



Understanding Your Customers: The Key to Driving and Deriving Product Value

**Presented by: Harris Kaplan
12-08-08**

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Shift Happens.....



*"Sir, the following
paradigm shifts occurred
while you were out."*

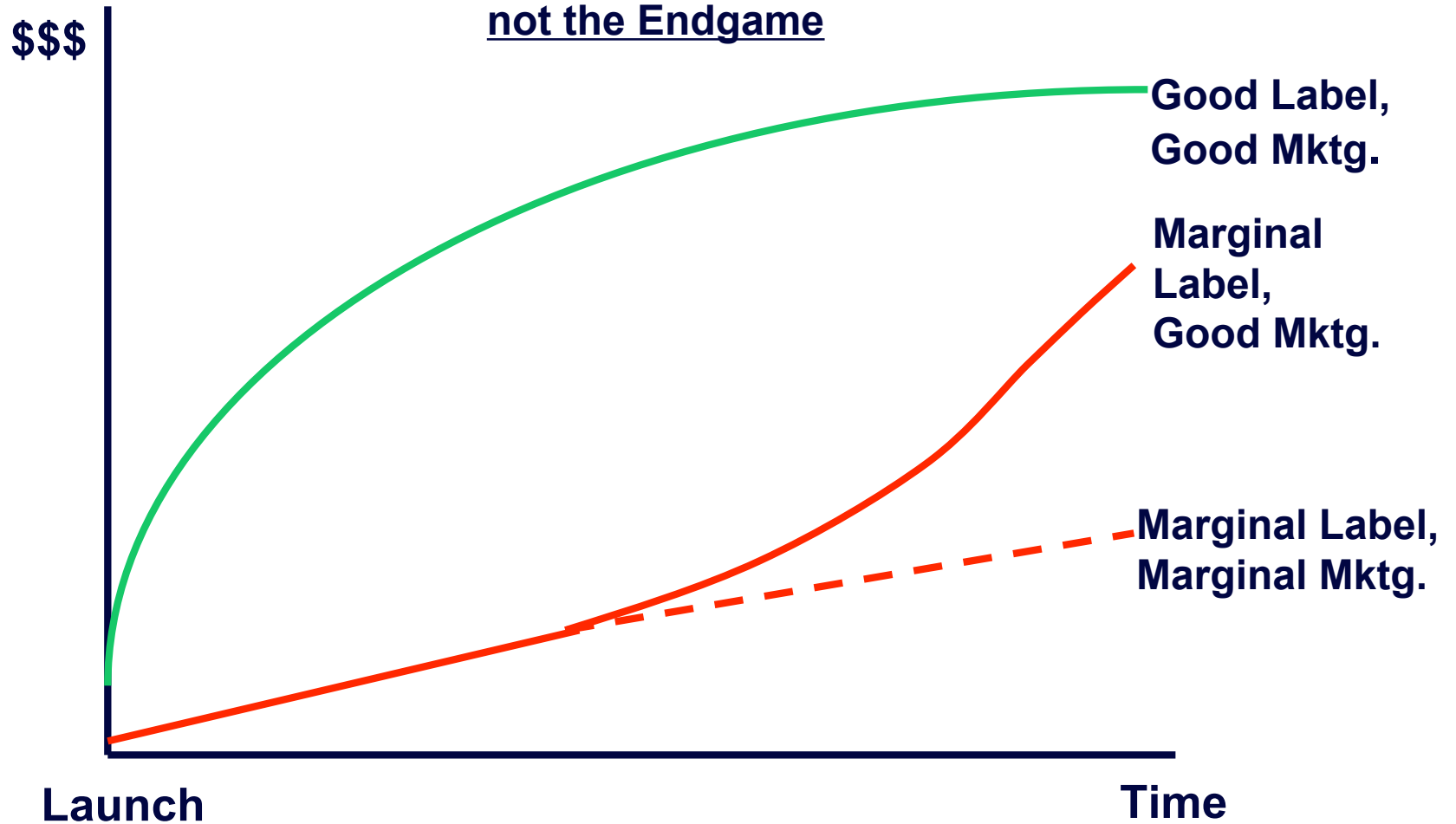
Failure to Understand Your Target Market: #2 on Fierce Biotech's List of Top 10 Greatest Mistakes

- ⦿ **Market Size and Product Differentiation** were identified as the two most important drivers of future success in the specialty pharmaceutical market
- ⦿ **Changing the Standard of Care** is More Important than Competitive Intensity
- ⦿ **Novel MOA** is not a sufficient differentiator

Source: McKinsey & Co. article, July 2008

In Developing New Products, It's Important to Begin with The End in Mind

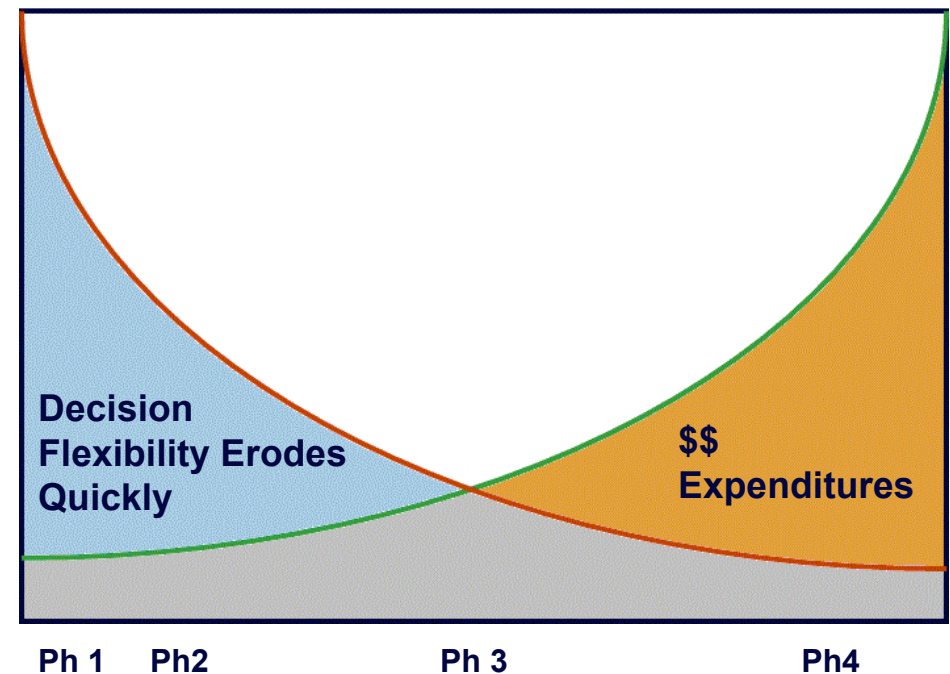
Regulatory Approval is the cost of admission,
not the Endgame



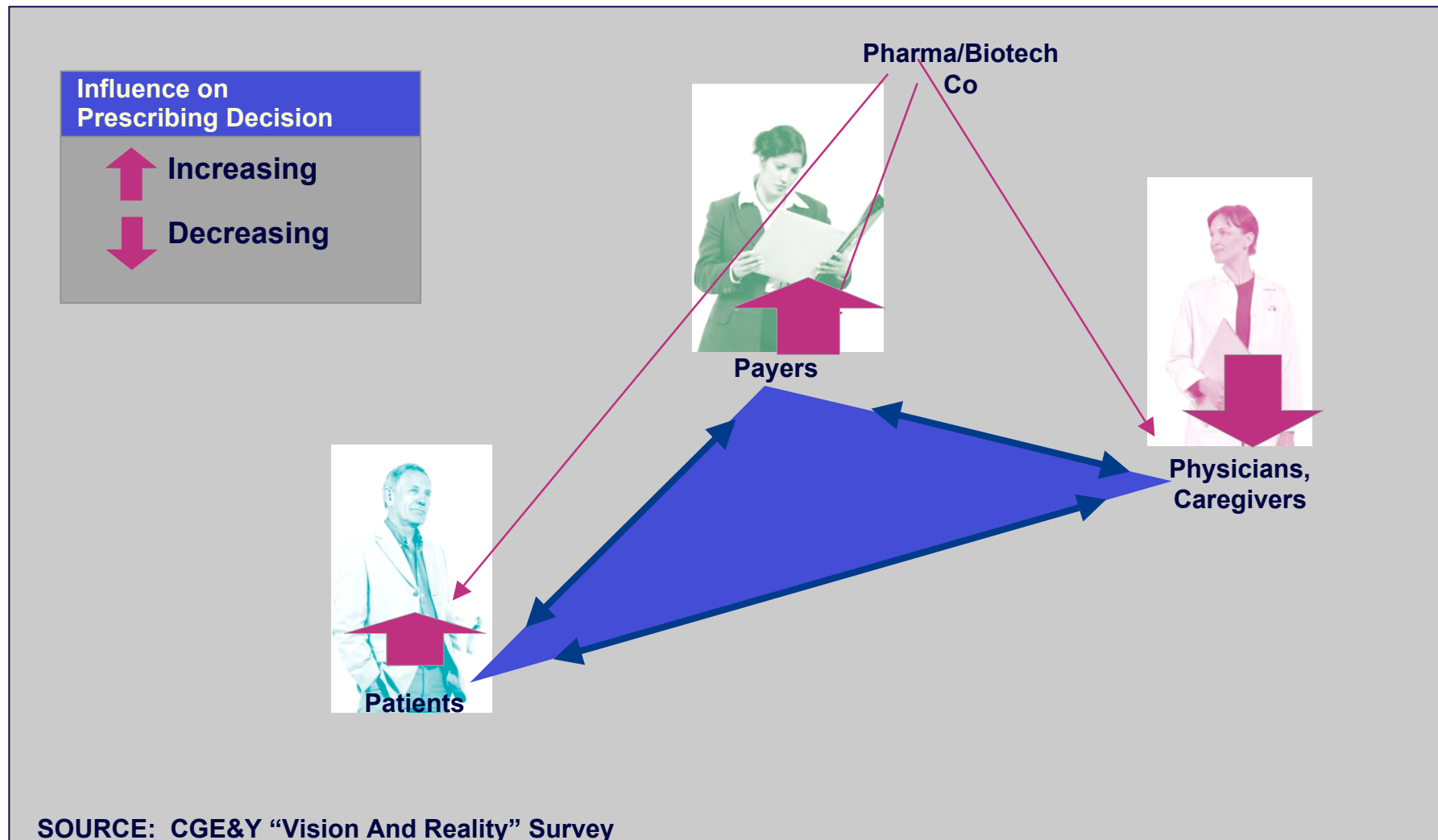
The Path to Future Market Share Needs to Be Defined Before Phase 3...

- Decision Flexibility Erodes Very Rapidly
- Getting a Molecule Back on Track is Expensive, Time Consuming and Significantly Depreciates Valuation and Market Potential
- What Pharma/Investors want is a Biotech Partner Who Understands the Road Ahead and has Reflected that in Their Valuation and Clinical Actions

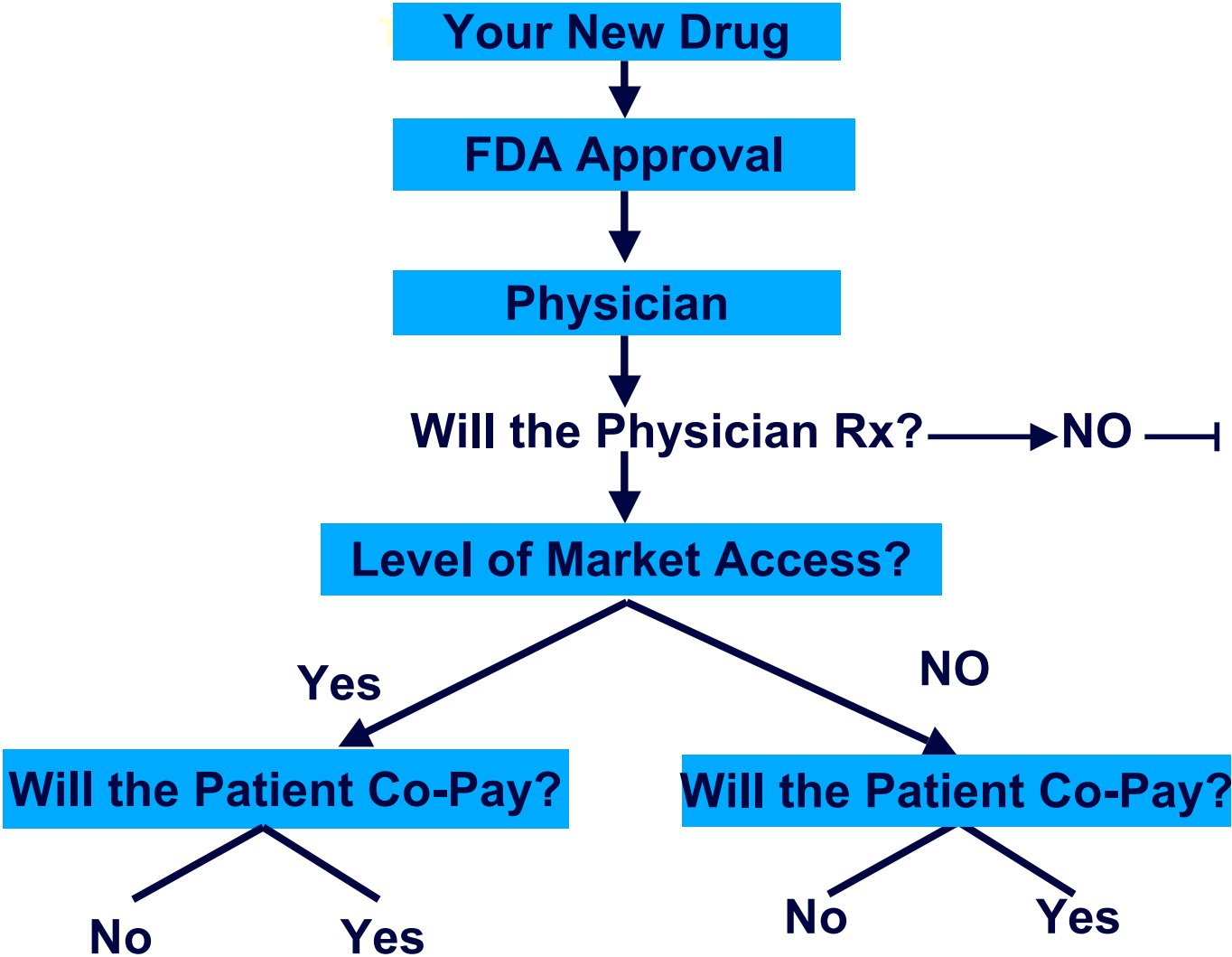
Long Term Product Value Gets Created Early



