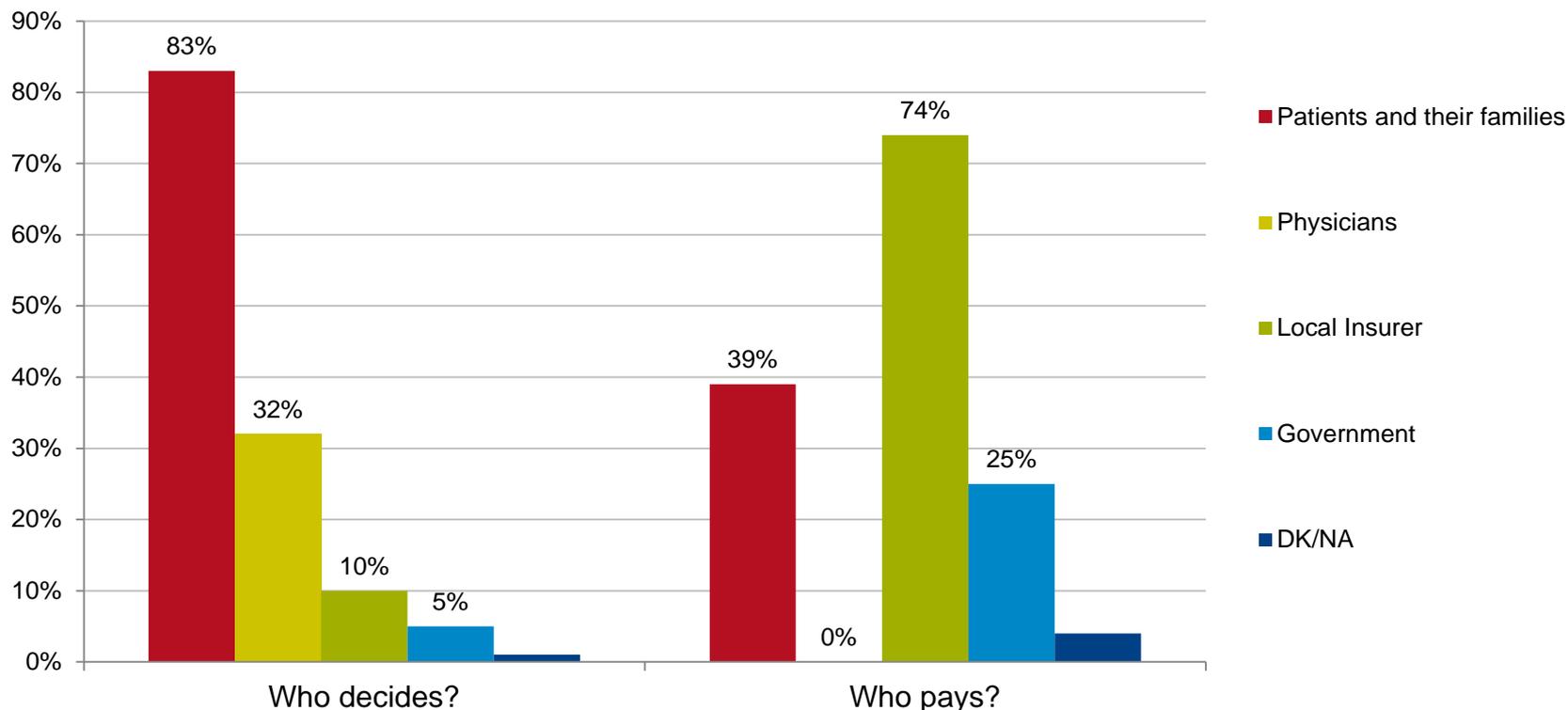
Patients feel vested in the treatment decision process with physicians, while insurers are expected to pay

Market share



Willingness to Prescribe

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



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

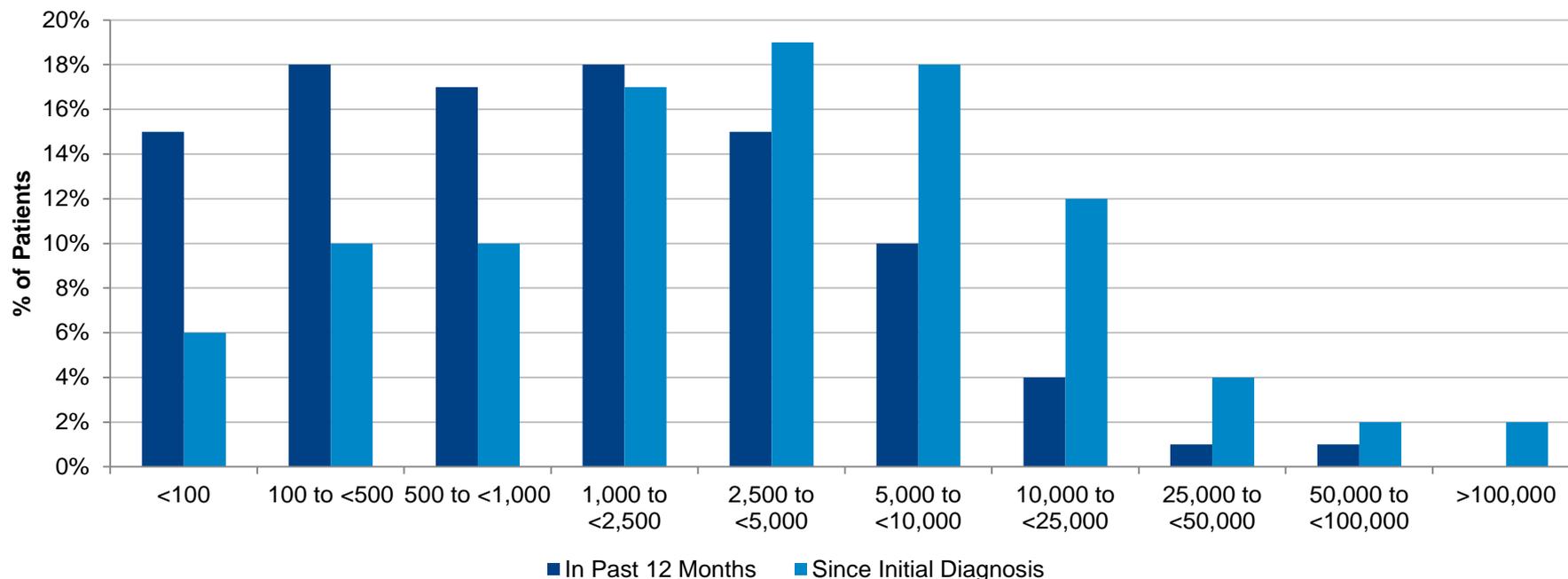
Patient Estimations of costs of treatment midjudge insurance coverage but are often less than \$10,000

Market share



Willingness to Pay (OOP)

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? (\$)



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

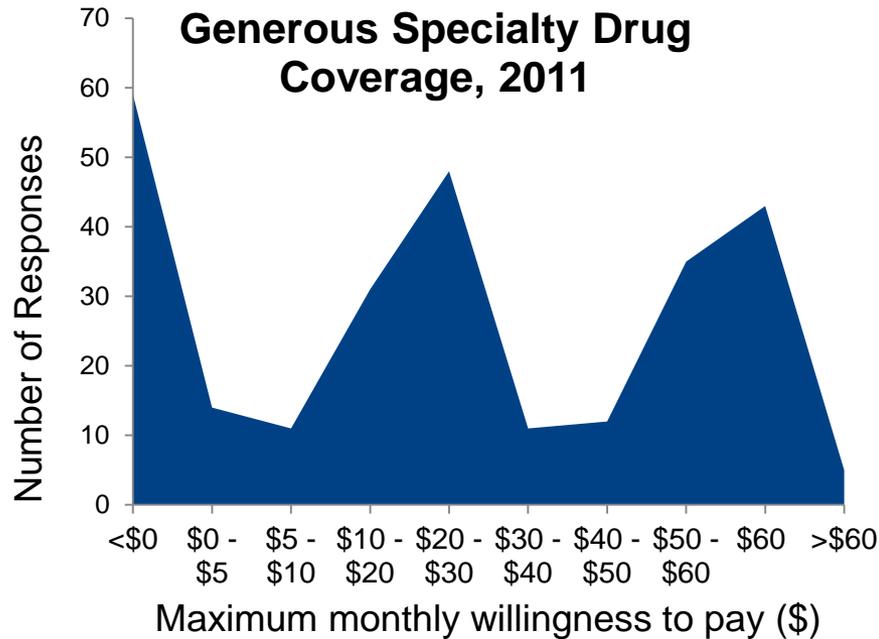
Patients are willing to pay more for generous specialty drug coverage – 50% would pay more than \$25 / mo.

Market share

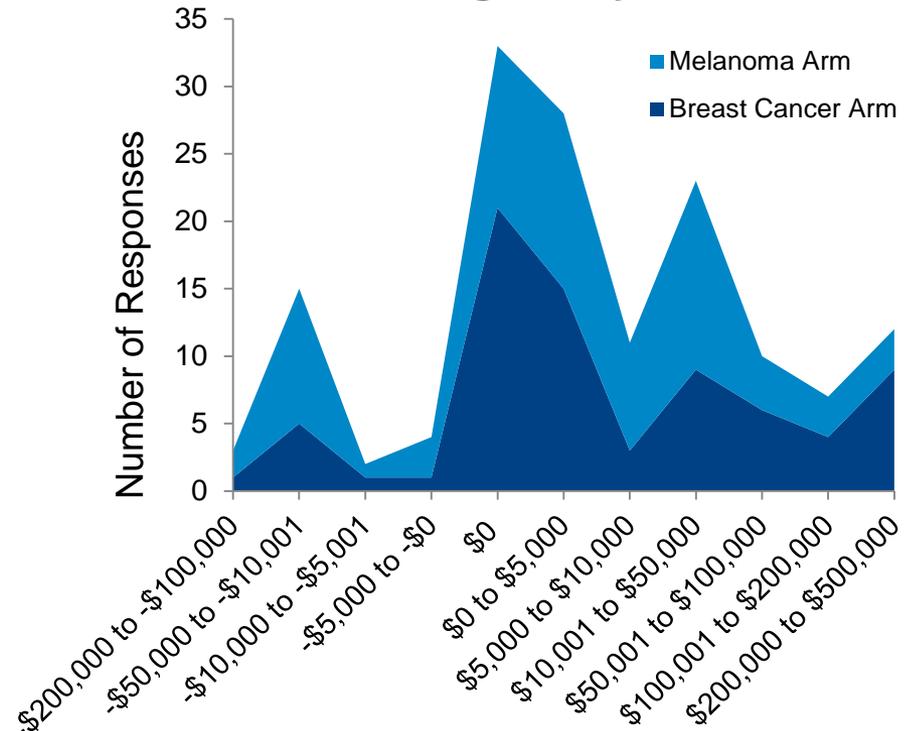


Willingness to Pay (OOP)

Respondents' Maximum Willingness To Pay Per Month For A Health Insurance Plan With A Generous Specialty Drug Coverage, 2011



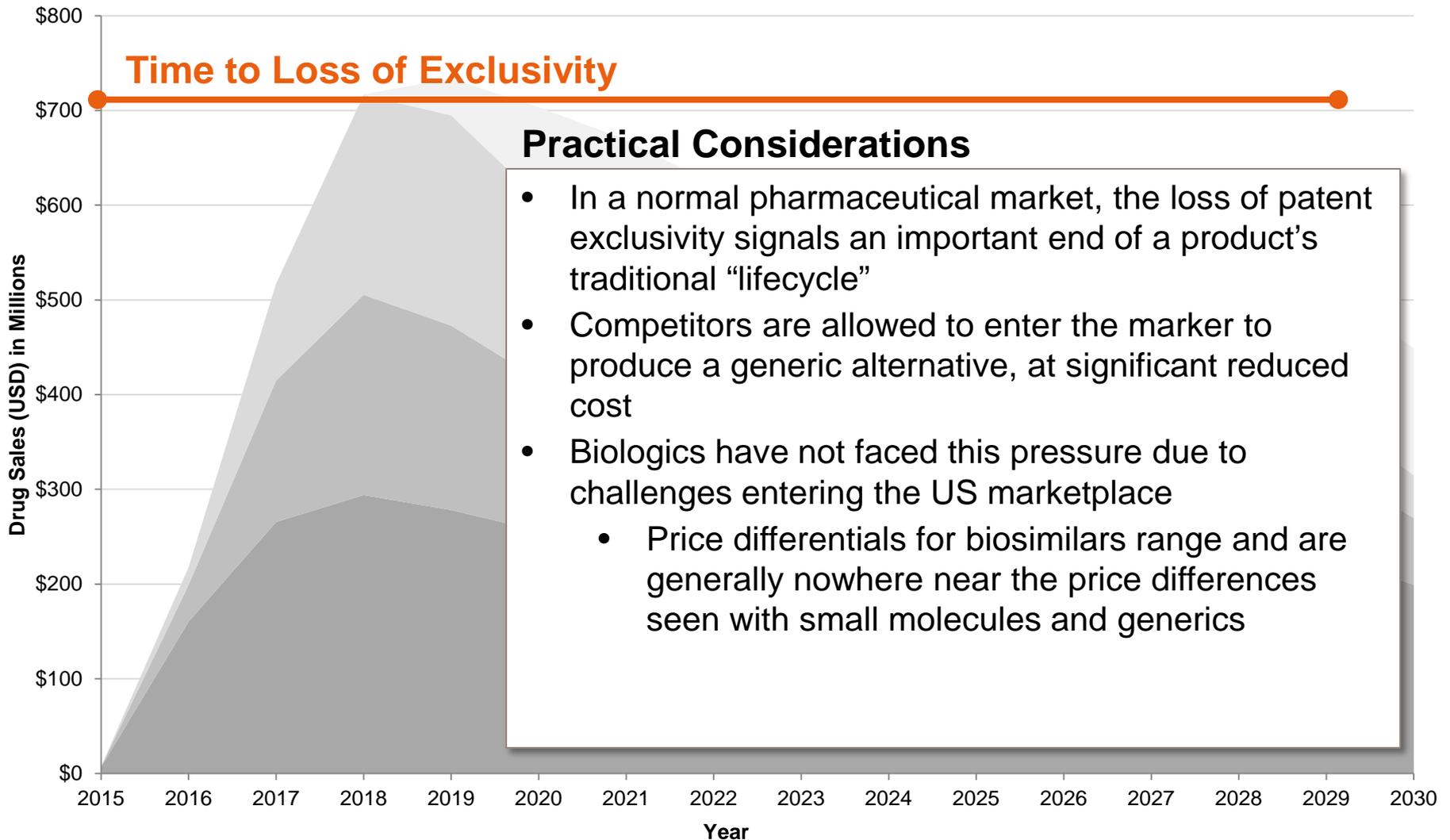
Cancer Patients Willingness to Pay For A Hopeful Therapy, By Dollar Amount Willing to Pay, 2011



▶ 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”

Source: Romley, J., Sanchez, Y., Penrod, J., Goldman, D. (2012) Survey Results Show That Adults Are Willing to Pay Higher Insurance Premiums for Generous Coverage of Specialty Drugs. *Health Affairs* 31, 683-690; Lakdawalla, D., Romley, J., Sanchez, Y., et al. (2012). How Cancer Patients Value Hope and the Implications for Cost-effectiveness Assessments of High-cost Cancer Therapies. *Health Affairs* 31, 676-682

Pricing Levers: Time to Loss of Exclusivity

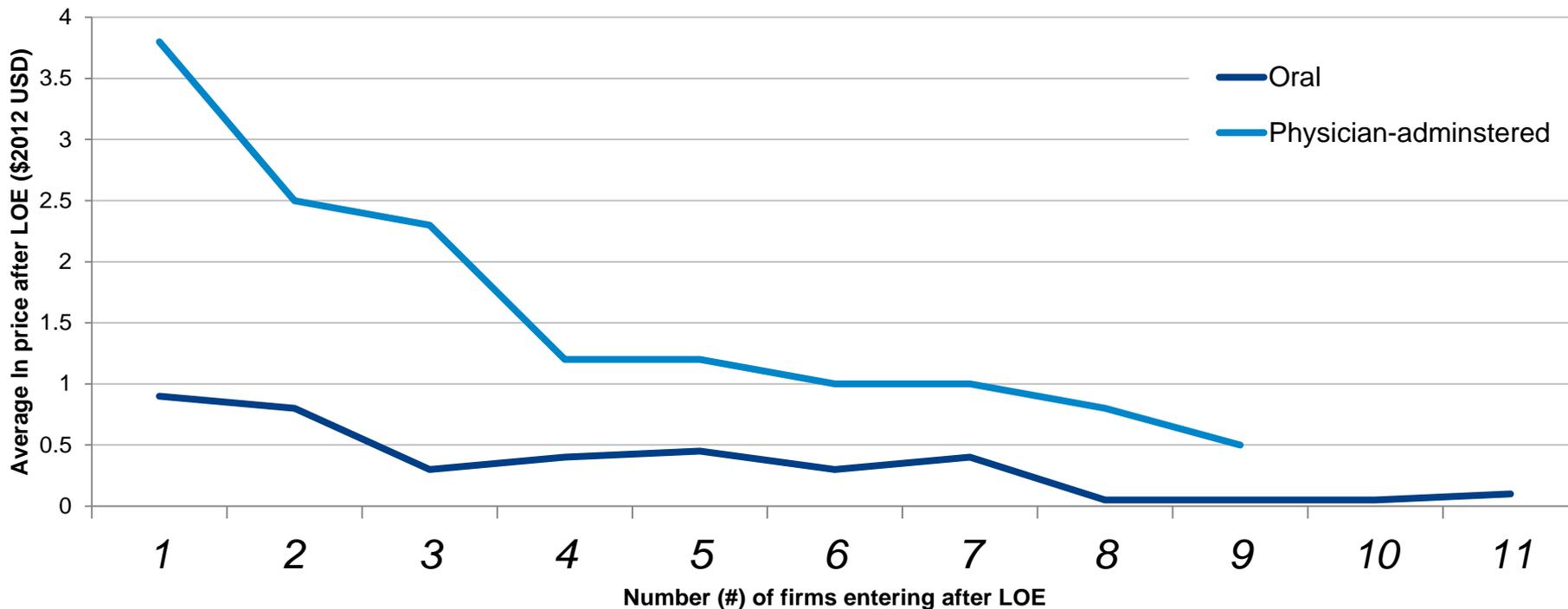


The number of firms competing post-LOE drive the price down

Loss of
Exclusivity



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



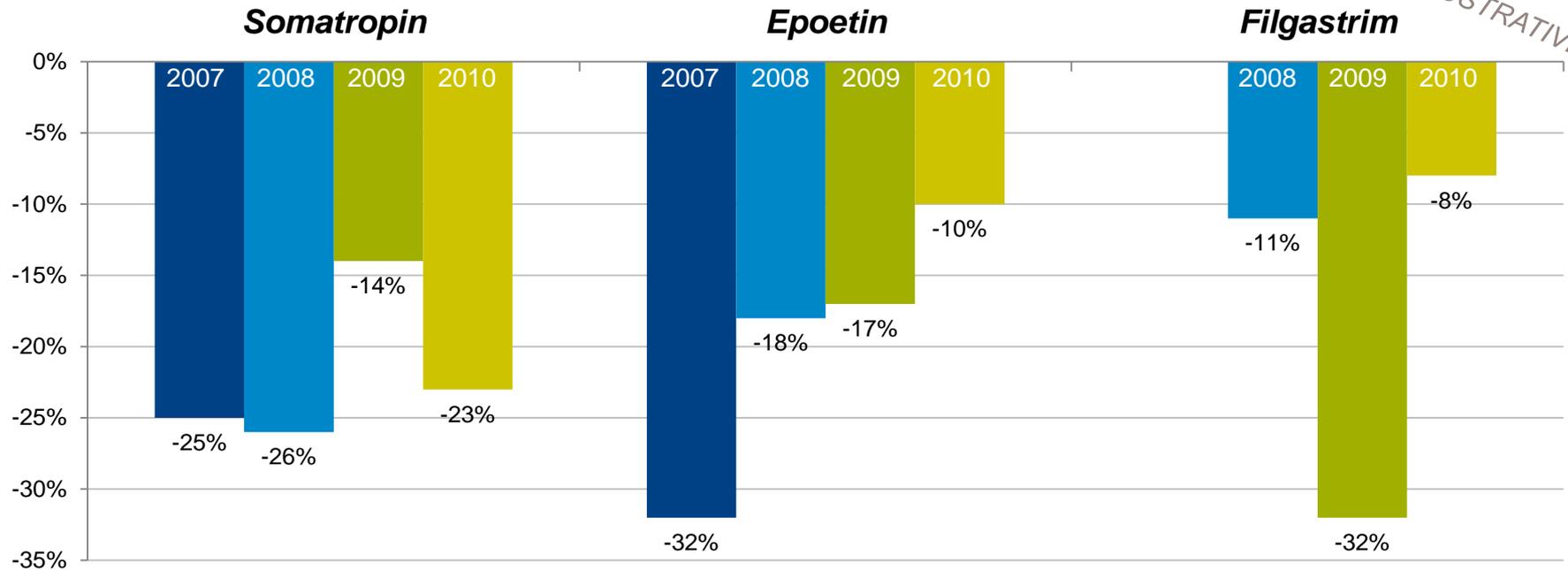
Competition drives down price in order for a manufacturer to secure access

Biosimilar prices in Europe demonstrate savings of 8 to 32% off the prices of originator prices

Loss of
Exclusivity



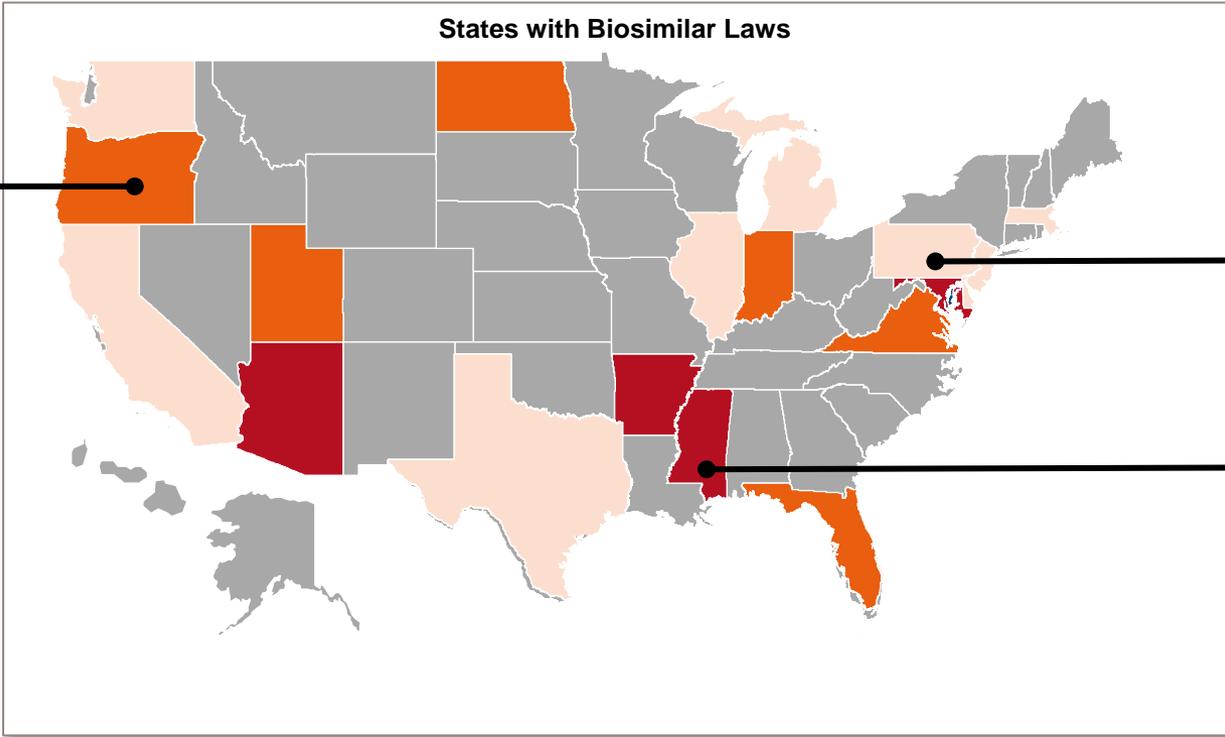
Mean biosimilar - reference product discount (2007-2010)



 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

Loss of
Exclusivity



Laws have passed that outline the biosimilar replacement process

Introduced biosimilar laws are under review

Proposed laws have been defeated

 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

Source: Karst, K. (2013) Biosimilars State Legislation Scorecard. Retrieved from http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2013/09/biosimilars-state-legislation-scorecard.html

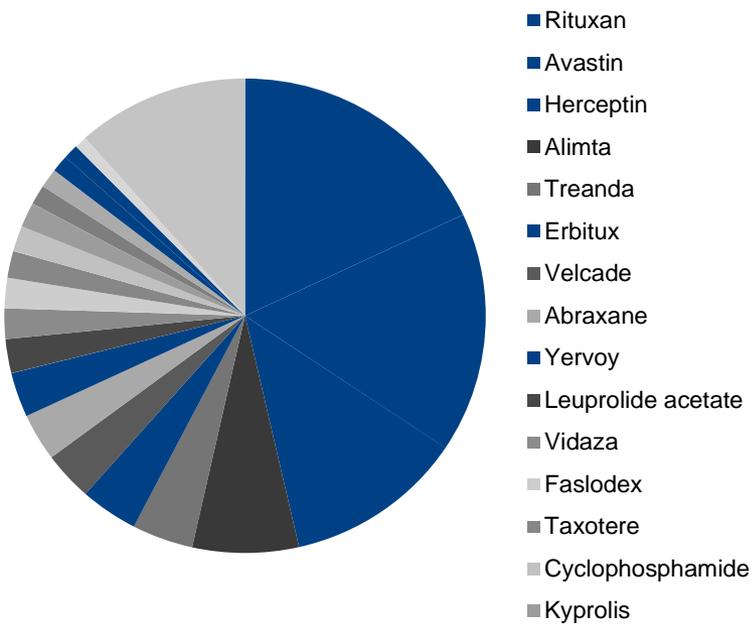
Biologic oncology drugs dominate the clinic expenditures