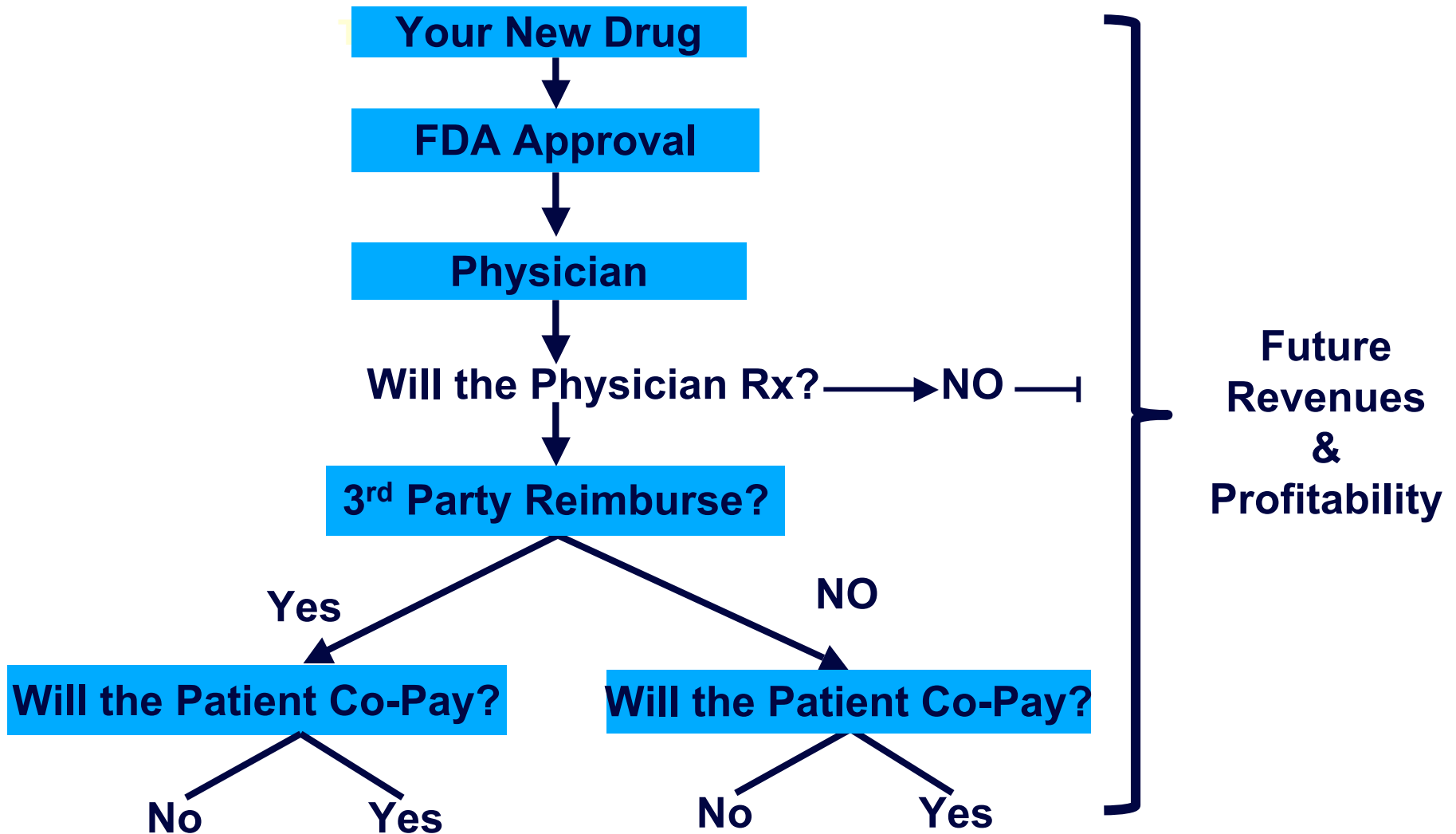
...And Needs to Incorporate the Needs and Changing Roles of the Different Customer Groups

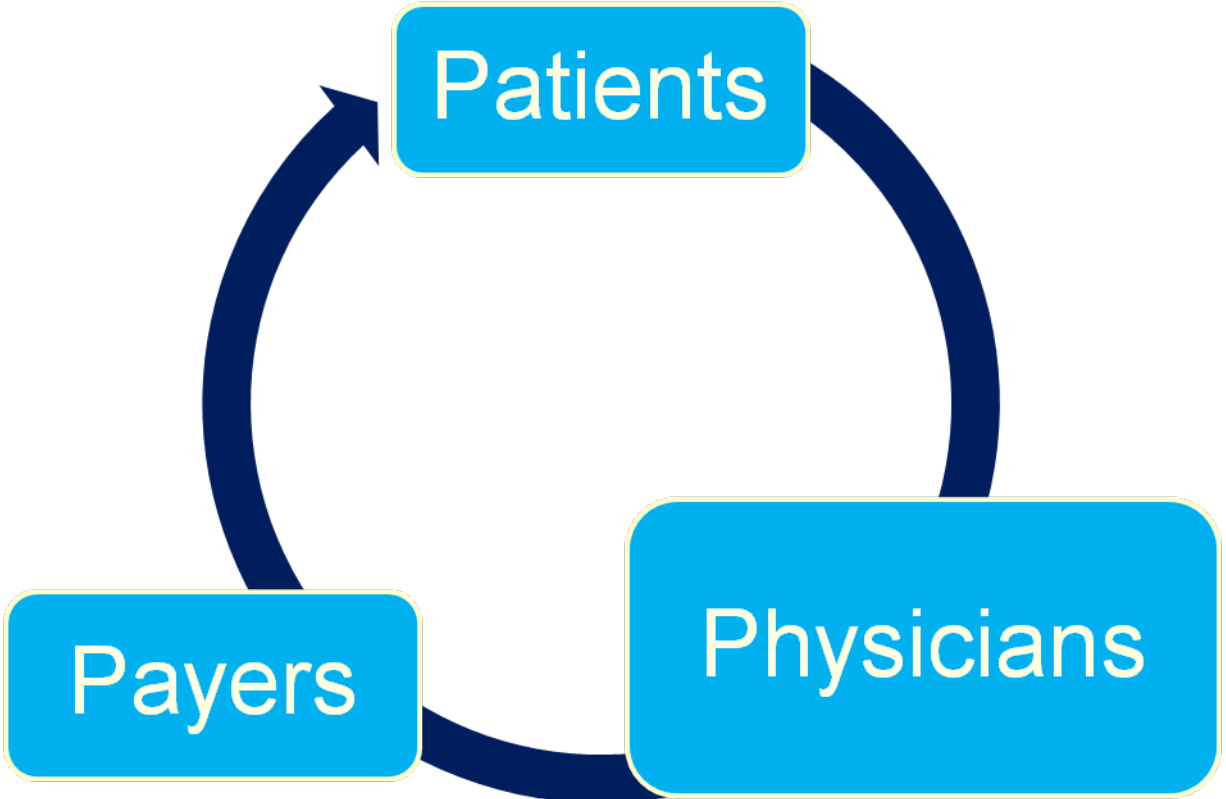


Creating Future Value Begins With an Understanding of the Value Chain

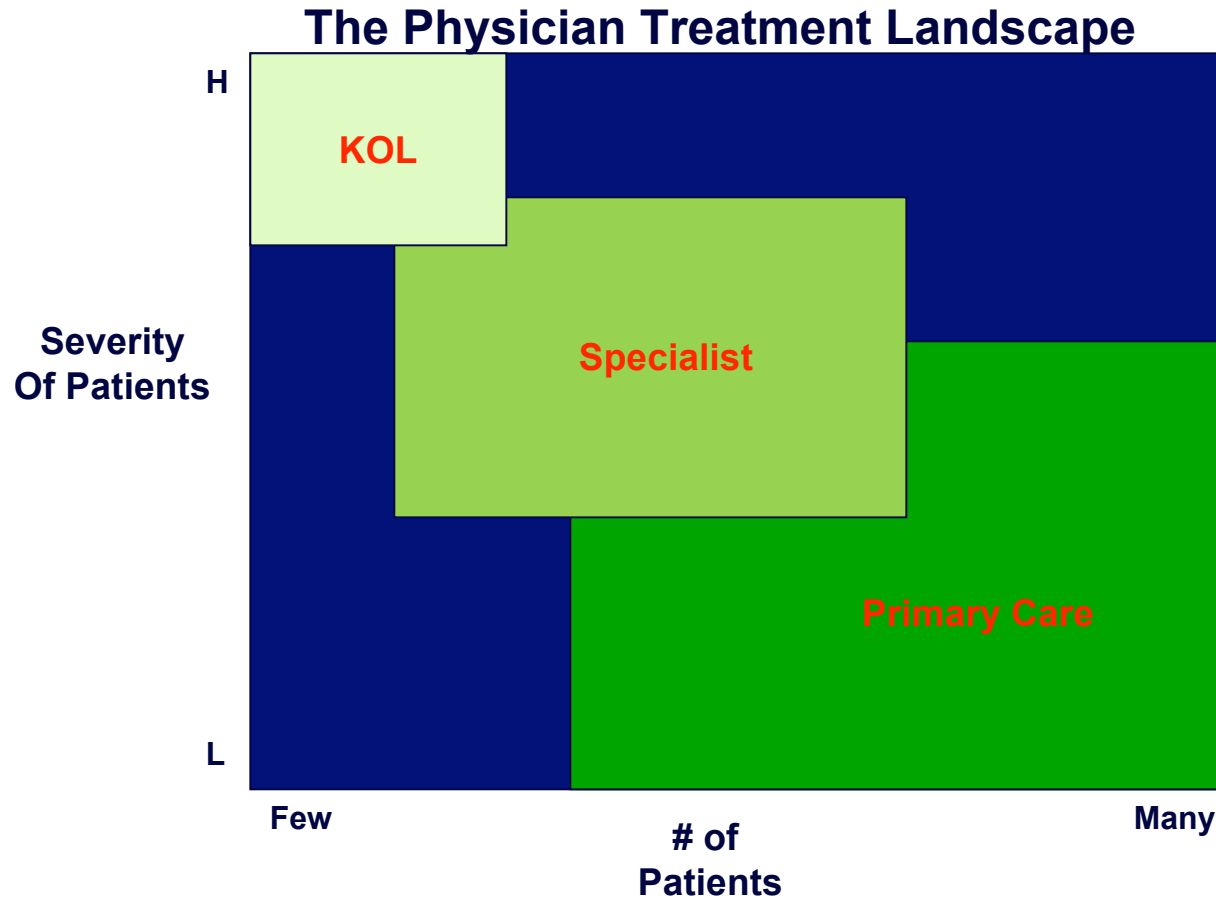


And How Each of the Customer Groups Affects Future Product Revenues and Profitability





KOL's Often Do Not Represent the Physician Norm.....