Loss of Exclusivity



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

Top 20 Antineoplastic Drug Expenditures in Clinics 2013



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

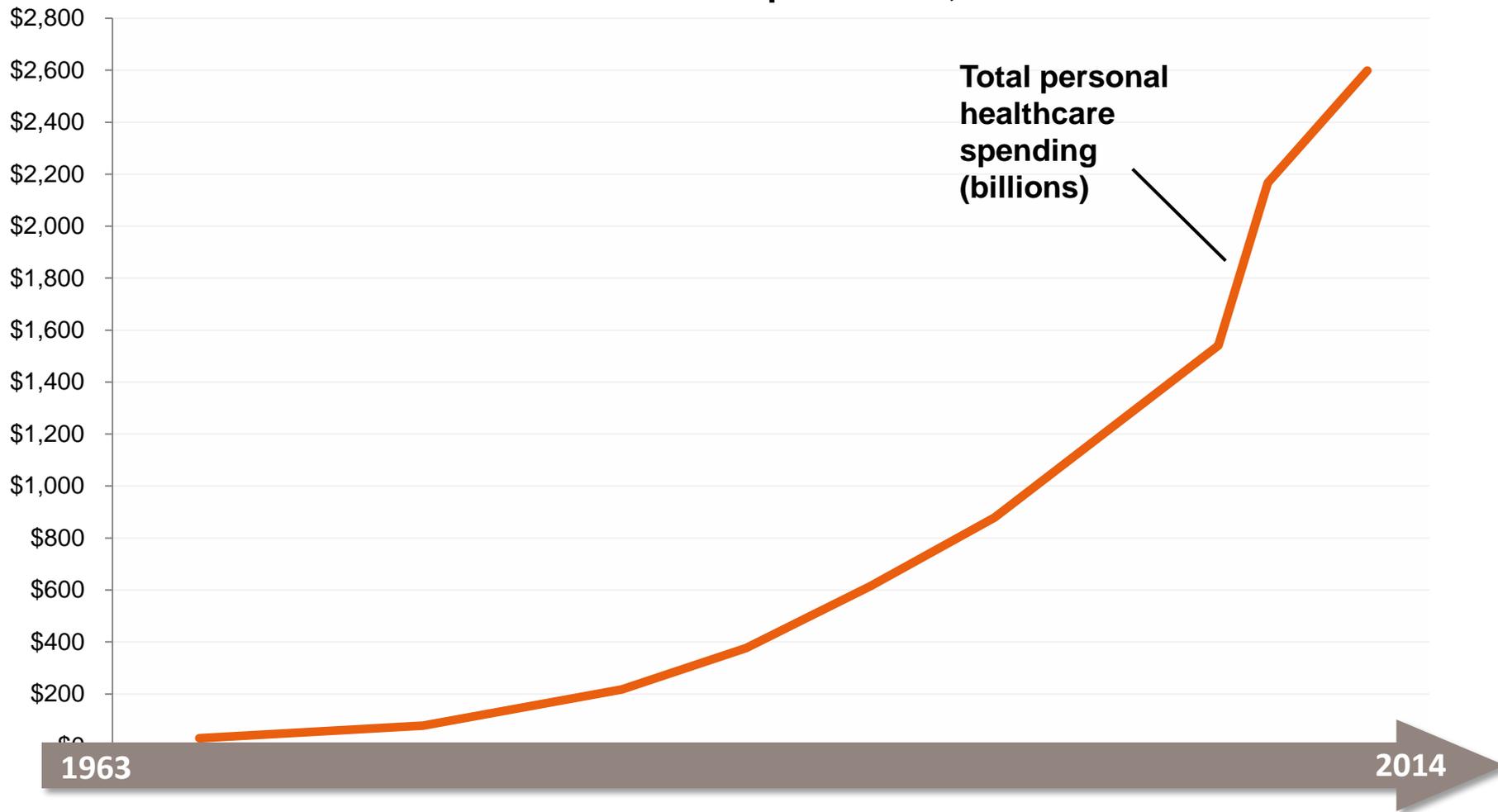
Source: Doloresco F, Fominaya C, Schumock GT, et al. (2014) National Trends in Prescription Drug Expenditures and Projections for 2014. American Society of Health-System Pharmacists. Retrieved from <http://www.ashpmedia.org/AJHP/DrugExpenditures-2014.pdf>

Crisis! (?)

US healthcare spending has been growing



National healthcare expenditures, 1963-2010

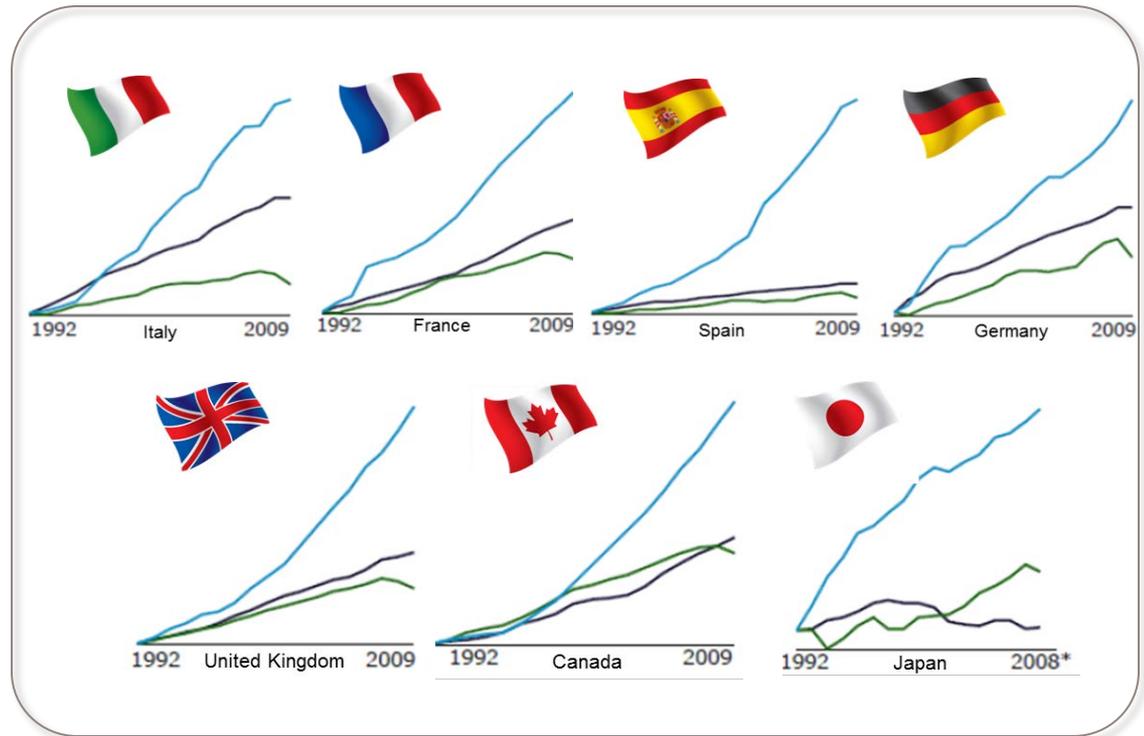
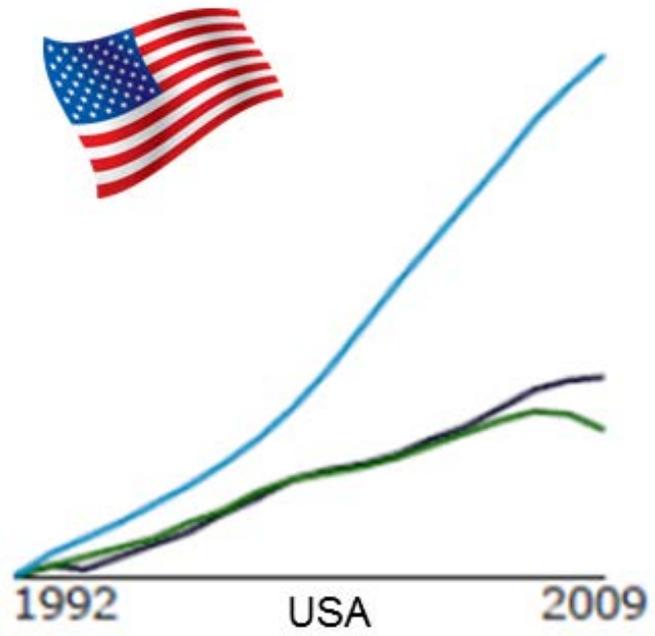


Source: Cancer Trends Progress Report, 2011-12 Update. *National Cancer Institute*. Retrieved from <http://www.cancer.gov/>

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



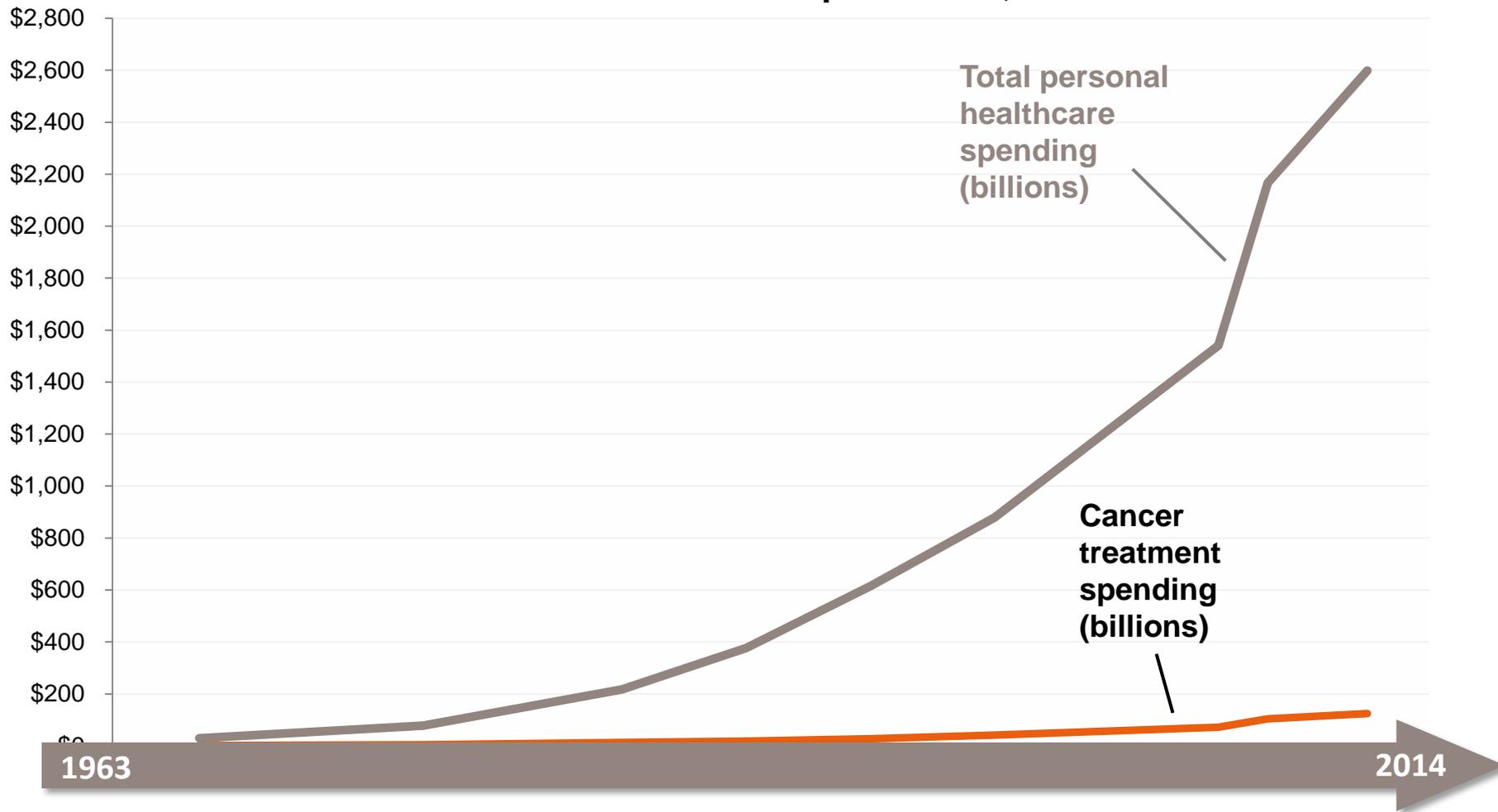
- Healthcare Spend
- Wages
- Real GDP

Source: Economist Intelligence Unit (EIU) (2011) Retrieved from <http://www.eiu.com/home.aspx> OECD Health Data (2011) Retrieved from <http://www.oecd.org/health/>
Walsh, K. (2013) Biosimilars' Utilization and the Role Payers do Play in Driving Uptake in Europe: An Industry Perspective. *Biosimilar Medicines 11th EGA International Symposium*, April 2013. Retrieved from <http://www.sandoz-biosimilars.com/cs/www.sandoz-biosimilars.com-v3/assets/media/shared/documents/presentations/Ken%20Walsh%20EGA%20Annual%20Meeting%202013.pdf>

Cancer still remains a small piece of total health spending



National cancer treatment expenditures, 1963-2010

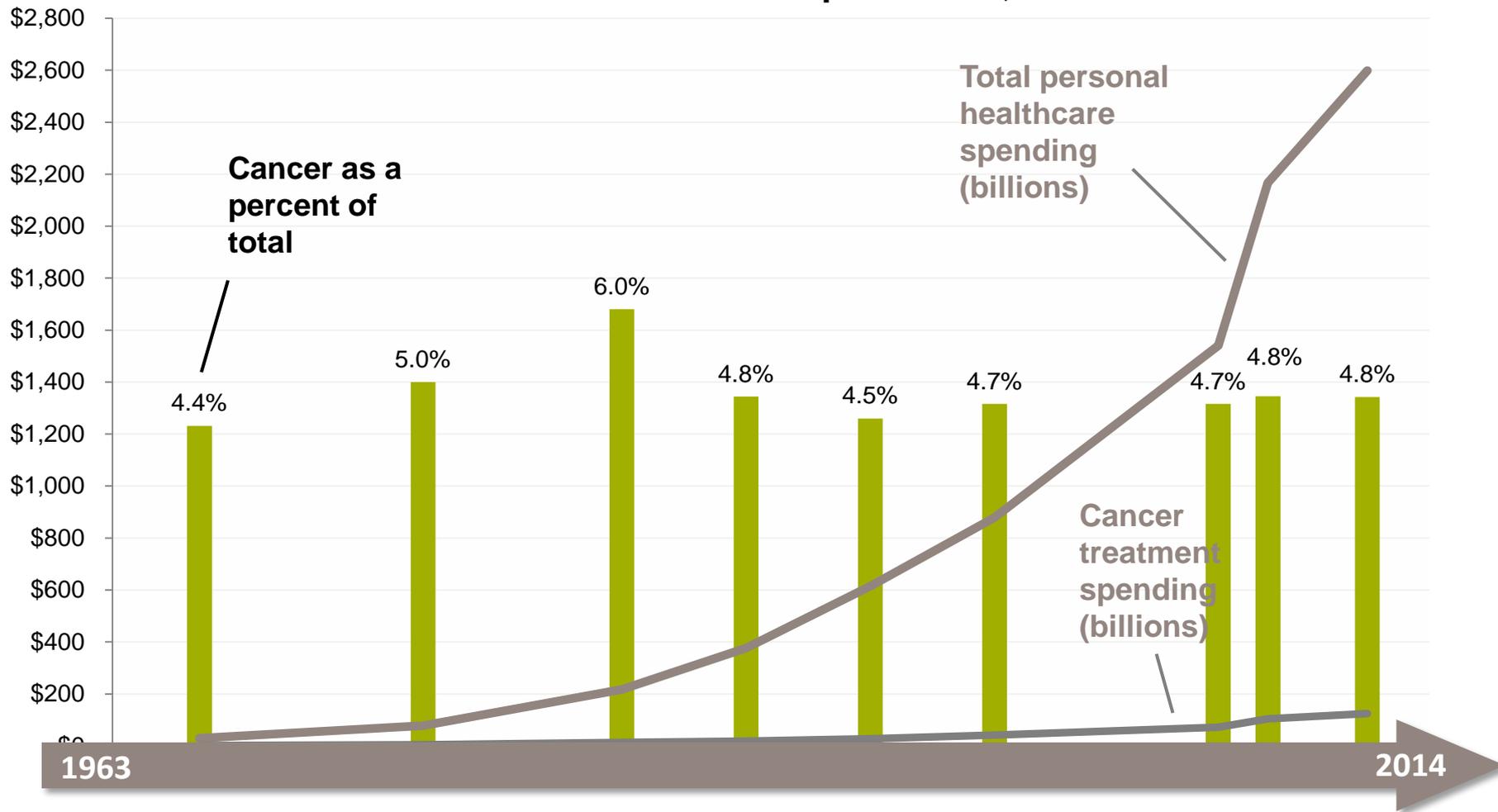


Source: Cancer Trends Progress Report, 2011-12 Update. *National Cancer Institute*. Retrieved from <http://www.cancer.gov/>

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

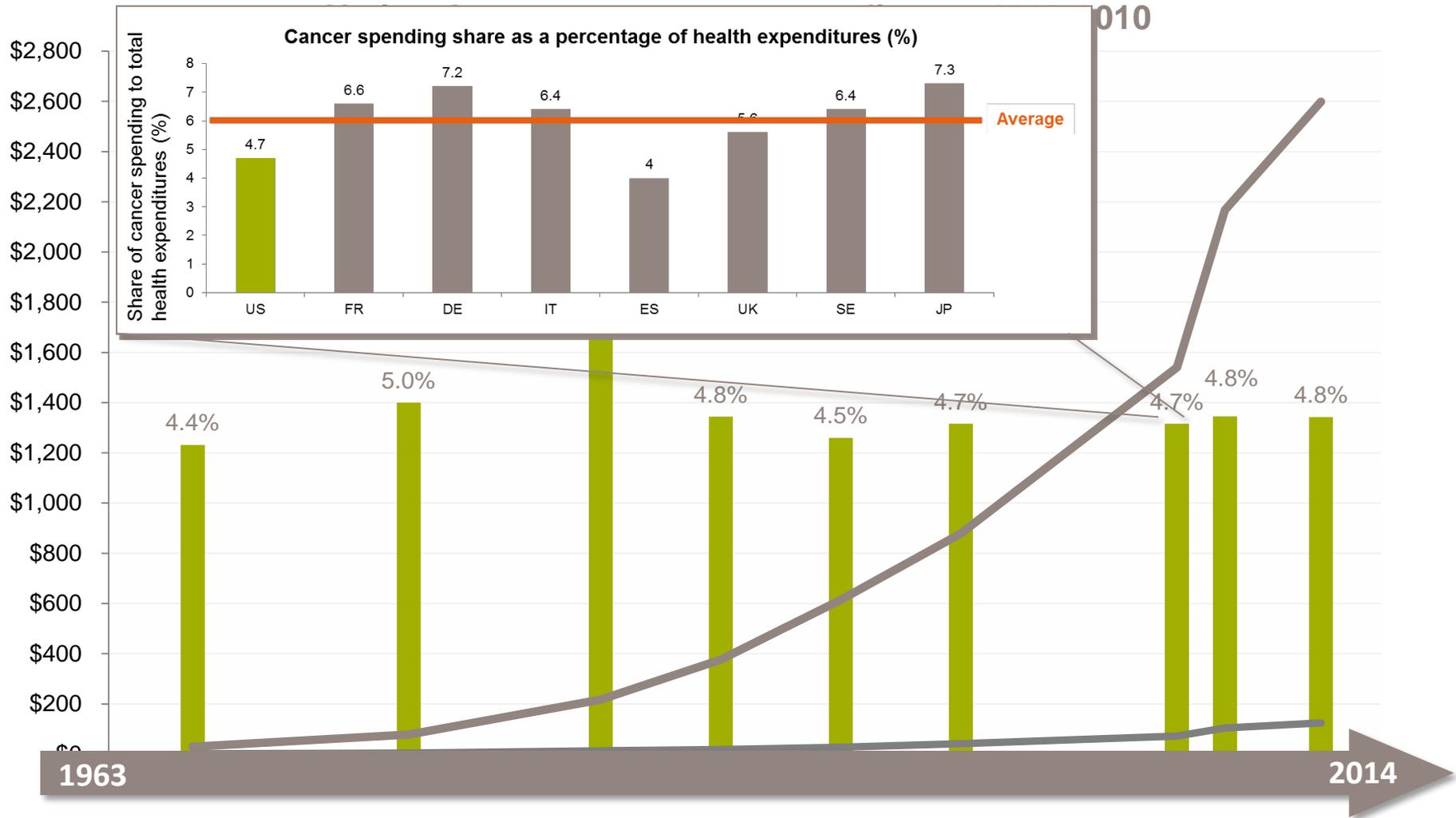


National cancer treatment expenditures, 1963-2010



Source: Cancer Trends Progress Report, 2011-12 Update. National Cancer Institute of the National Institutes of Health. Retrieved from <http://www.cancer.gov/>

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

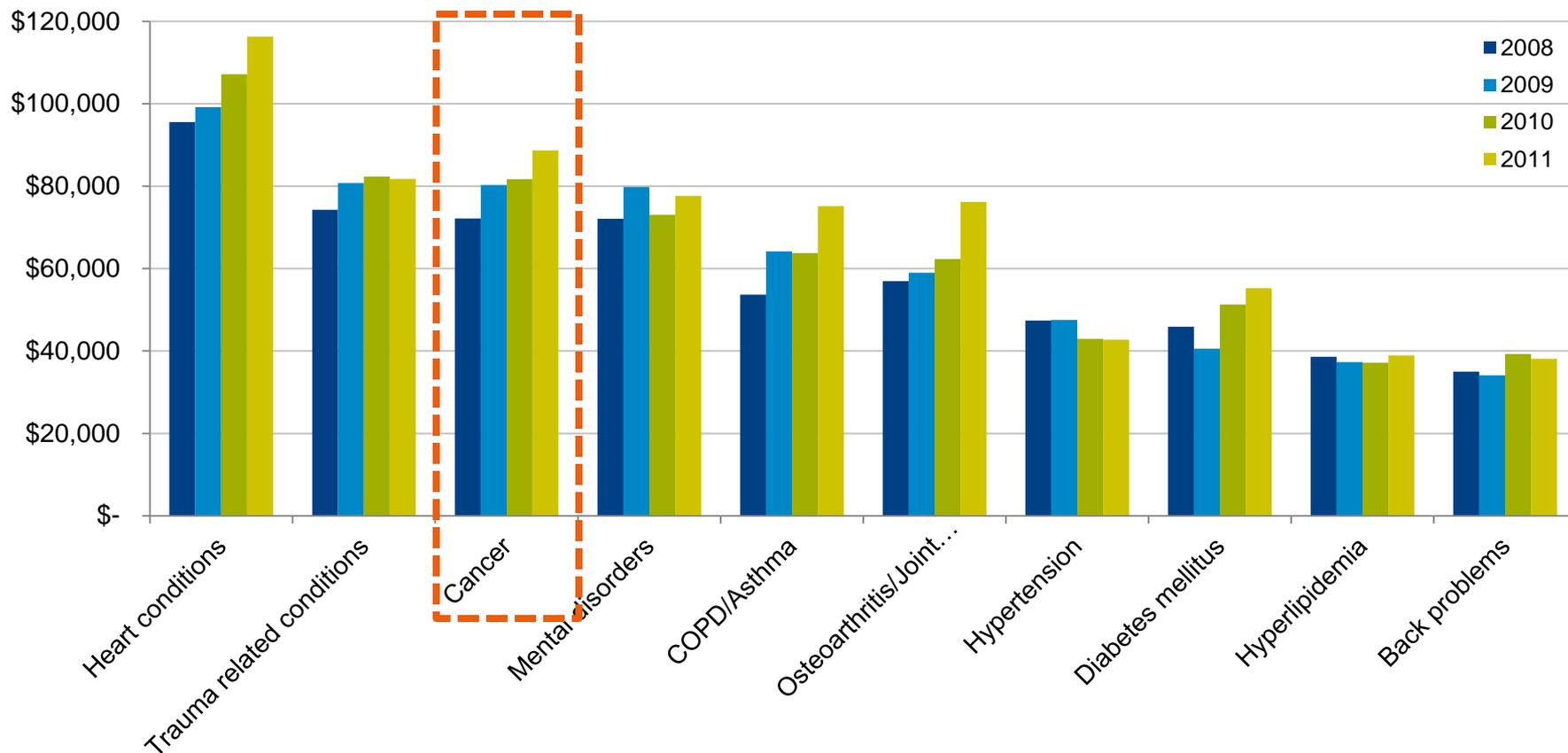


Source: Cancer Trends Progress Report, 2011-12 Update. National Cancer Institute of the National Institutes of Health. Retrieved from <http://progressreport.cancer.gov/>
 Hogberg, D. (2011) Journal of Public Health and Epidemiology

Top 10 costly conditions from 2008-2011



Total expenses (in \$millions) for top 10 costly conditions, 2008 - 2011



Source: Household Component of the Medical Expenditure Panel Survey (2008). Center for Financing, Access, and Cost Trends, AHRQ. Retrieved from http://meps.ahrq.gov/survey_comp/household.jsp

“The sky is falling!”



2014

...but it started a long time ago



The New York Times

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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.



1988

2014

...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



1971

2014

...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, 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.

1966

The New York Times

The Troubling Cost of Drugs That Offer Hope

SAN FRANCISCO, Feb. 8 — The Anesthetist Pharmaceutical Company introduced a major drug in October for the third time during the past 10 months, using the tactic of limited supply. The price increase of the new drug, which is usually obtained only when the hospital would require extra supplies or other unusual drug treatments.

There was one catch: The high-priced drug costs five to eight times as much as other 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.

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 \$25 for a basic physical checkup, today it charges \$85. In those same years the going rate for an appendectomy in New York rose from \$48 to \$1,175 and the cost of an average hospital stay,

costs, at a time when accumulated inflation has swollen most economic indicators, are straggling. This year Americans—through their own pocketbooks, their Federal, state and local governments, and their health insurance companies—will spend almost \$50 billion for



2014

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



DRUG PRICES HERE HELD INEQUITABLE

Citizens Group Urges New Congressional Hearing

By EDWARD C. BURKS

A citizens group charged yesterday that prescription drug pricing here is so unfair and mystifying that the public often pays a high price when the identical drug is available at a fraction of the cost.