What Physicians Want: Efficacy and Risk Commensurate with the Condition

Drivers of Product Use

- ⦿ Extension of Patient Life
- ⦿ Improvement in Patient Quality of Life
- ⦿ Reduction in Signs and Symptoms
- ⦿ Improvement in Dosing and Form of Administration
- ⦿ Managed Markets Access



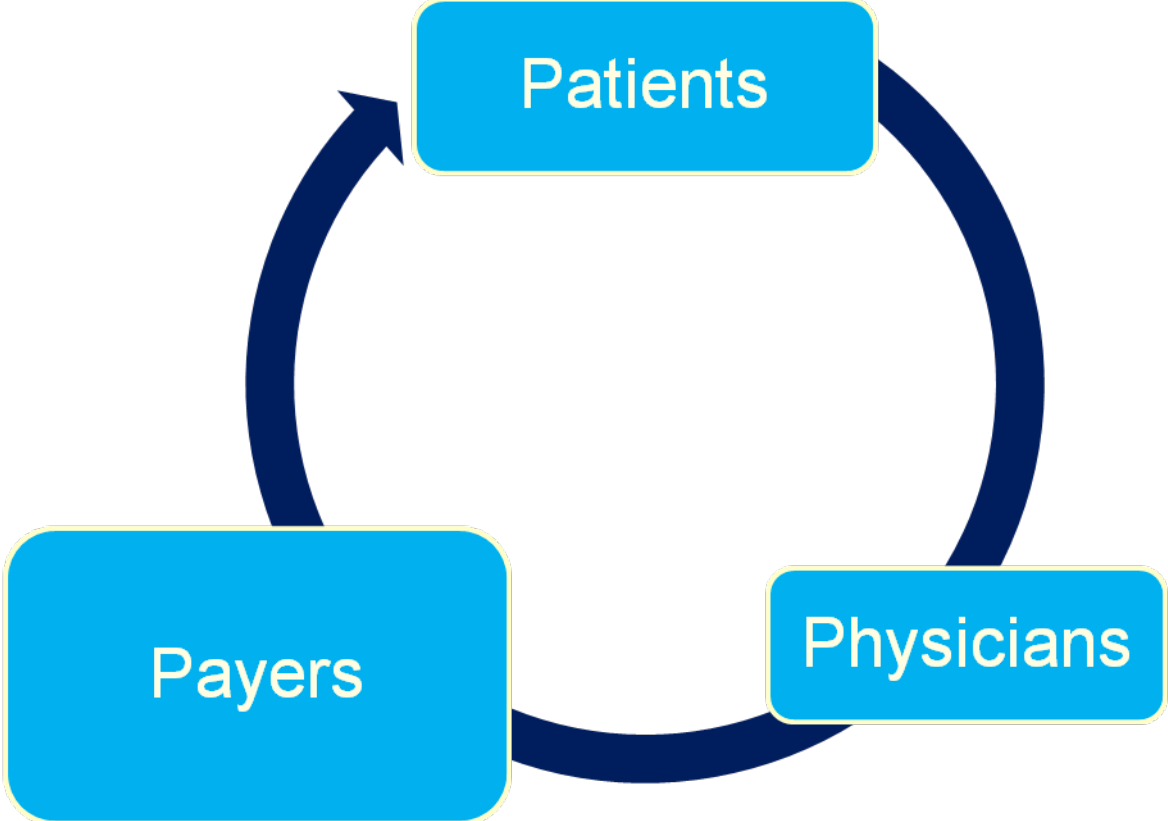
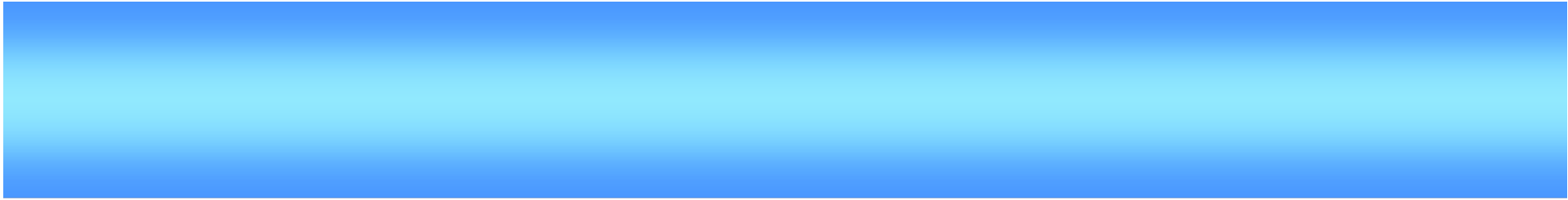
Deterrents of Product Use

- ⦿ Safety Concerns
- ⦿ Side Effects
- ⦿ Lack of Quality of Clinical Data
 - ⦿ Comparator
 - ⦿ Number of Patients
 - ⦿ Length of Time Studied
- ⦿ Dosing and Mode of Administration

- ⦿
- ⦿
- ⦿ “Time is Money”
- ⦿ One “Oh ___ Wipes Out a Thousand Positive Experiences
- ⦿ Patient Feedback Trumps Clinical Data

Physicians Prescribe...but Do Not Pay for Medications. They are necessary, but rarely sufficient to drive future demand

- ⦿ **Physicians usually have little idea of what drugs cost**
 - ⦿ What level of managed care access does a product have?
 - ⦿ What is the co-payment required of my patients?
- ⦿ **Most physicians will not “do battle with managed care” to get a drug prescribed.**
- ⦿ **Most physicians will not “do battle with their patients” as far as their taking a particular medication.**



“He Who Has the Gold Makes the Rules”



The Perspective of the Payer

- ⦿ **Goal is to manage costs without compromising patient health**
- ⦿ **Facing Increasing pressure to control healthcare costs**
- ⦿ **Greater investments in systems and infrastructure equals greater insight into what's working and greater ability to control physician behavior**
- ⦿ **Continue to offload expense and risk onto the consumer as this is a highly effective means of controlling utilization and cost without the use of formal policies**

The Payer's View is Very Aggregated

- ⦿ **Have 50+ therapeutic categories to think about**
- ⦿ **Generally very supportive of achievement of quality care goals and outcomes**
- ⦿ **View care and cost at a very high level - PM/PM**
- ⦿ **Plan medical directors don't usually mandate physician behavior.**

The Continued Growth, Utilization, and Cost of Specialty Drugs Puts Them Clearly in Payer's Sightlines

***“Payers View a Host of Undifferentiated Biologics in Development,
Especially Those in a Crowded Oncology Market, as Manna from Heaven”***

KDS Consulting

***“We also read the Wall Street Journal and that we are very much aware of
Drug Development Trends and Upcoming Patent Expirations.”***

Payer

***“In the current economic climate, employers are screaming about their
health insurance premiums, we have no choice but to examine every
source of possible savings. Drug costs are an easy target for savings.”***

Payer

Payers Decide the Level of Access for New and Marketed Products

Some Key Questions

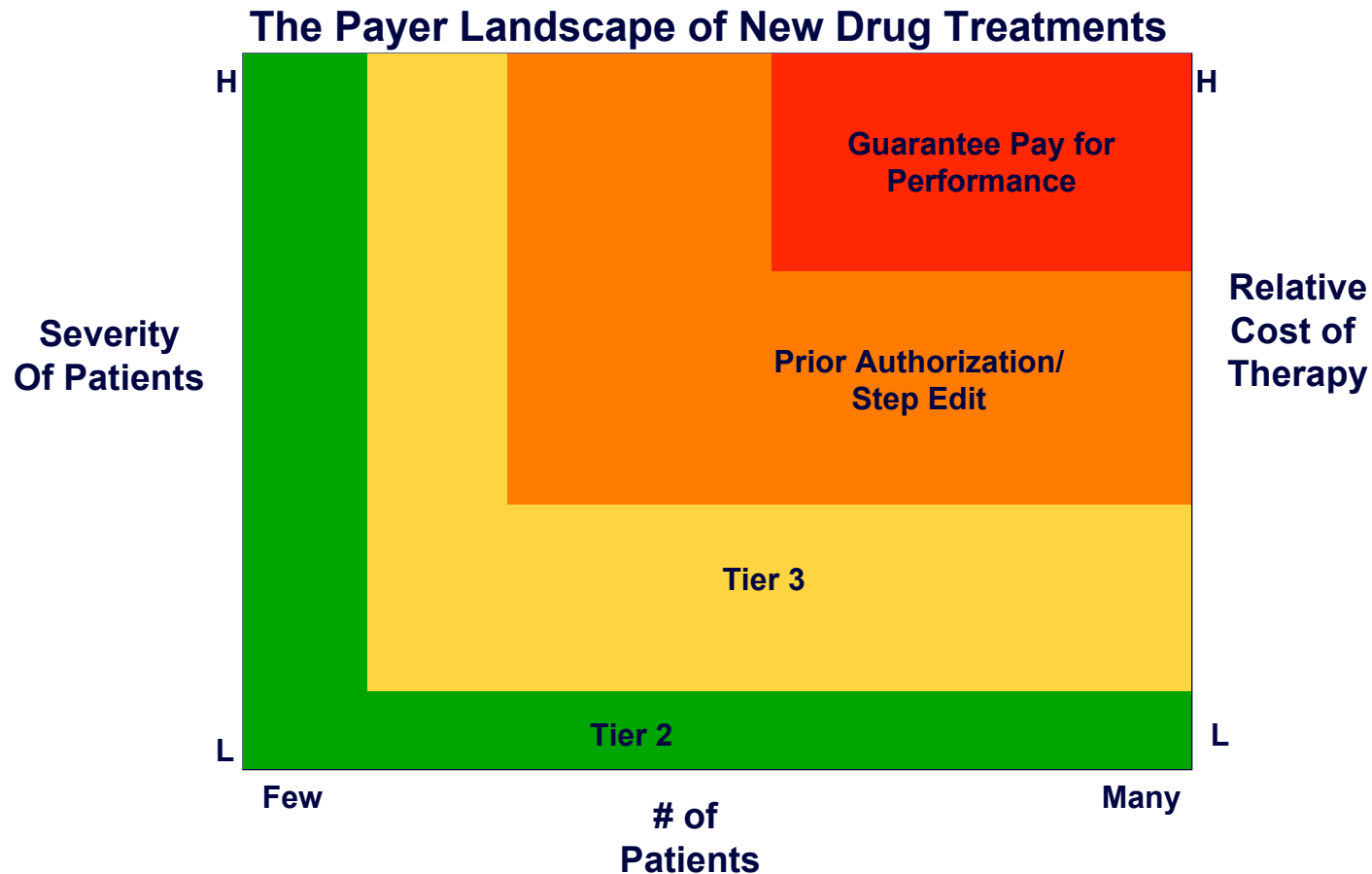
- How significant an improvement relative to current therapies is a new product?
- How important is that improvement?
- How clearly has that improvement been documented?
- What is the probability that the economic story will be realized?
- How many people are affected by the disease or condition?
- How much will the incremental cost be to the plan?

Some Key Decisions

- Will the Product be on the Formulary?
- What Tier or Level of Access Will the Product be Given?
- Will Prior Authorization be Required for the Product to be Prescribed?
- For what period of time will the product be allowed to be prescribed?
- If there is a lapse in therapy, how long a period is allowed before that patient is considered a new patient?



The More Expensive the New Drug Therapy and the More Patients For Which It is to be Used, The Greater the Proof Payers Will Require to Provide Unrestricted Access

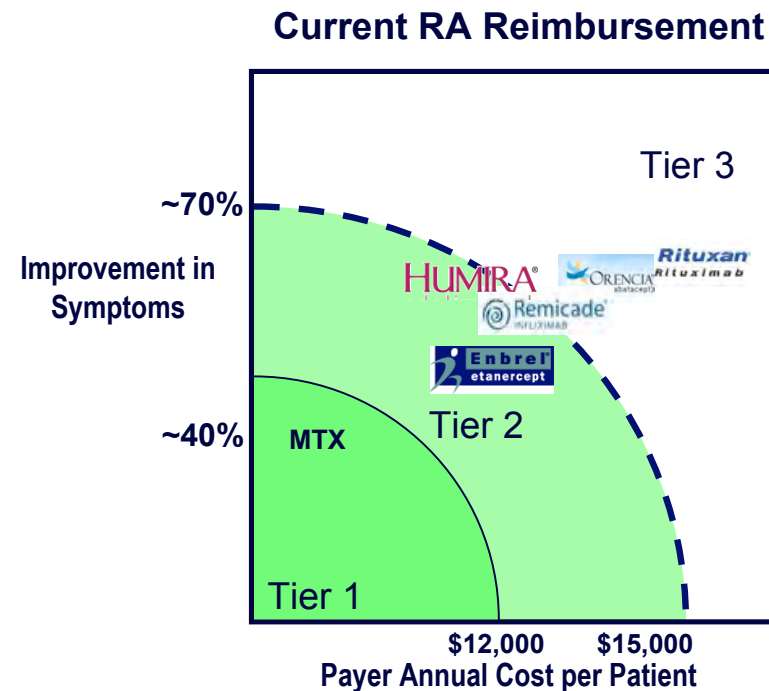


An Example of How Payers Work

- ◉ **The cost of RA treatment is \$12,000 to \$18,000 per year for biologic therapy.**
 - ◉ Trend toward earlier use in therapy
- ◉ **There are currently few access restrictions in place in the US. Most are either Tier 2 or a Co-insurance of 20%**
- ◉ **There are currently 4 Anti-TNF's**
 - ◉ # 5 to be introduced in 2009
- ◉ **Given the similarities, payers decide to offer one preferred Status**
 - ◉ Triggers a price war between all of the market participants
- ◉ **The result is that one brand potentially gains considerable market share, but overall costs to payers are reduced.**