After a spot survey of three drugs in 12 Manhattan areas, the Citizens Committee for Metropolitan Affairs, Inc., reported that highly expensive brand names are promoted by vigorous advertising campaigns designed to make physicians favor them. These brands can cost as much as four or five times the identical nonbrand-

1965

Dilemma in Health Care: Rising Cost and Demand

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The New York Times

The Troubling Cost of Drugs That Offer Hope

SAN FRANCISCO, Feb. 8—The Annual Pharmaceutical Congress introduced a major drug in October for the third time during before the Senate subcommittee on the health care bill. The price of the drug, \$110, is usually obtained only when the hospital would contract with the supplier or other financial arrangements.

There was one catch: The high-tech drug costs five to eight times as much as other versions, bringing the cost of a year's supply to more than \$10,000. That puts the drug out of the reach of many patients for whom it is a matter of life and death.



2014

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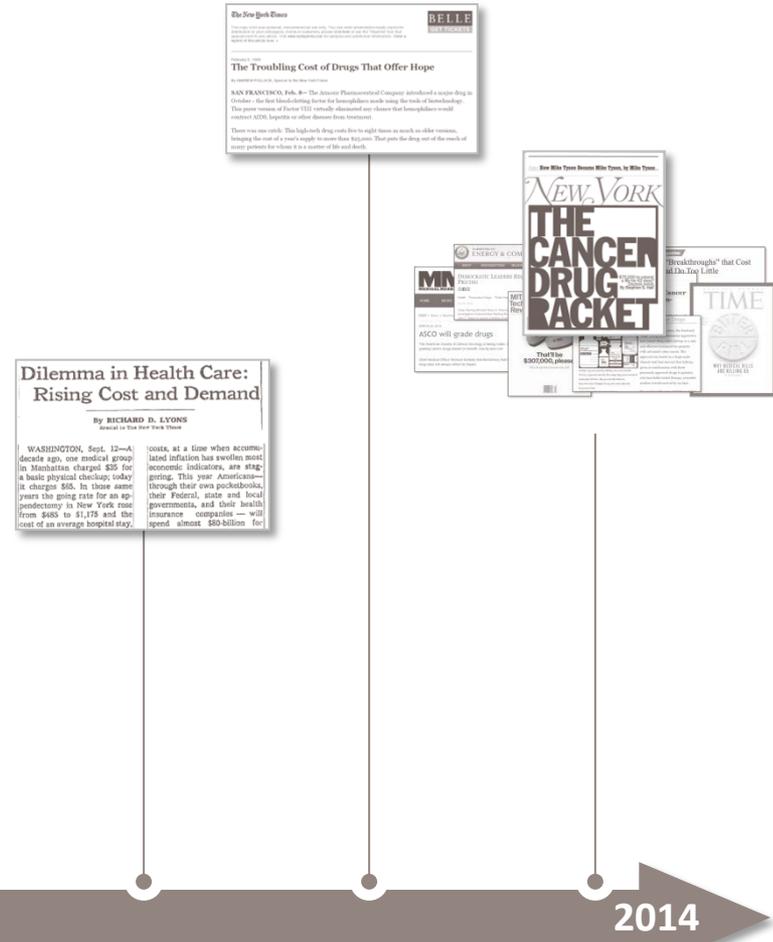


**Kefauver Seeking Anew
To Reduce Drug Prices**

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

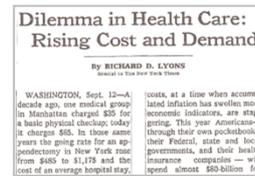
Sen. Estes Kefauver (D-Tenn.) wound up hearings on the pricing of some so-called wonder drugs yesterday and charged that evidence "clearly shows" Americans are being required to pay too much for them.

Kefauver closed hearings of his Senate Antimonopoly Subcommittee after investigators reported that Upjohn Co. bought female sex hormones for 14 cents a gram and sold

tablet while charging U. S. customers \$17.90.

Upjohn defended the pricing practices which subcommittee counsel Rand Dixon had described.

The drug company head was also asked why Upjohn sold bulk quantities of the arthritis drug to another manufacturer at a price 14 times less than that charged druggists for the finished product. The female sex hormones



1959

2014

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Americans, World's No. 1 Pill Takers, Feel They Pay Too Much for Drugs

By Roger D. Greene
Associated Press

Americans are the world's greatest pill takers. They pay nearly \$50 million a year to swallow about 53 million aspirin a day. They gulp nearly \$230 million worth of vitamin capsules annually.

They order almost 400 million prescriptions a year at a cost of nearly a billion dollars.

That's a big bill. So big, in fact, that a great many Americans are complaining about its size.

Surveys show that from 64 to 71 per cent of all drug customers think they're paying too

example, they point to the fact that six companies gambled millions of dollars to mass produce a polio vaccine before they knew the result of mass tests.

Because of such expensive activities, the industry contends, today's prescription dollar is worth more than ever.

\$10 a Year Per Capita

Theodore G. Lumpp, president of the National Pharmaceutical Council, says the average per capita cost of drugs is about \$10 a year, compared with \$55 for alcoholic beverages, \$32 for tobacco and \$11 for auto repairs.

Is the druggist getting rich?

A survey by Eli Lilly & Co., one of the leading United States drug manufacturing firms, noted that the average retail druggist has an income of \$12,825 a year. But he usually works long hours, including Sundays and holidays.

By comparison, the United States Department of Commerce says the average physician has an income of \$12,518, the average lawyer \$9,375 and the dentist \$7,743.

With the drug industry growing swiftly, the agency is hard pressed to police it efficiently. Larrick says, adding: "We have



1955

2014

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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

DRUG PRICES HERE HELD INEQUITABLE

Citizens Group Urges New Congressional Hearing
By EDWARD C. BURKS

A citizens group charged yesterday that prescription drug pricing here is so unfair and inequitable that the public often pays a high price when the identical drug is available at a fraction of the cost. After a rapid survey of three drugs in 12 Manhattan streets, the Citizens Committee for Metropolitan Affairs, Inc., today urged Congress to hold a hearing on the matter.

By Roger S. Green
Americans are the world's largest drug market. They pay more for their medicine than any other people in the world. The reason is not that they are sick more often, but that the drug companies charge them too much for their medicine.

10,000% Drug Mark-up Cited

By Patricia Higgins
Drug Price Increases

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."

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 \$25 for a basic physical checkup, today it charges \$85. In those same years the going rate for an appendectomy in New York rose from \$48 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 \$50 billion for

The Troubling Cost of Drugs That Offer Hope

By Patricia Higgins
Drug Price Increases
SAN FRANCISCO, Feb. 8.—The Annual Pharmaceutical Congress introduced a major drug in October. But the blood-drawing tubes for the new medicine made using the method of blood-drawing. The price of the tubes of the new medicine was \$100,000. The price of the tubes of the old medicine was \$100. The price of the tubes of the new medicine was \$100,000. The price of the tubes of the old medicine was \$100.



1947

2014

...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 \$20. 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 \$35 to \$40, is now \$150 per 75 pound flask. Permanganate of potassium, 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 20 percent higher, and continues to go up. Camphor is 50 percent higher than two years ago.

...all mercury-iodine spirals in the drug field by manufacturers to go up. The reason for the rise is that the public is given of "higher eyes of this and labor" sounds too low in view of the fact that some manufacturers are giving the greatest profit ever. The prices given by NAM in the "line" were ever since by now the motives and clearly visible. The public is in a guilty state of mind and the price of the rise in price of

DRUG PRICES HERE HELD INEQUITABLE

Citizens Group Urges New Congressional Hearing

By EDWARD C. BURKS

A citizens group charged yesterday that prescription drug prices here is so unfair and inequitable that the public should demand a new hearing at a fraction of the cost.

After a spot survey of three drugs in 12 Manhattan areas, the Citizens Committee for Metropolitan Affairs, Inc., reported that the price of morphine had risen 100 percent in the last two weeks.

Americans, World Feel They Pay Too Much

10,000% Drug Mark-up Cited

By Patricia Wiggin

Kefauver Seeking Anew To Reduce Drug Prices

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

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The Troubling Cost of Drugs That Offer Hope

SAN FRANCISCO, Feb. 8.—The Annet Pharmaceutical Company introduced a major drug in October that has been driving faster the pharmaceutical search using the field of immunology. The past success of Factor III usually stimulated any chance that biotechnology would confer relief, hope or other benefits from treatment.

There was one catch. The high-tech drug costs five to eight times as much as other remedies, 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.

THE CANCER DRUG RACKET

NEW YORK TIMES

ASCO will grade drugs

MIT report

"Breakthrough" that Cost \$100,000,000

TIME

Dilemma in Health Care: Rising Cost and Demand

By RICHARD D. LYONS

WASHINGTON, Sept. 12.—A decade ago, one medical group in Manhattan charged \$20 for a basic physical checkup, today it charges \$85. In those same years the going rate for an appendectomy in New York rose from \$480 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 \$50 billion for

1917

2014

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



CUT PRICES ON DRUGS.
Chicago Daily Tribune (1872-1922); Jan 15, 1893;
 pg. 16

CUT PRICES ON DRUGS.

**ARRANGING TO CARRY THE CON-
 FLIOT INTO THE COURTS.**

**Economical Company Will Endeavor to
 Prove That the Retailers and the
 Wholesalers in the City Have Entered
 Into a Conspiracy to Drive It Out of
 Business—The Regular Dealers Accused
 of Extortion—What Suburban Apothec-
 aries Have to Say of the War.**

The determination of the Economical Drug
 company to carry the drug war to the courts
 and determine whether or not it has a right to
 conduct a store at a reasonable rate of profit,
 even though it conflicts with the usual prac-

The Troubling Cost of Drugs That Offer Hope

SAN FRANCISCO, Feb. 8.—The Annet Pharmaceutical Company introduced a major drug in October for the first time during years the pharmaceutical trade using the mark of the medicine. The pure nature of the new pill usually obtained any chance that hospitals would consider other hospitals or other business firms interested.

There was one catch. The high-level drug costs due to eight times as much as other venues, 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.

**Dilemma in Health Care:
 Rising Cost and Demand**

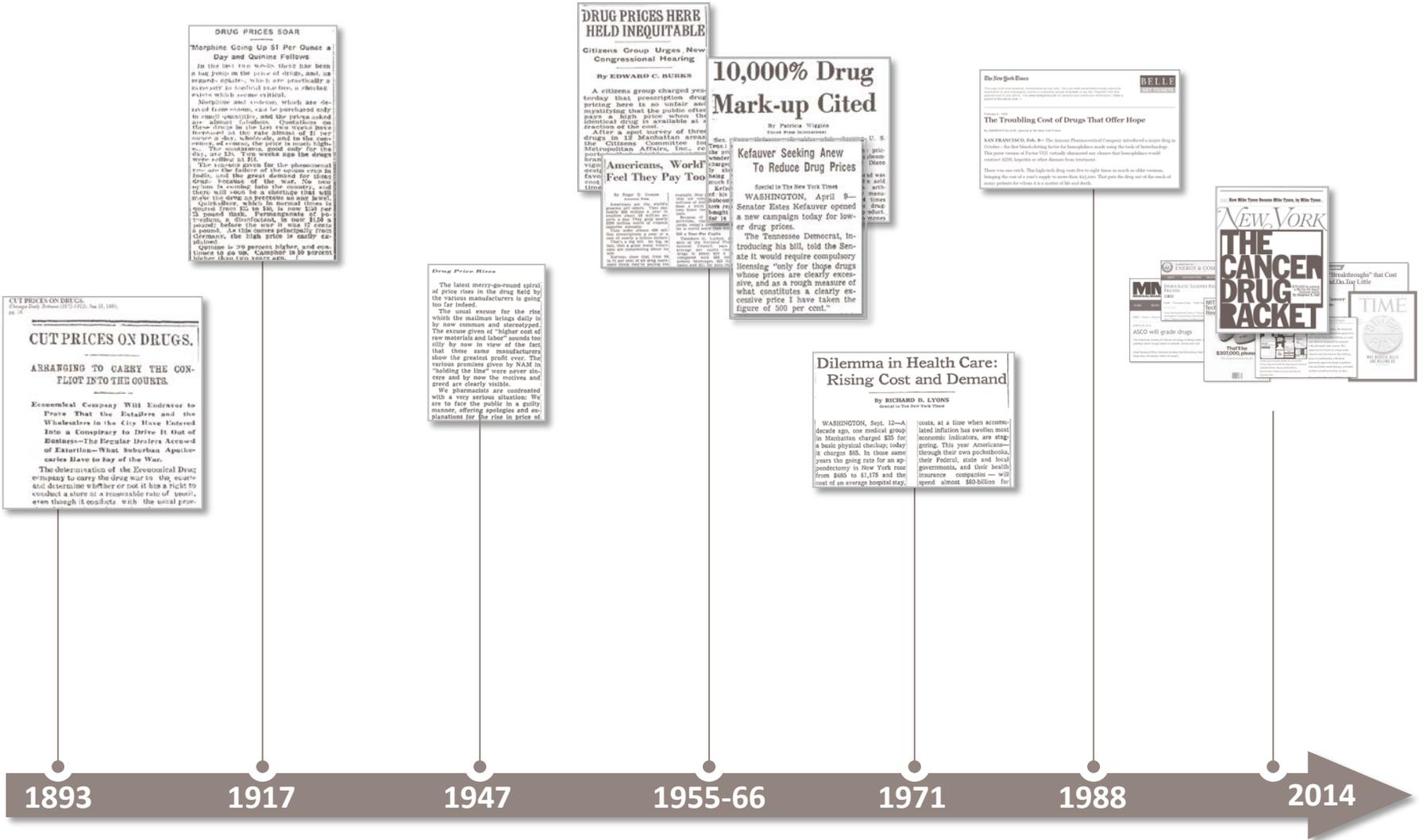
By RICHARD D. LYONS
 correspondent for New York Times

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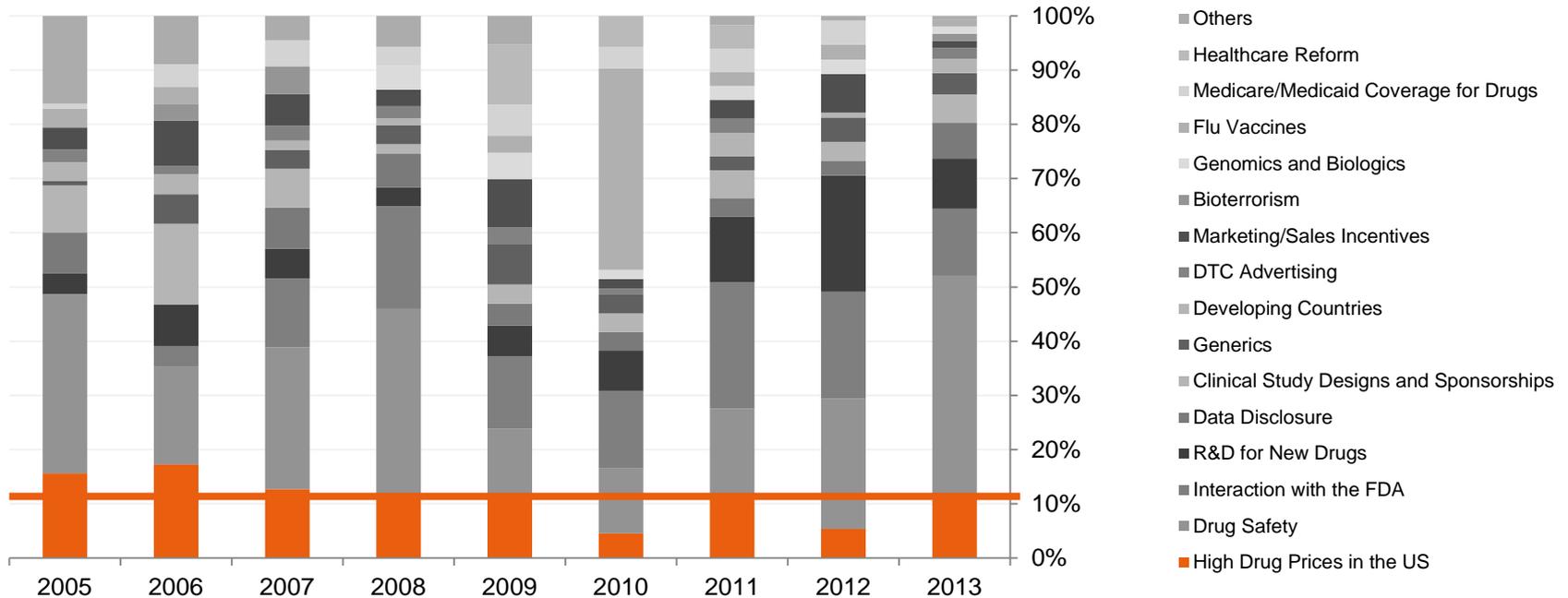


Source: Drug Prices Soar (1917). *The Boston Globe* Retrieved from <https://secure.pgarchiver.com/bostonglobe>

Pricing is a persistent issue in the press



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



2005

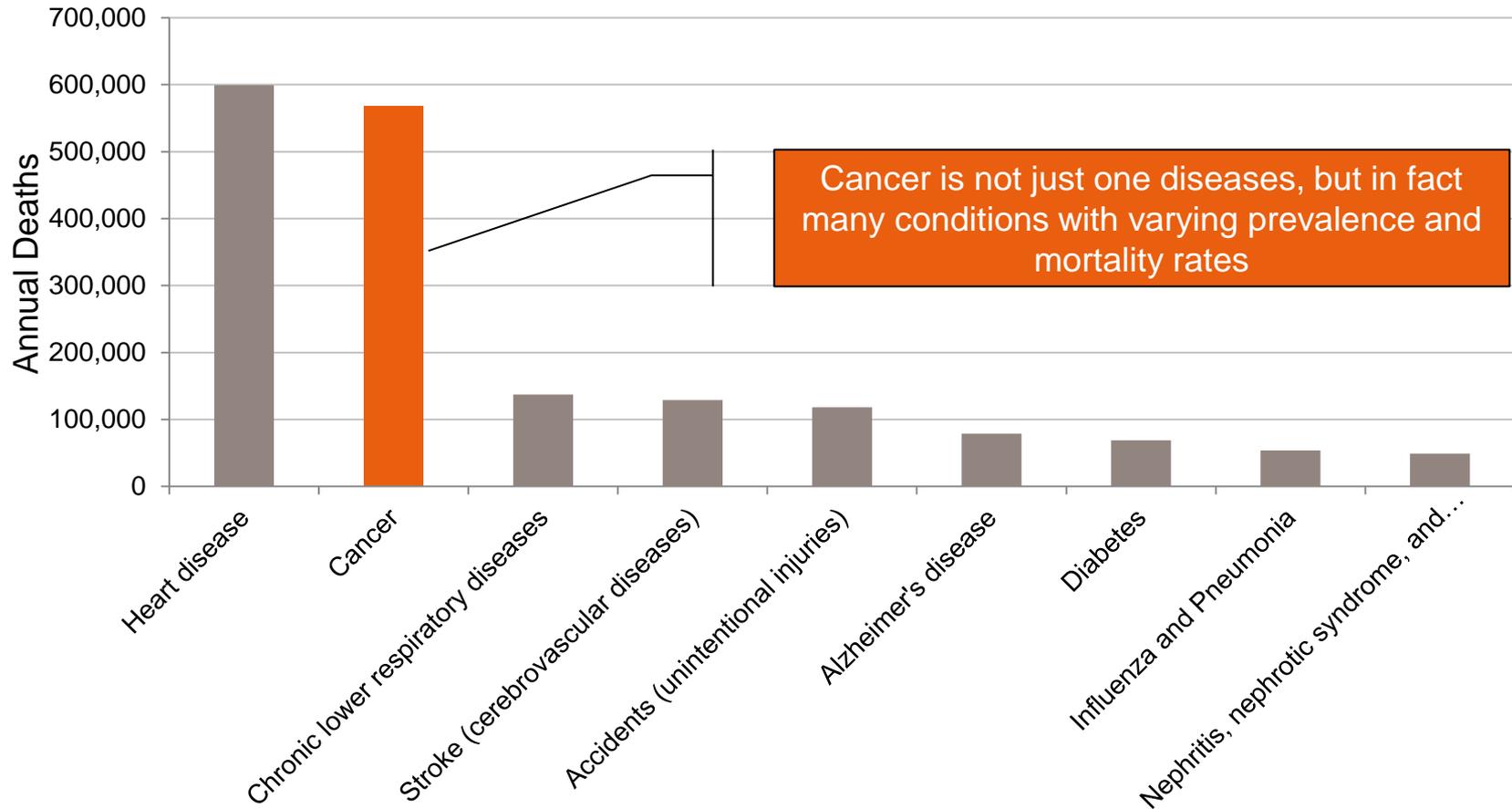
2014

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



Top 10 Leading Causes of Death, USA (2010)

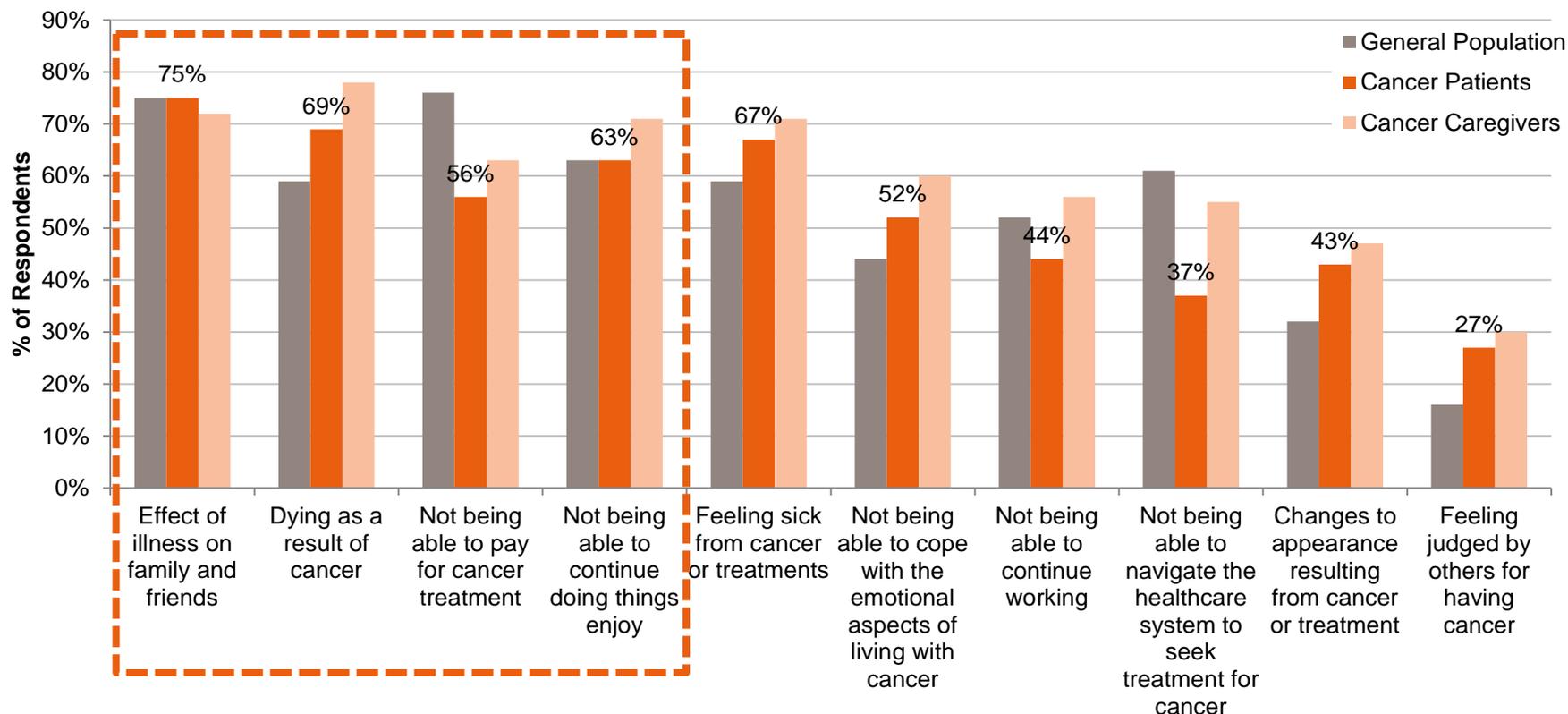


Source: Household Component of the Medical Expenditure Panel Survey (2008) Center for Financing, Access, and Cost Trends, AHRQ. Retrieved from http://meps.ahrq.gov/survey_comp/household.jsp

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



- System**
 - Pricing underlies the investment framework for oncology
 - State laws and regulations limit the options payers have in oncology
 - Faster launches with limited data are likely to remain common
- Influence**
 - Pricing strategy depends on competition, volume, and WTRx / WTP
 - Cancer drug labels have been getting smaller & narrower for a decade
 - Competitive crowding and CE can add pressure to cancer drug pricing
- Agents of Change**
 - Physicians & hospitals are fraught with perverse and conflicting incentives, encouraging a high willingness to prescribe
 - Patients face an OOP burden but demonstrate a high WTP
 - Biosimilars, like generics, present opportunities for conversion post-LOE
- Trends**
 - Forecasted health spending is set to rise – a trend felt around the world
 - Oncology spending as a % of total health spending has remained flat
 - Media sensationalism on drug pricing has existed for at least a century

APPENDIX

While the US has the highest health expenditure share of GDP, many EU markets have a higher cancer share of total healthcare expenditures