An Example of How Payers Work

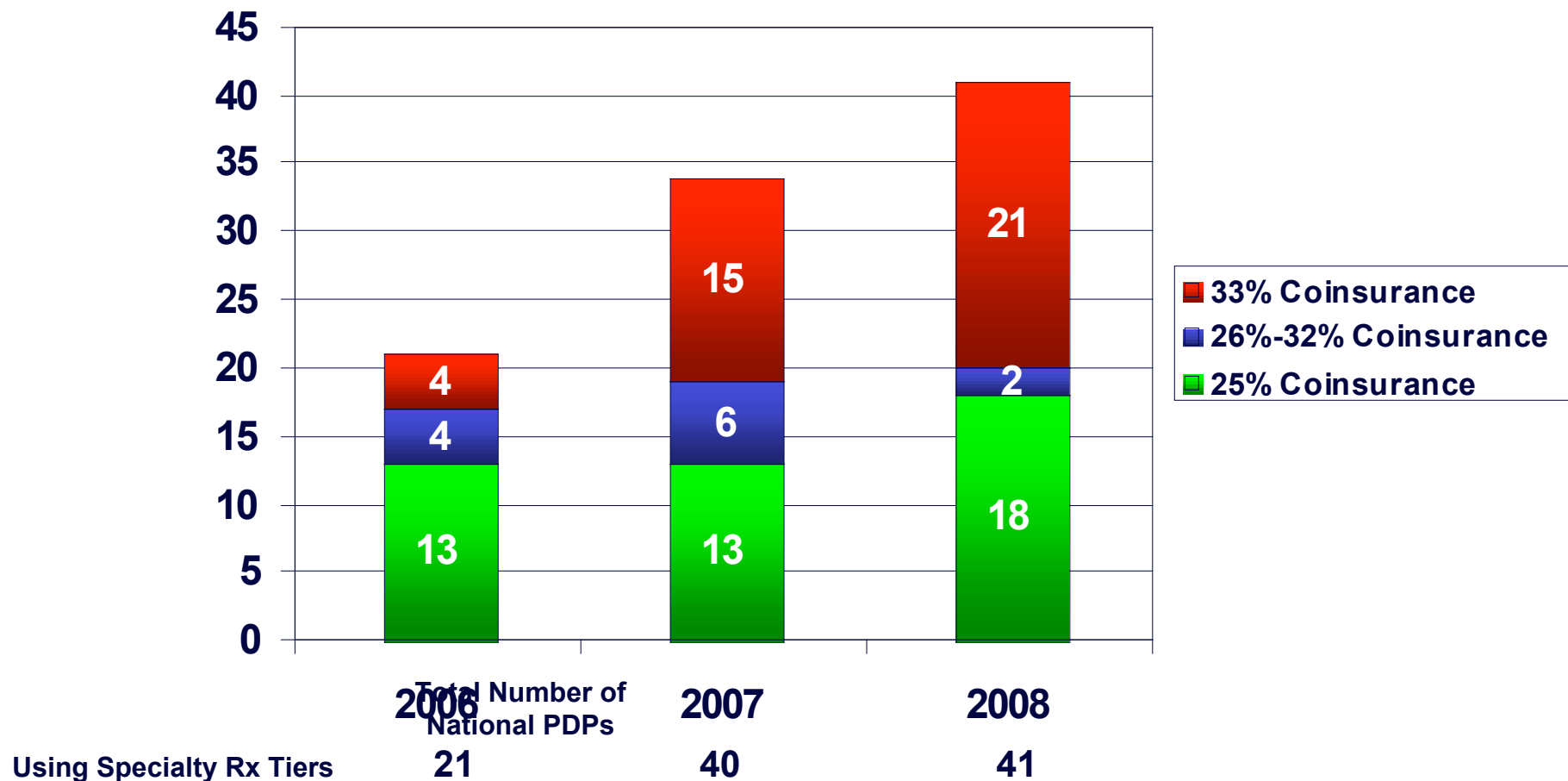
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- There are currently few access restrictions in place in the US. Most are either Tier 2 or a Co-insurance of 20%
- There are currently 4 Anti-TNF's
- Given the similarities, payers decide to offer one preferred Status
- The result is that one brand potentially gains considerable market share, but overall costs to payers are reduced.
- The only question is whether Payers will actively attempt to switch patients on existing therapies?



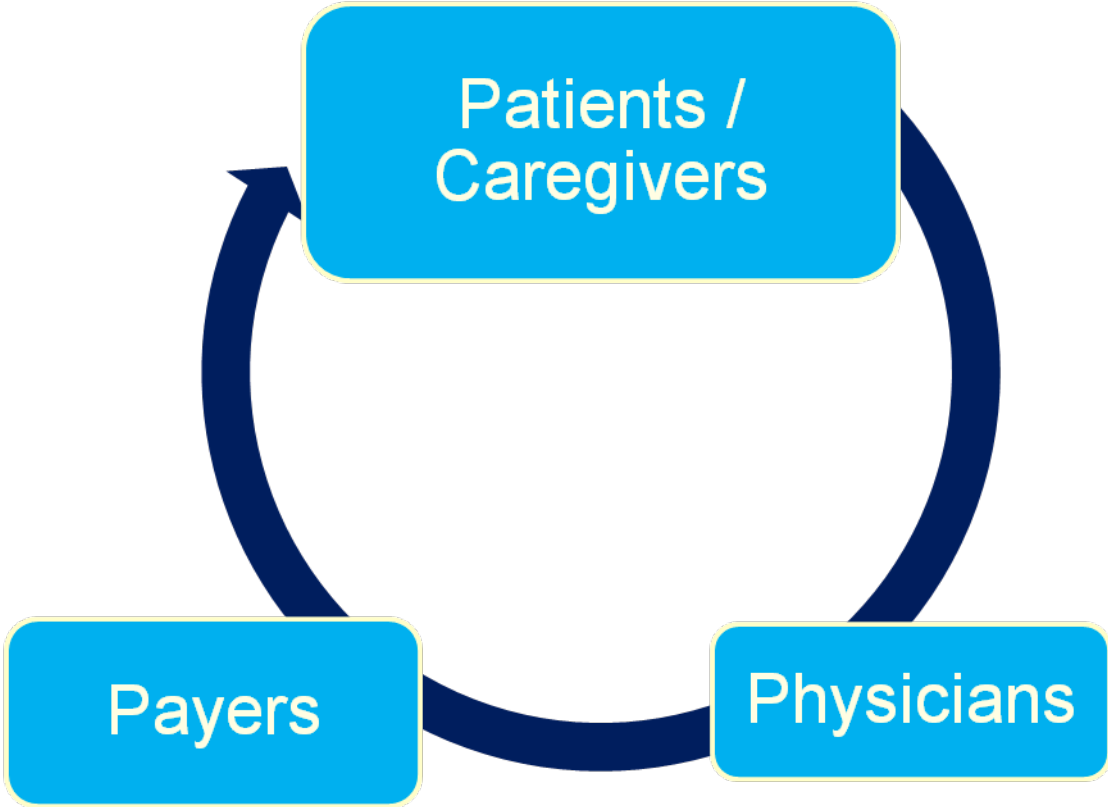


Specialty Pharmaceuticals Are Next On The “Hit List”

Specialty Rx Tiering In Medicare Part D
(Among The 47 National PDP Plans)



SOURCE: Hoadley et al analysis of data from the CMS Medicare Prescription Drug Plan Finder on Medicare.gov, 2006-2008, for the Kaiser Family Foundation





Who Is The “Average” Consumer?

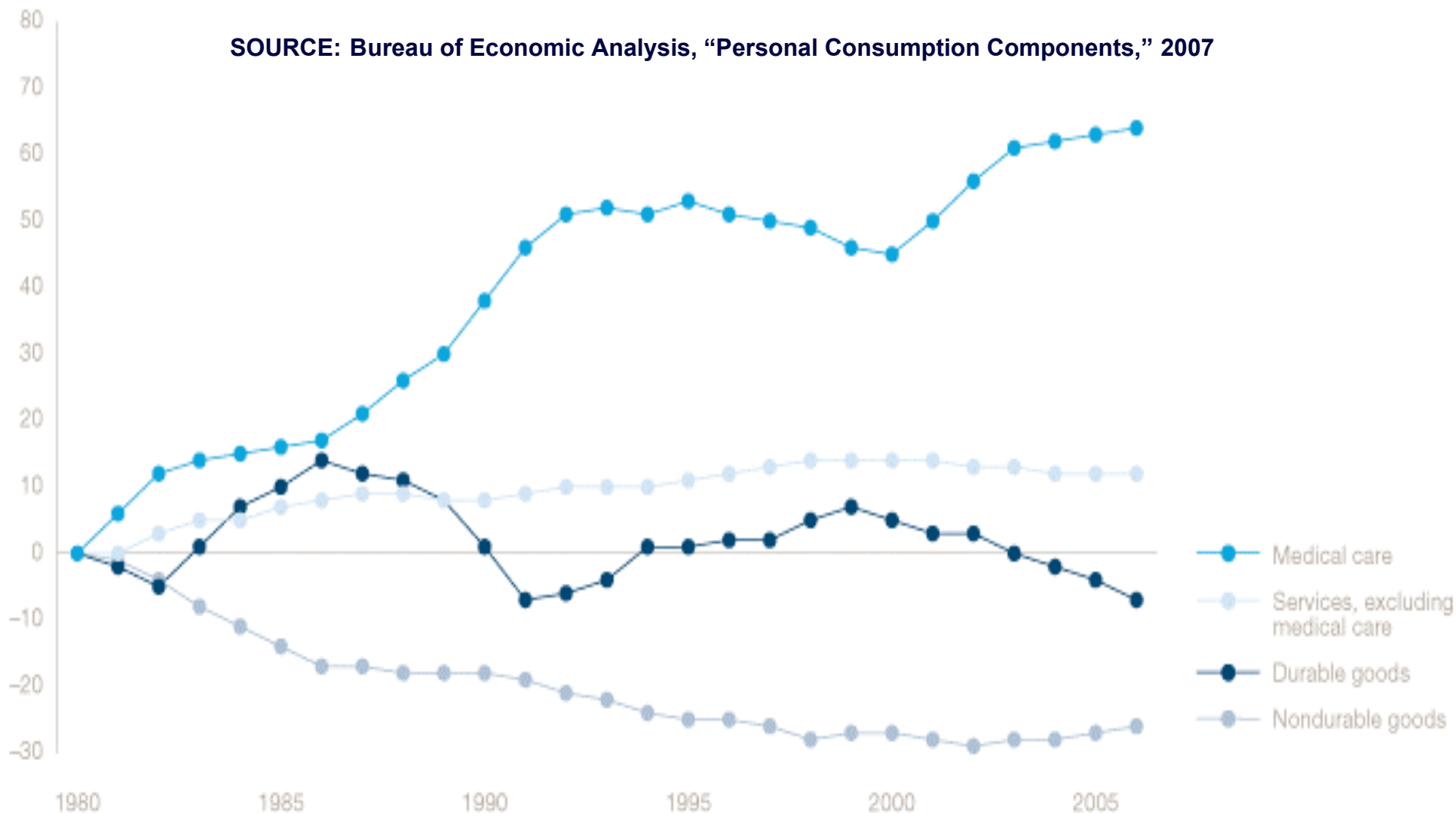
- Mean household income of ~\$58,000 (median is ~\$48,000)
- High school graduate, maybe “some” college
- Current post-tax expenses equal 80% of pre-tax income (95% for median income)
- Minimal financial assets
- Reads at 6th-8th grade level
- Roughly 30%-50% chance of being “*health illiterate*,” “*health innumerate*” or both