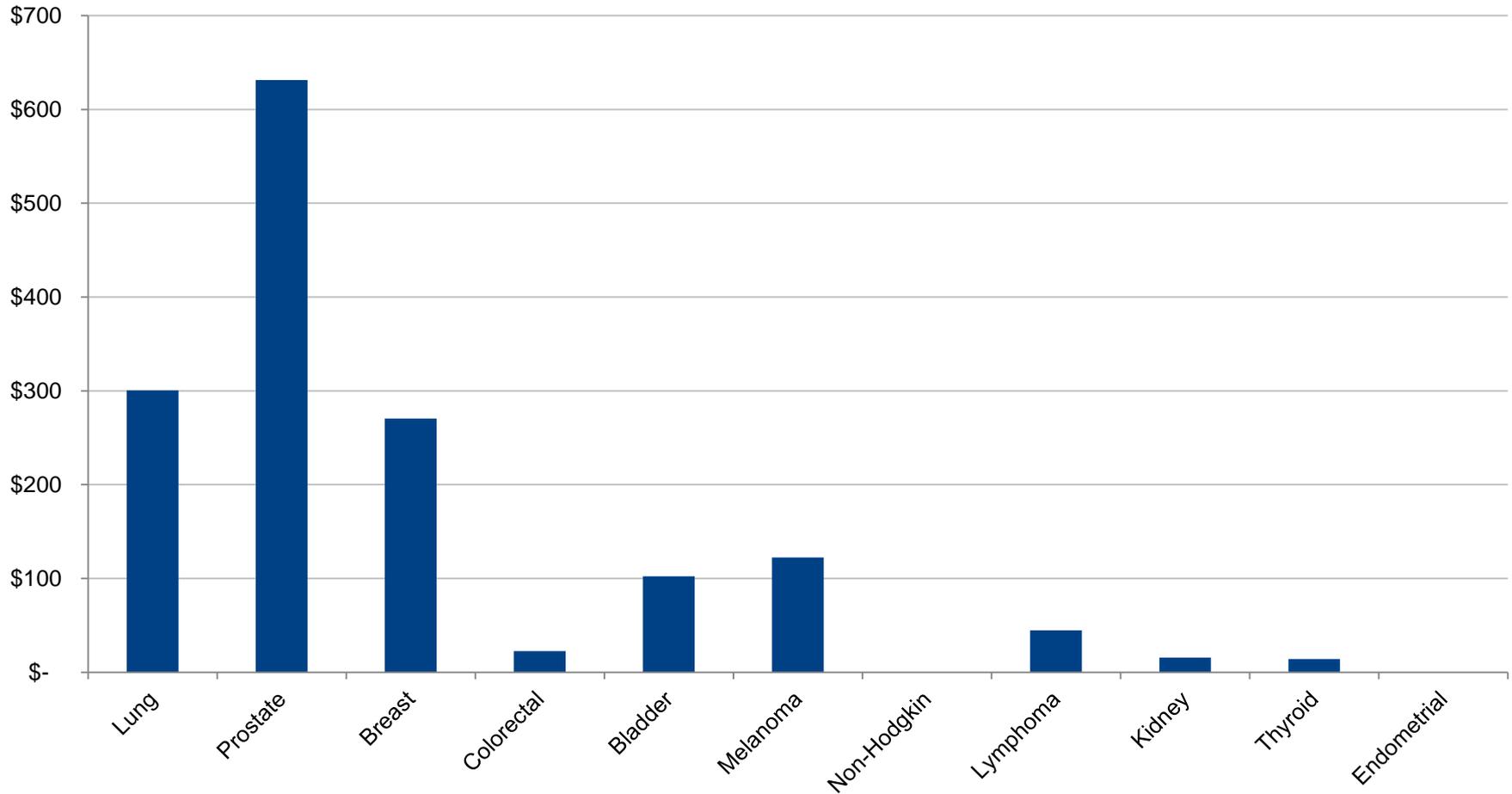
Estimated direct costs of cancer, 2006 (US\$, PPP-adjusted)

Country	Total expenditures on health, MUS\$	Health Expenditure share of GDP (%)	Total expenditure on health per capita	Cancer share of health expenditures (%)	Direct costs of cancer per capita
	2,074,861	15	6,719	4.7	314
	223,830	11	3,420	6.6	226
	208,856	11	3,465	7.2	249
	155,346	9	2,631	6.4	168
	113,409	8	2,466	4.0	99
	174,647	8	2,815	5.6	158
	29,535	9	3,162	6.4	202
	328,897	8	2,581	7.3	188

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



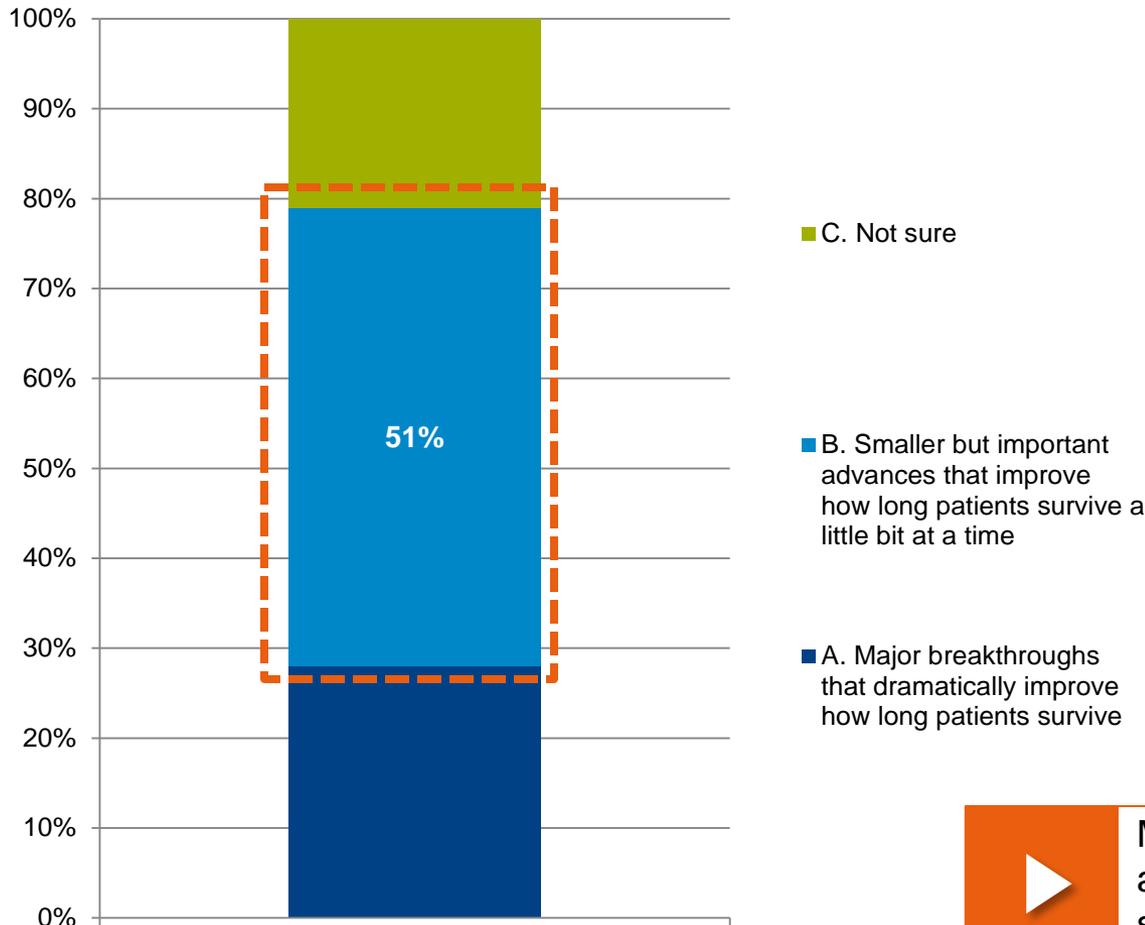
NCI spending in FY 2010 for the 10 most common types of cancer in the United States (\$ millions)



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

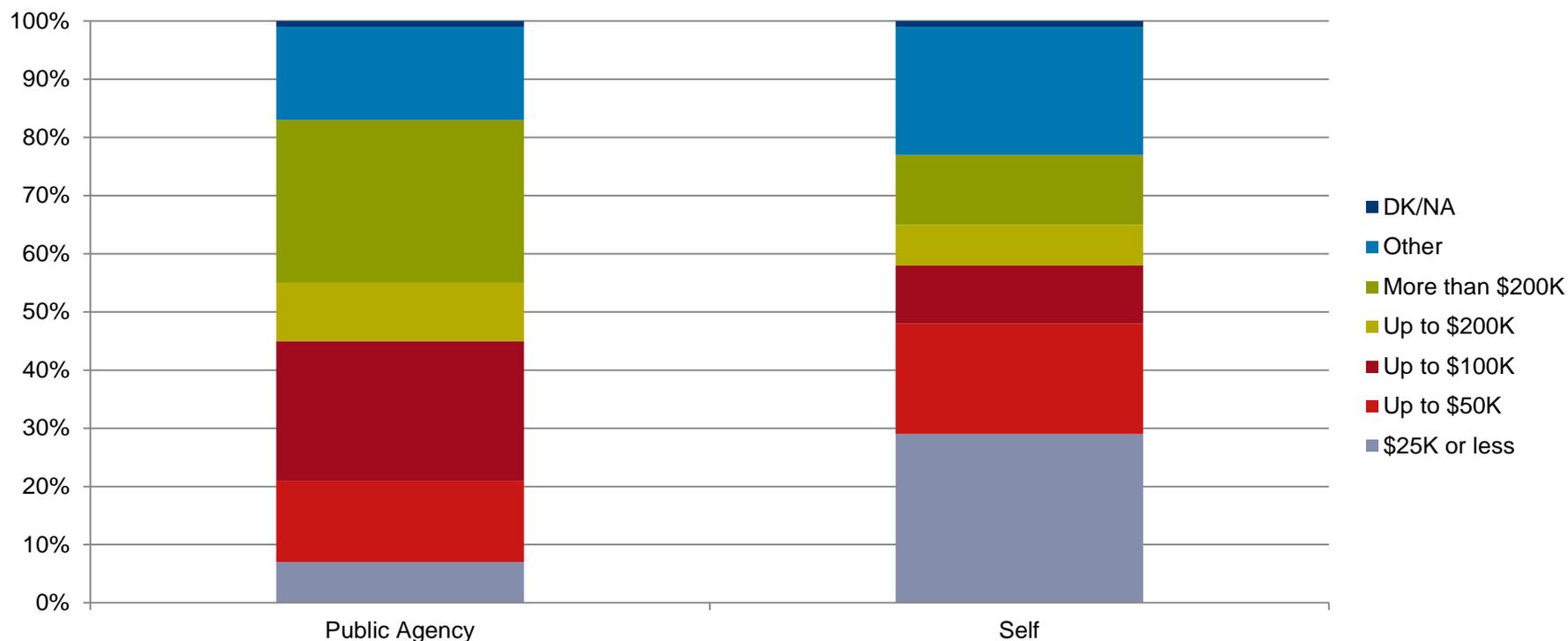


 Most people realize that small advances drive longer cancer survival

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

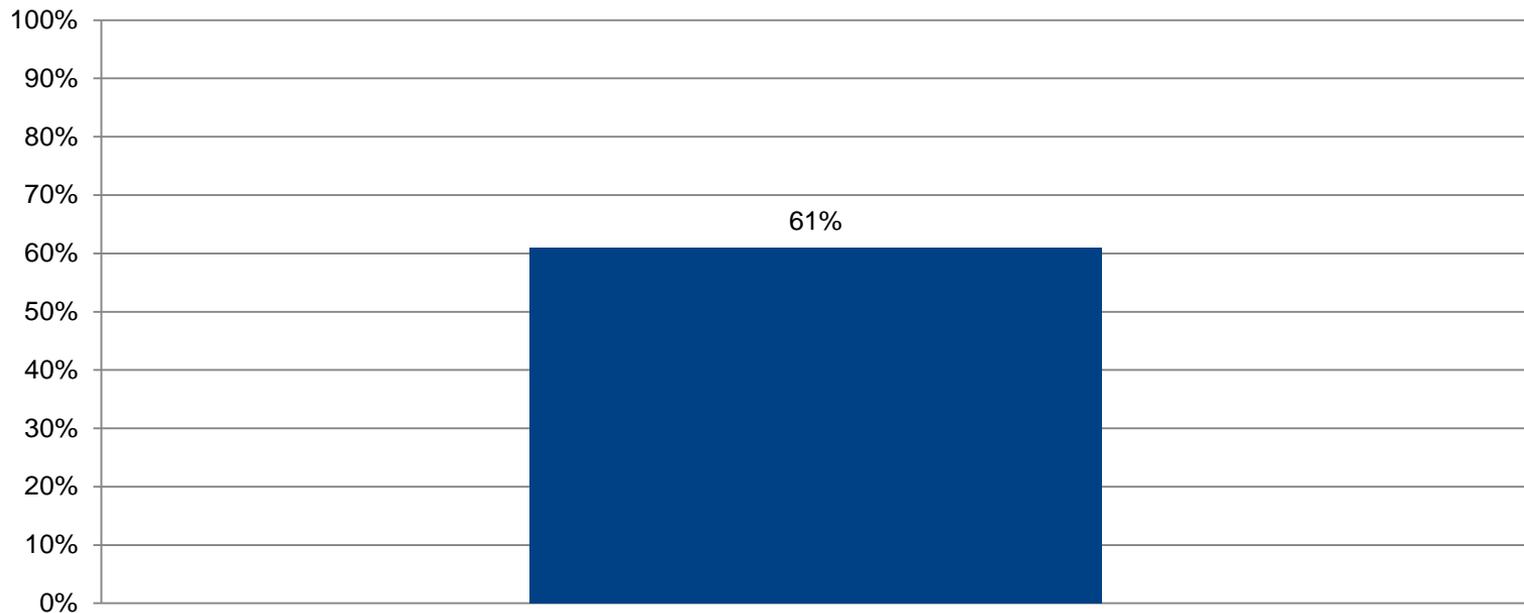


 Cancer patients feel that payers should pay up to \$100,000 or more for one extra year of life