Healthcare's Growing Share Of Consumer Spending

Percent Change In Wallet Share Of Personal Consumption Components

SOURCE: Bureau of Economic Analysis, "Personal Consumption Components," 2007

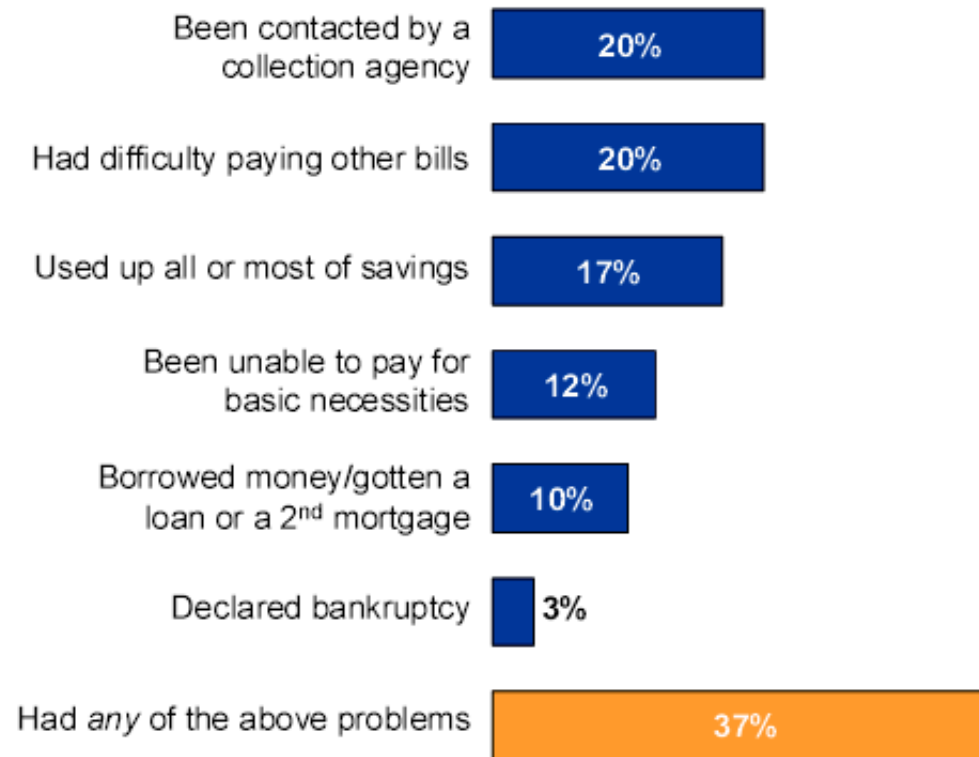




Medical Costs Create Larger Financial Problems For Consumers

Financial Consequences of Medical Bills

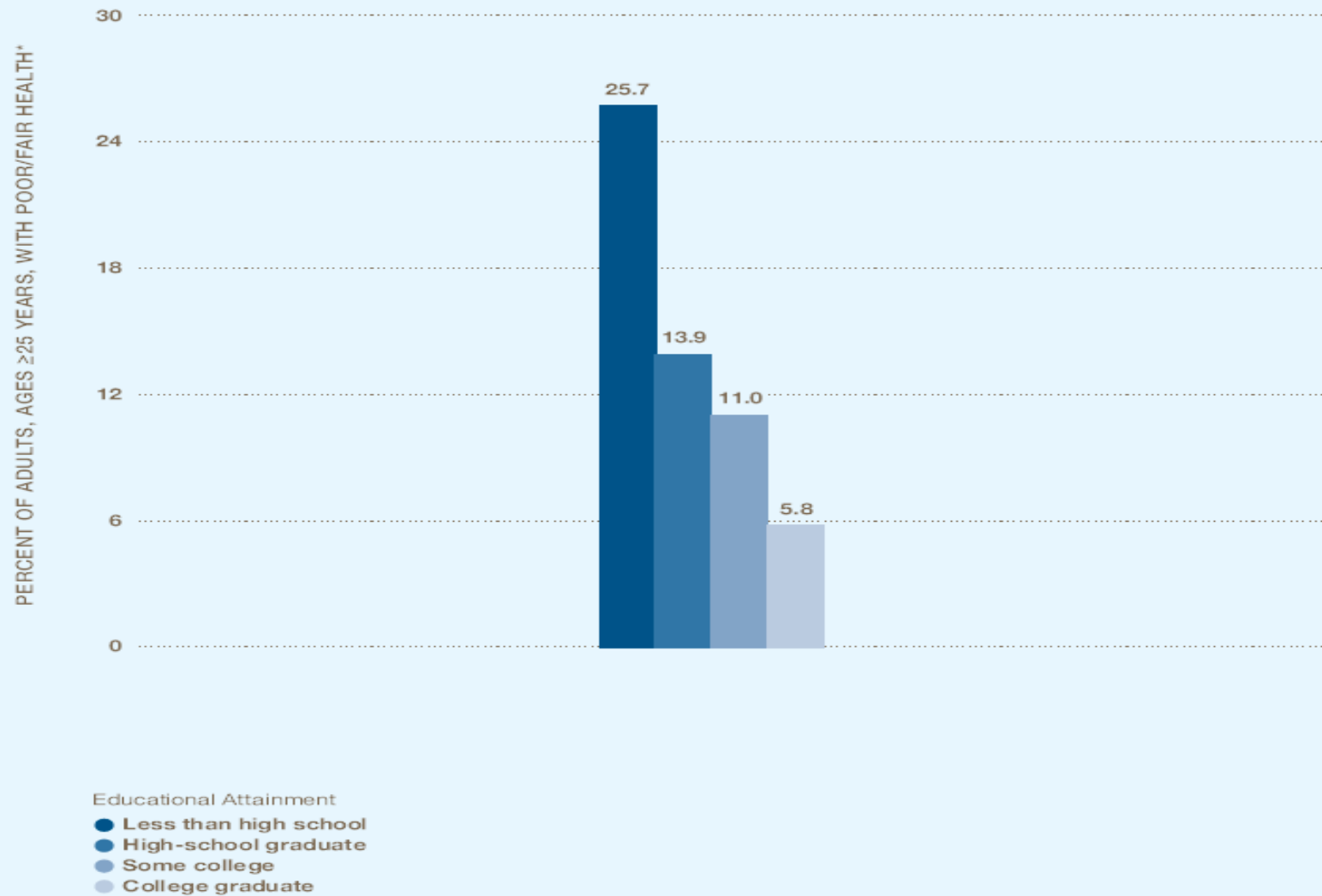
Percent who say they have experienced each of the following in the past 5 years because of medical bills...



2

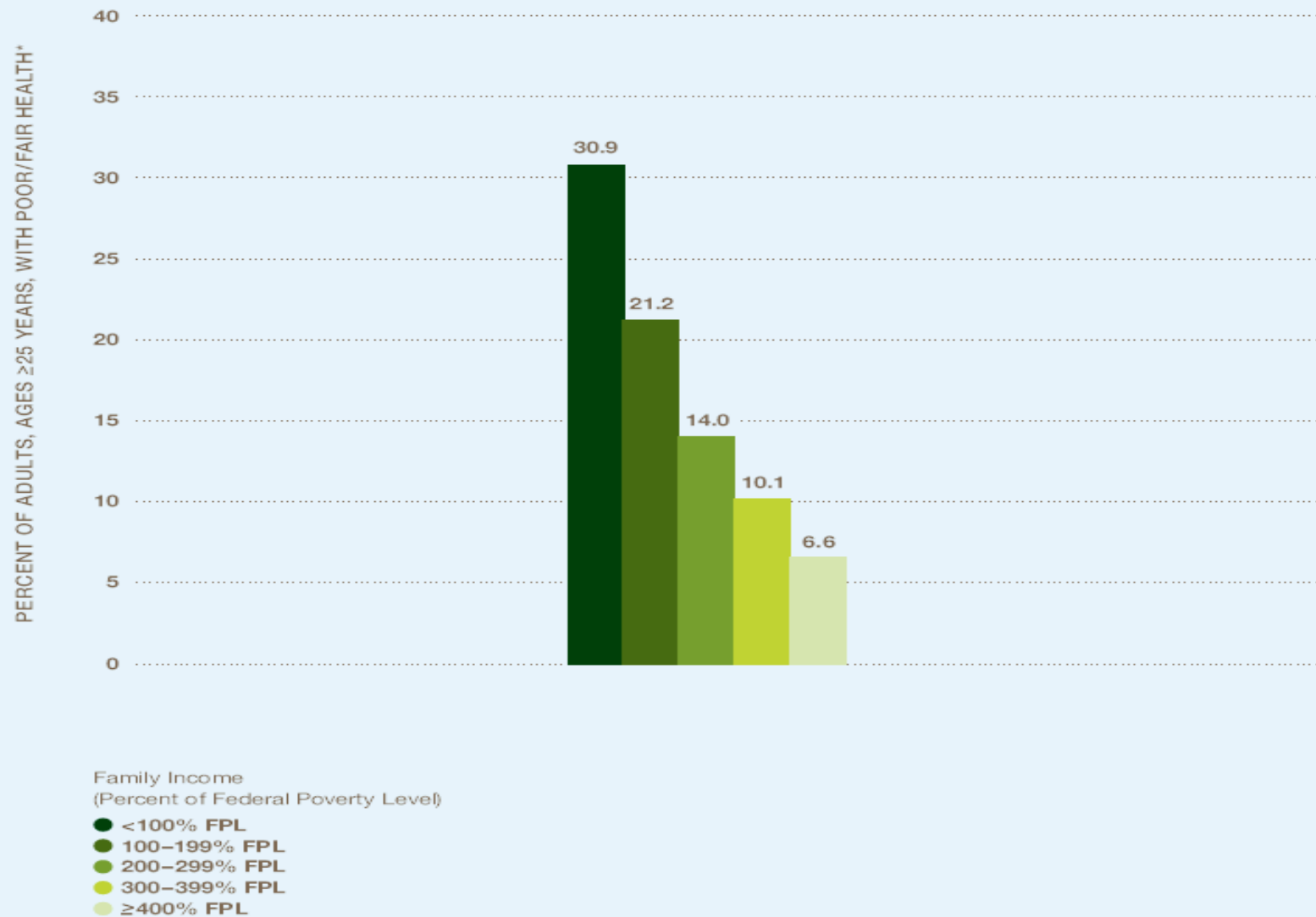
Less Education-Worse Health

SOURCE: Robert Wood Johnson Foundation



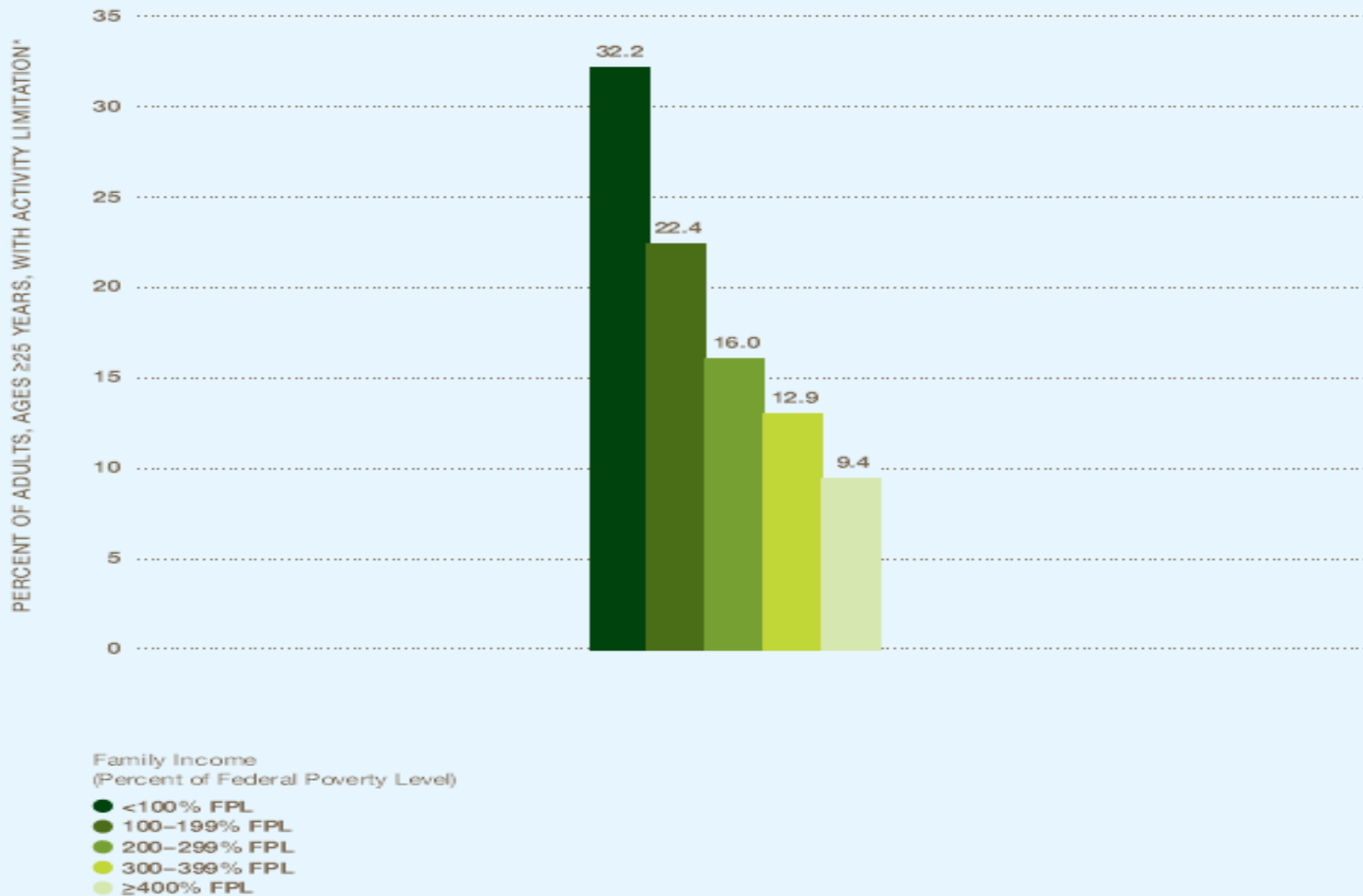
Lower Income—Worse Health

SOURCE: Robert Wood Johnson Foundation



...And More Chronic Disease

SOURCE: Robert Wood Johnson Foundation





Healthcare's New "Alphabet Soup"

CDHP, HDHP, HSA, HRA



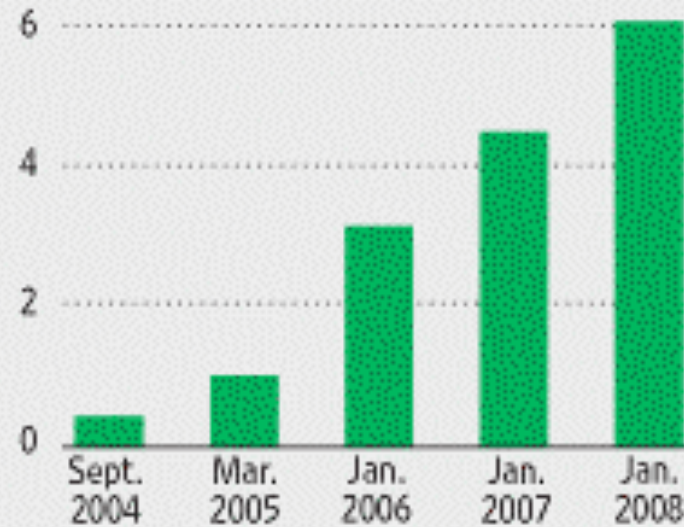


CDHP Enrollment Growth

But many more are in high deductible plans with no savings accounts

Healthy Numbers

Eligibility for HSA plans has surged since 2004 (in millions)



Source: 2008 America's Health Insurance Plans' HSA/HDHP Census



“High Deductible” Health Plan Consumers Are More Non-Compliant Because Of Cost

(Source: Harris Interactive Strategic Health Perspectives—2007)

In the past 12 months, was there a time when, *because of cost*, you...

	General Public %	HDHP%	Difference %
Did not fill a prescription	21	27	-6
Had a specific medical problem but did not visit a doctor	32	38	-6
Did not receive a medical test, treatment or follow-up that was recommended by a doctor	23	29	-6
Took a medication less often than your doctor recommended	19	23	-4
Took a lower dose of a prescription medication than what your doctor recommended	12	17	-5

Source: Harris Interactive, Strategic Health Perspectives 2007.



**HEALTH
AFFAIRS**
*The Policy Journal
of the Health Sphere*

The Impact Of Consumer-Directed Health Plans On Prescription Drug Use

**Enrollees in high-deductible plans were much more likely than those
in other plans to discontinue their chronic-illness medicines.**

... July/August 2008



**HEALTH
AFFAIRS**
*The Policy Journal
of the Health Sphere*

Do Consumer-Directed Health Plans Drive Change In Enrollees' Health Care Behavior?

**Enrollees in high-deductible plans were more likely than those in
PPOs to delay seeking care because of cost.**

... July/August, 2008

San Francisco Chronicle

22% Of Americans Surveyed Cut Visits To Doctor

Nearly a quarter of Americans have reduced the number of times they see their doctor because they want to save money in these tough economic times, according to a survey released Tuesday by the country's state insurance regulators...

...Eleven percent of those surveyed also said they had cut back the number of prescription drugs they take or the dosage of those medications to make the prescription last longer.

Some physicians noted an increase in such behaviors by their patients and were concerned about potential health consequences.

... August 13 2008

THE WALL STREET JOURNAL

Patients Curb Prescription Spending Already Ailing, Drug Industry Takes Hit On Higher-Priced Brand Name

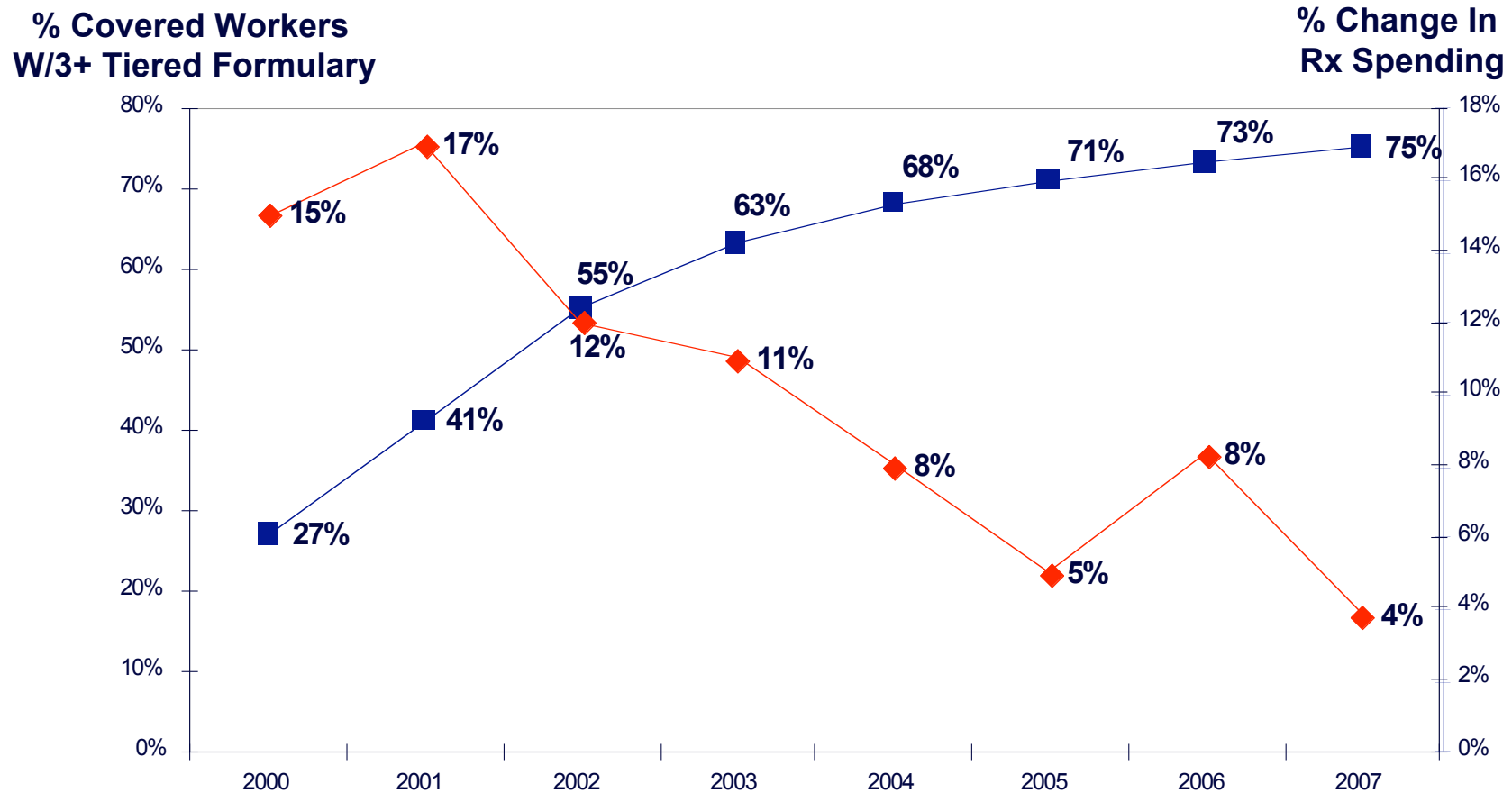
The pharmaceutical industry by conventional wisdom is resistant to economic downturns, because people need medicine in good times and bad. But data from market researcher IMS Health and Wall Street analysts indicate that the rate of prescription growth has fallen steadily since early last year and in recent months has slipped in and out of negative territory...

...The hit is coming at the expense of some of the industry's biggest brands. In May, branded medicines accounted for 30.6% of treatments dispensed, down from 45.9% in 2003, according to IMS. Pills for such chronic conditions as cardiovascular disease are vulnerable, since patients tend to think they can do without treatments for so-called silent diseases more easily than for conditions such as cancer or HIV.

... *July 16, 2008*



Payers Have Successfully Countered Biopharma Promotion By Changing Consumer Cost Sharing (Three Tier Co-Pay And Effect On Rx Demand)

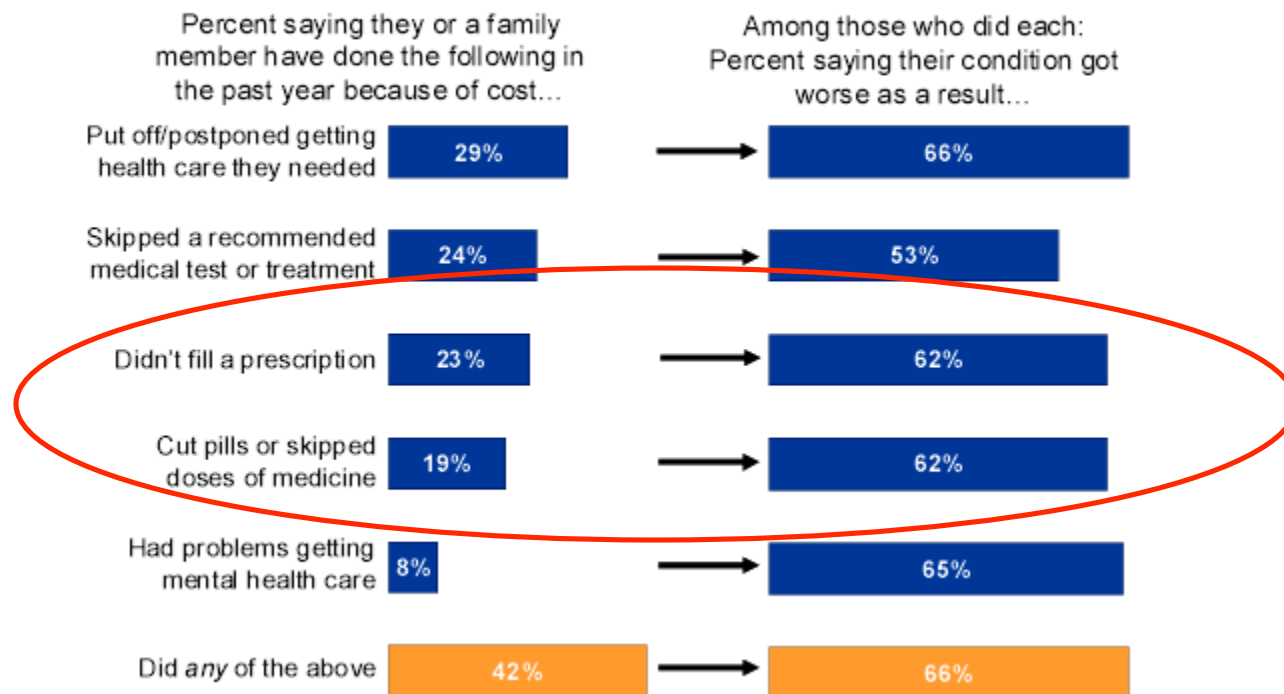


SOURCES: Kaiser Family Foundation & IMS Health



Cost Issues Limit Access To Care (Including Rx)

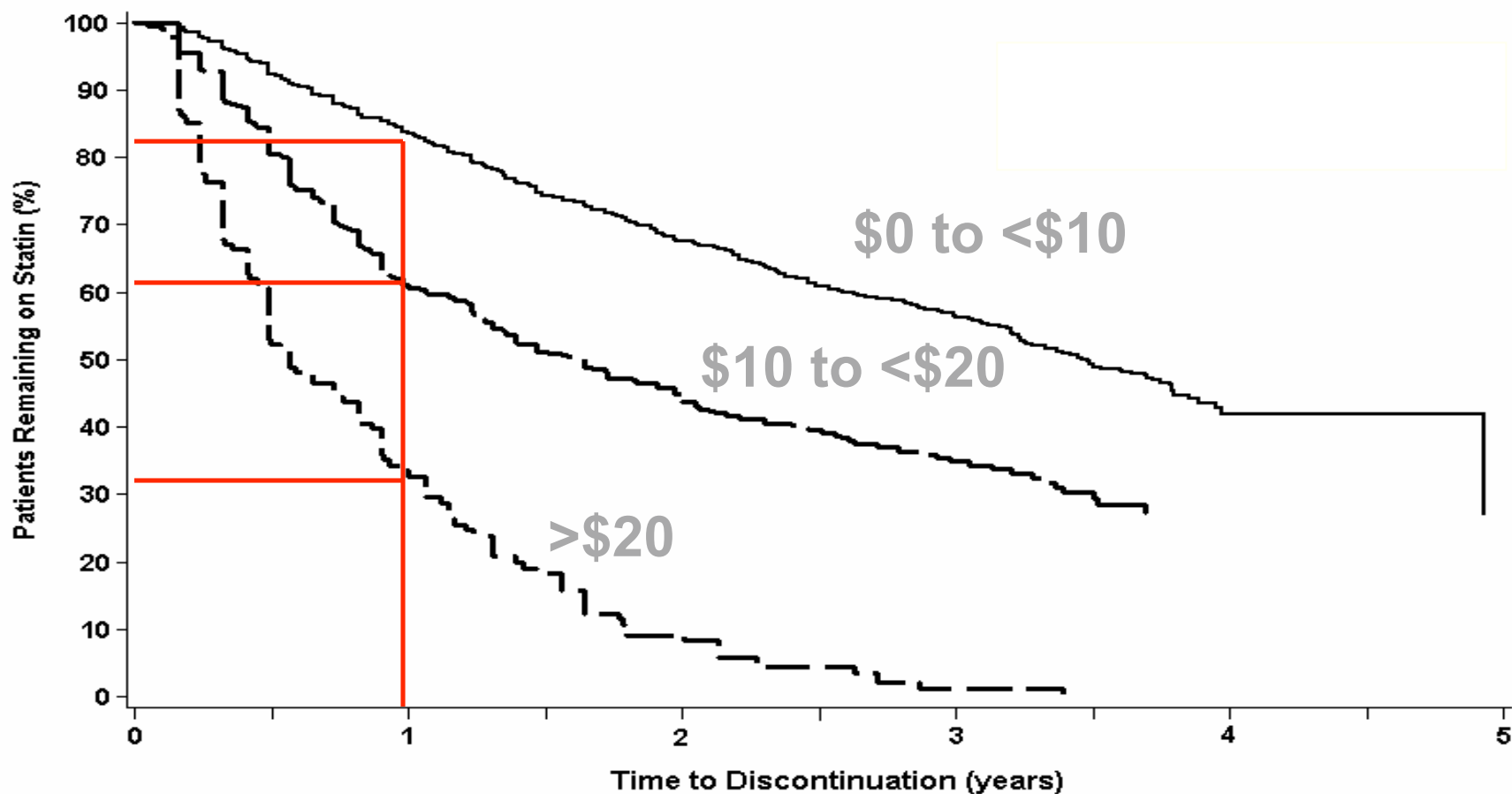
Problems Accessing Health Care Due to Cost





Even Small Co-Payment Differentials Matter

Compliance with Statin Therapy Stratified by Mean Prescription Copayment



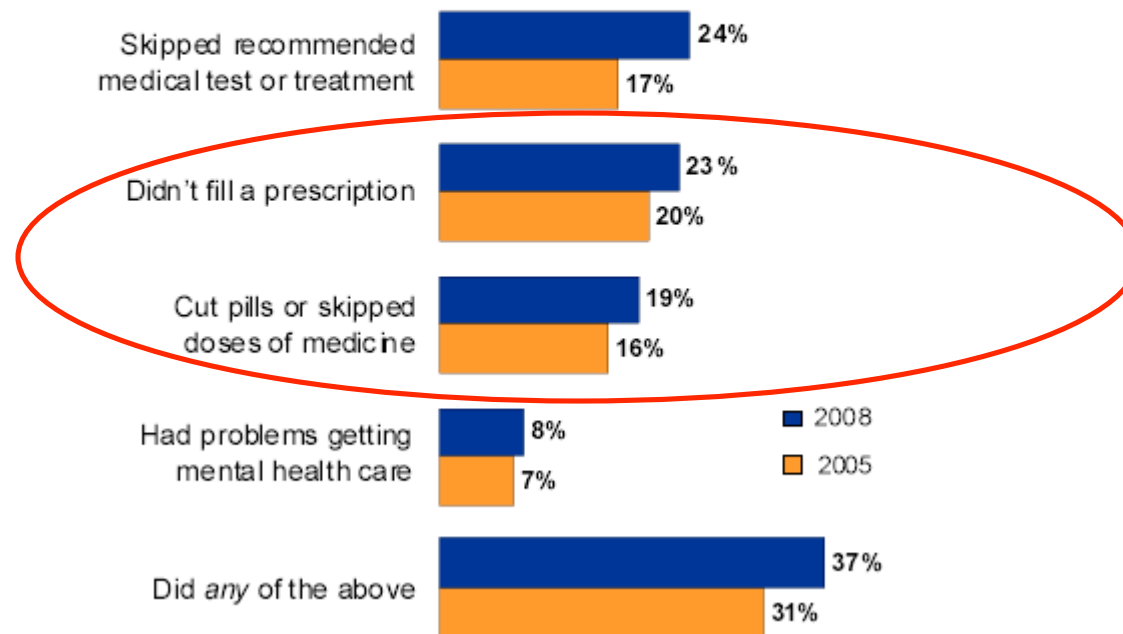
SOURCE: Ellis JJ. J Gen Intern Med 2004;19:639-646.