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



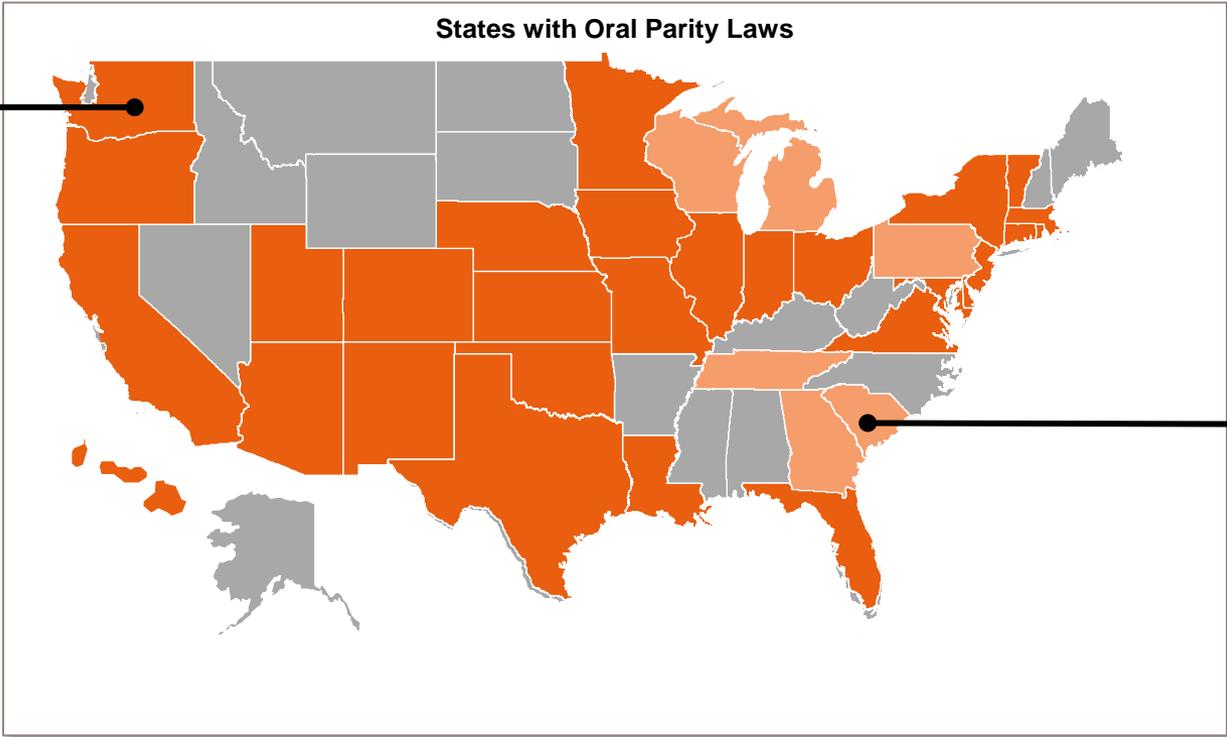
Proportion of public willing to change to a different physician to participate in a clinical trial



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

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

Price



Payers in these states have limited options for managing oral chemotherapies more than in those that do not have parity law

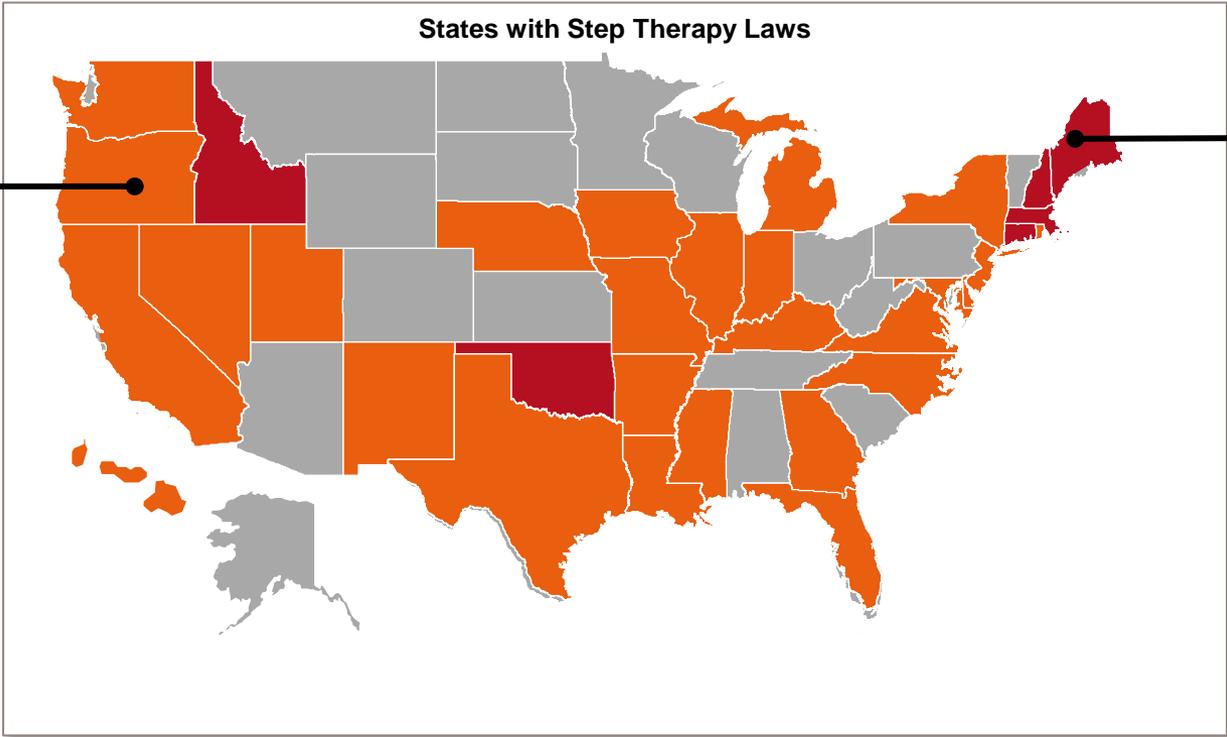
Oral parity laws have recently been introduced

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

Source: Abbott, S. (2014) ACCC Hill Day Primer-Issue #3: Pass Oral Parity Legislation. Retrieved from <http://acccbuzz.wordpress.com/tag/oral-parity/>

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

Price



State laws require payers to inform patients about step therapy policies or have an option to override

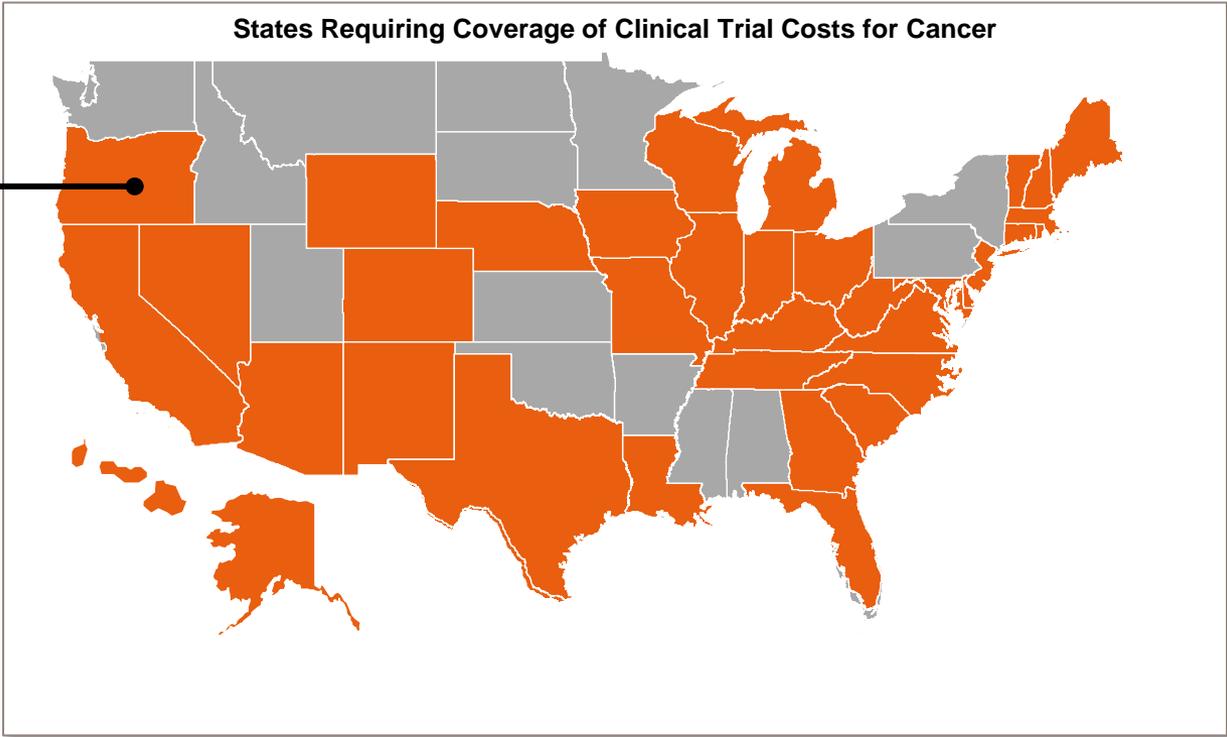
Proposed laws have been defeated

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)
Source: Fail First/Step Therapy Legislation by State. (2010) *Fail First Hurts/Global Healthy Living Foundation* Retrieved from http://failfirsthurts.org/fail-first-by-state_NEW.html

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

Price

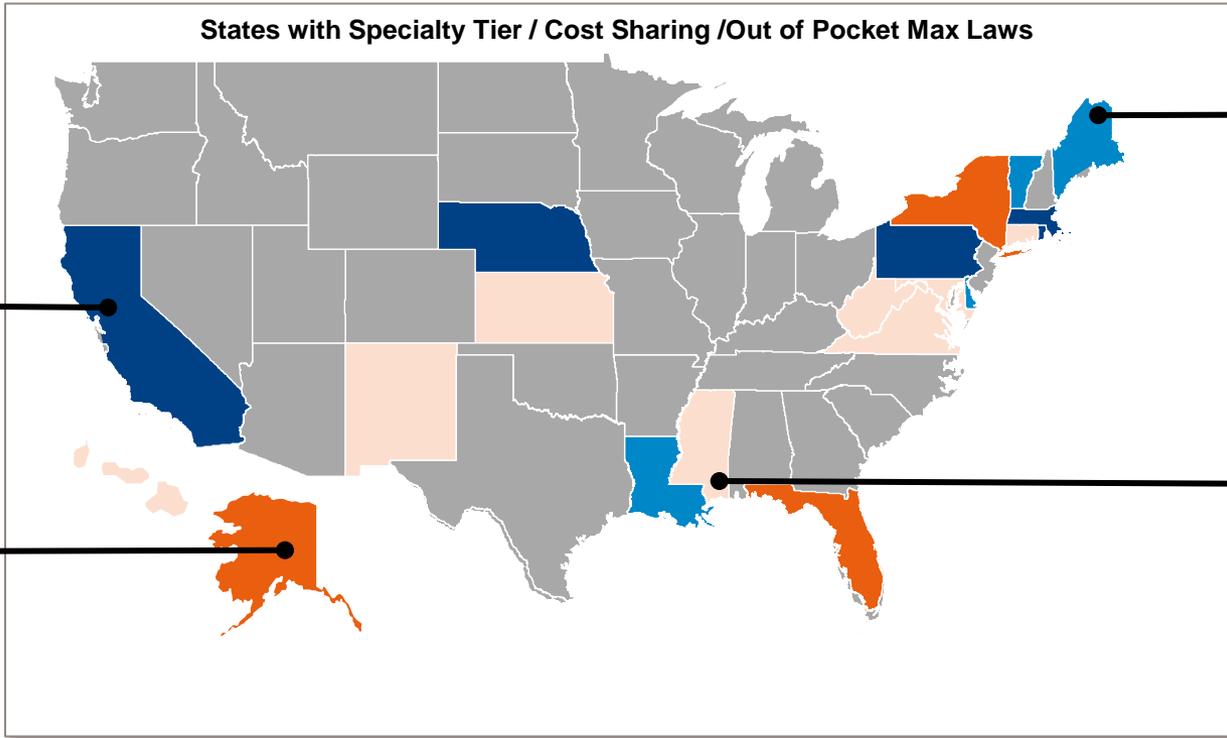


Lack of insurance coverage for routine patient care is a barrier to enrollment of patients who might otherwise take part in a clinical trial

Source: States Requiring Coverage of Clinical Trial Costs. (2012) *National Cancer Institute at the National Institutes of Health*. Retrieved from <http://www.cancer.gov/clinicaltrials/learningabout/payingfor/laws>

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

Price



States with a combination of cost sharing and out-of-pocket spending limits

States with a combination of specialty tier laws and out of pocket spending limits

States with a specialty tier laws

Pending legislative decision or study to assess financial impact

State have implement 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

Source: Brooker, C. (2013) Waging War on Specialty Pharmaceutical Tiering In Pharmacy Benefit Design. Health Law & Policy Brief Retrieved from <http://digitalcommons.wcl.american.edu/hlp/vol7/iss2/2/>



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