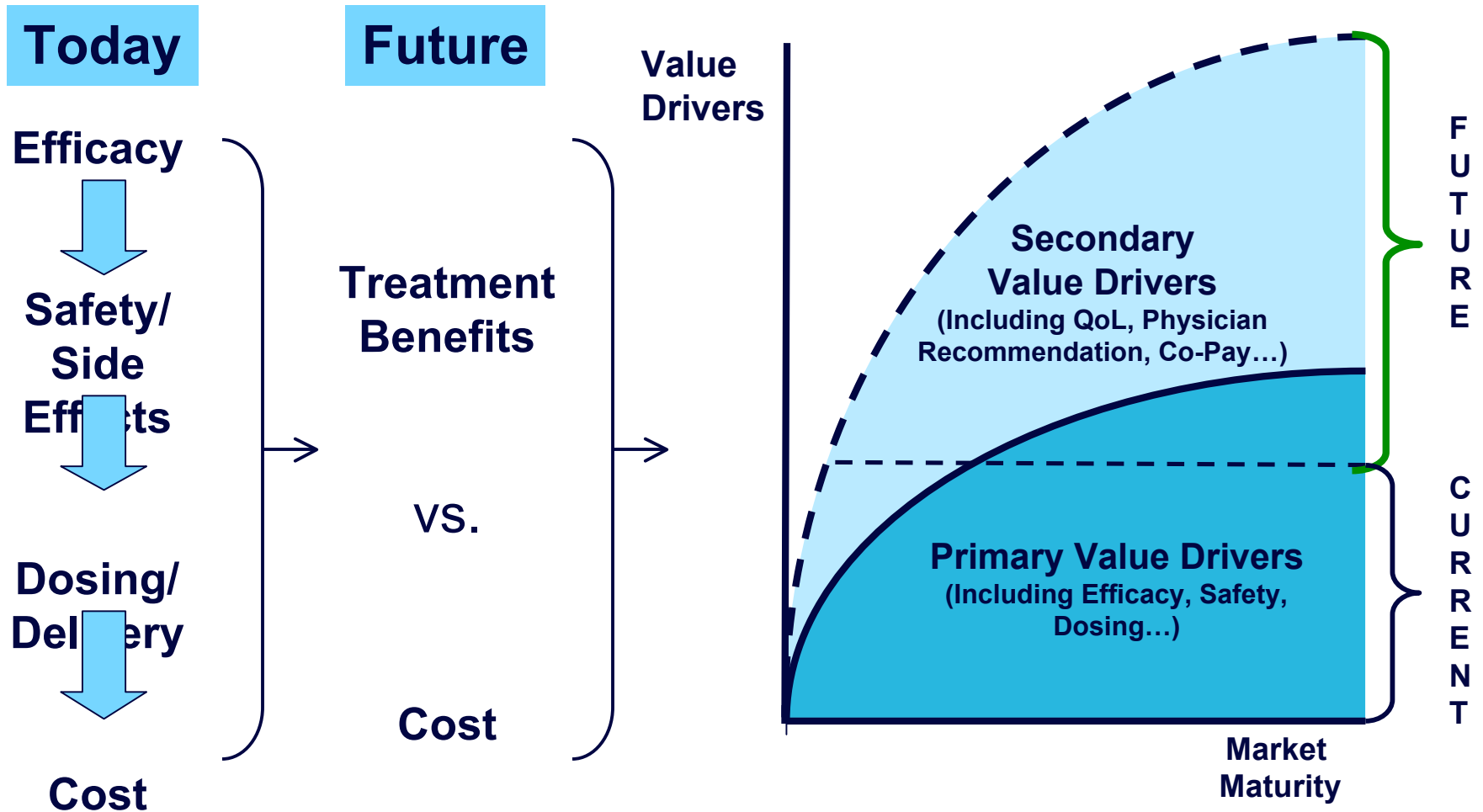
The Problems Appear To Be Getting Worse With Time

Trend in Problems Accessing Health Care Due to Cost

Percent who say they or a family member have done each of the following in the past year because of cost...

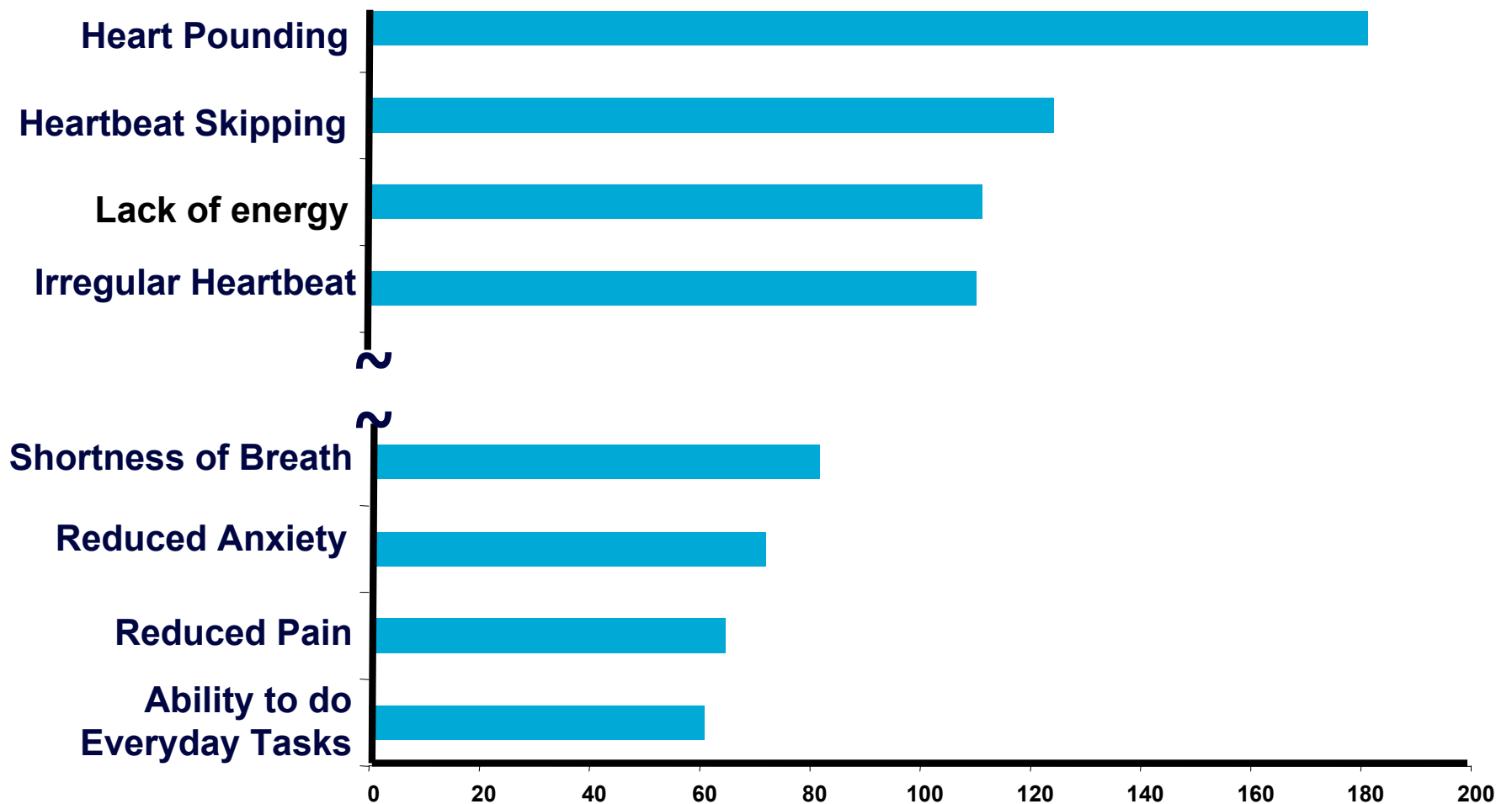


Addressing the Need of Patients Requires Understanding What They Value

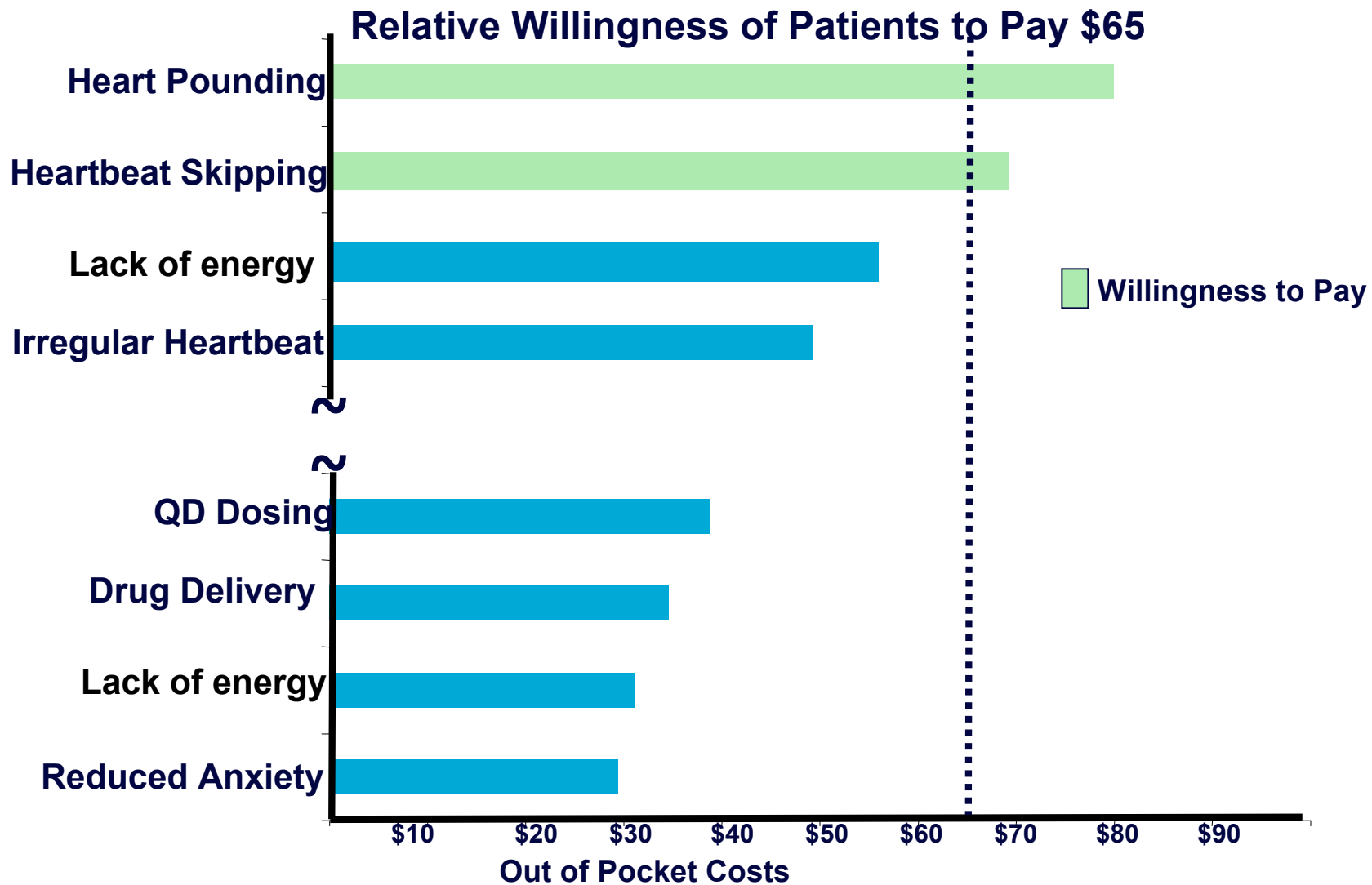


Patients Want to Live Long and Live Well

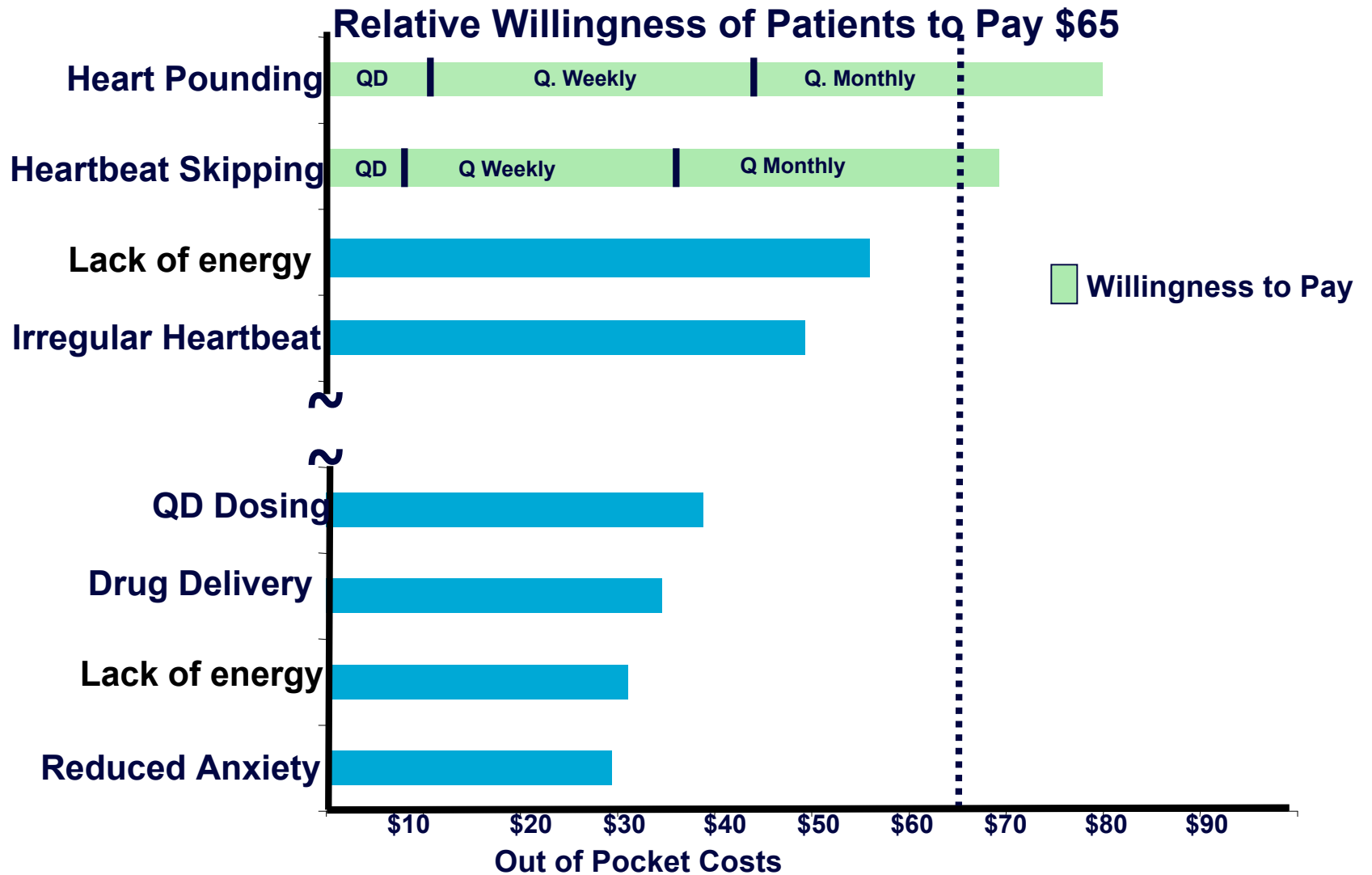
Relative Importance to Patients



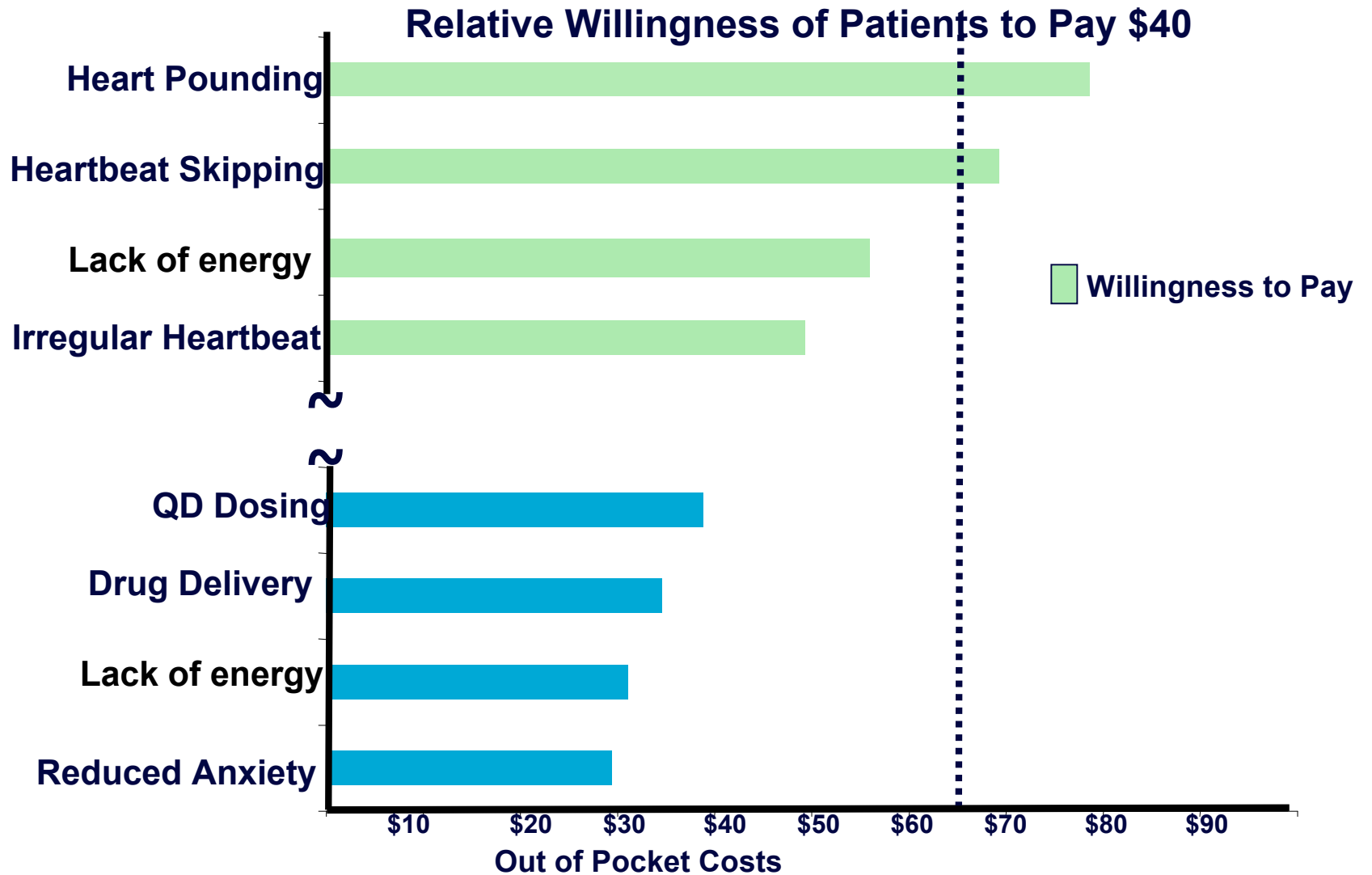
“You Want Me to Pay How Much?.... ...Can’t I Have a Generic?”



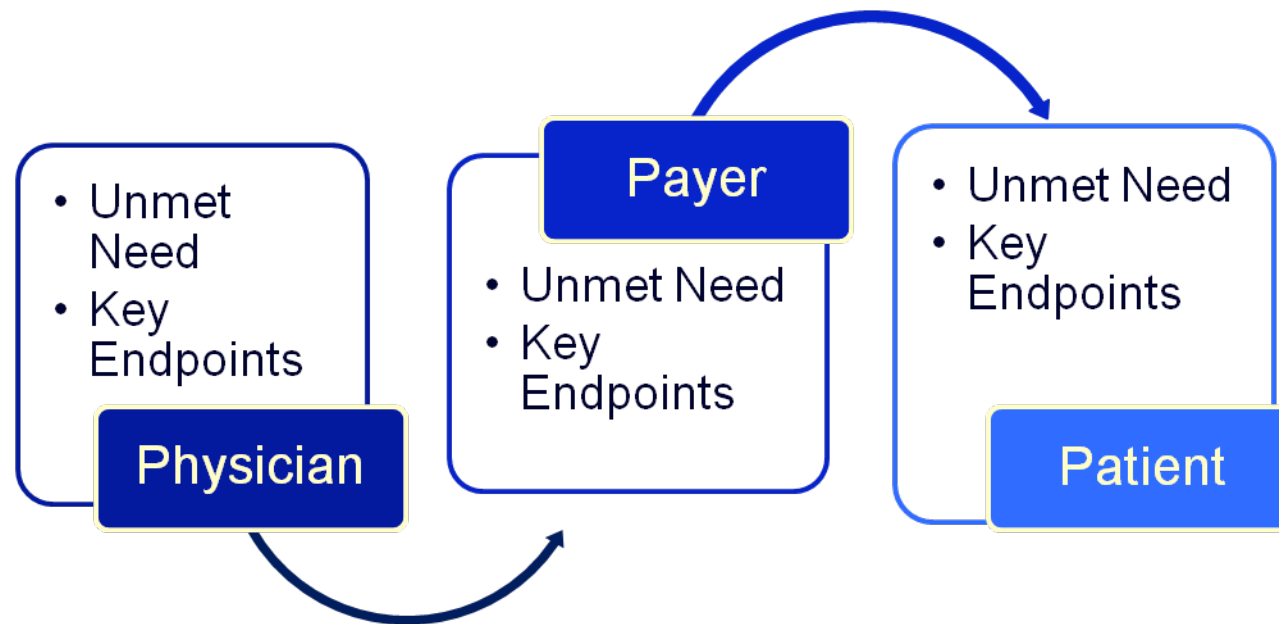
“What’s So Special I Have to Pay \$65?”



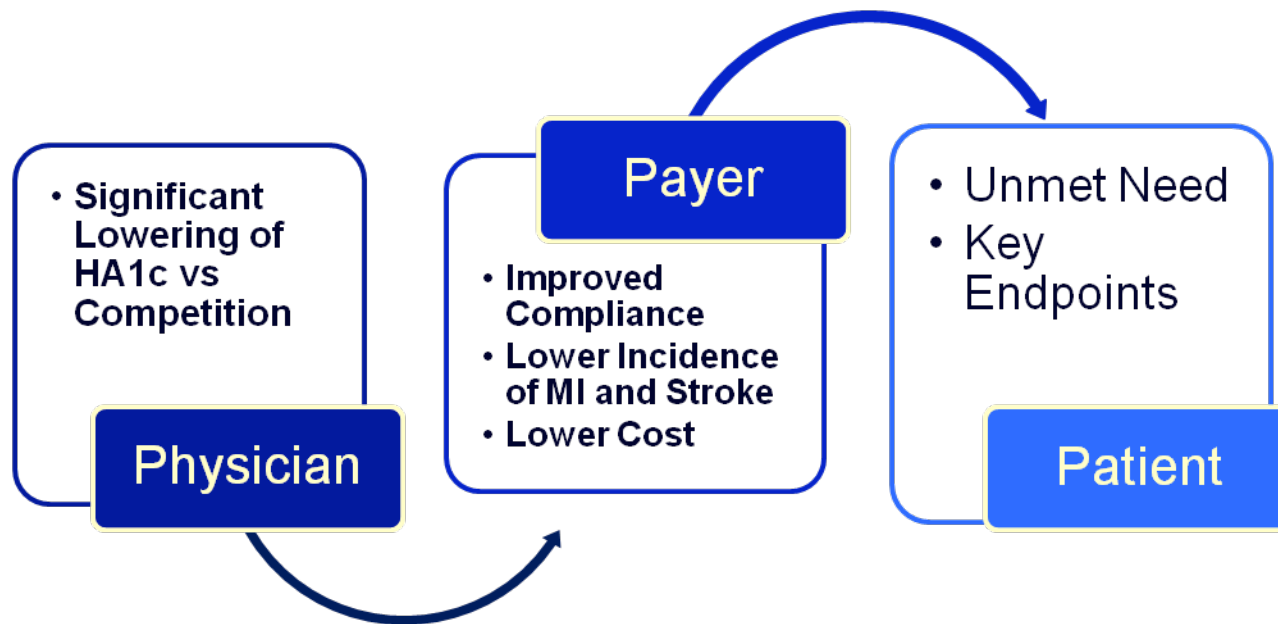
“\$40...Now That’s More Like It...I’m Feeling Better Already!”



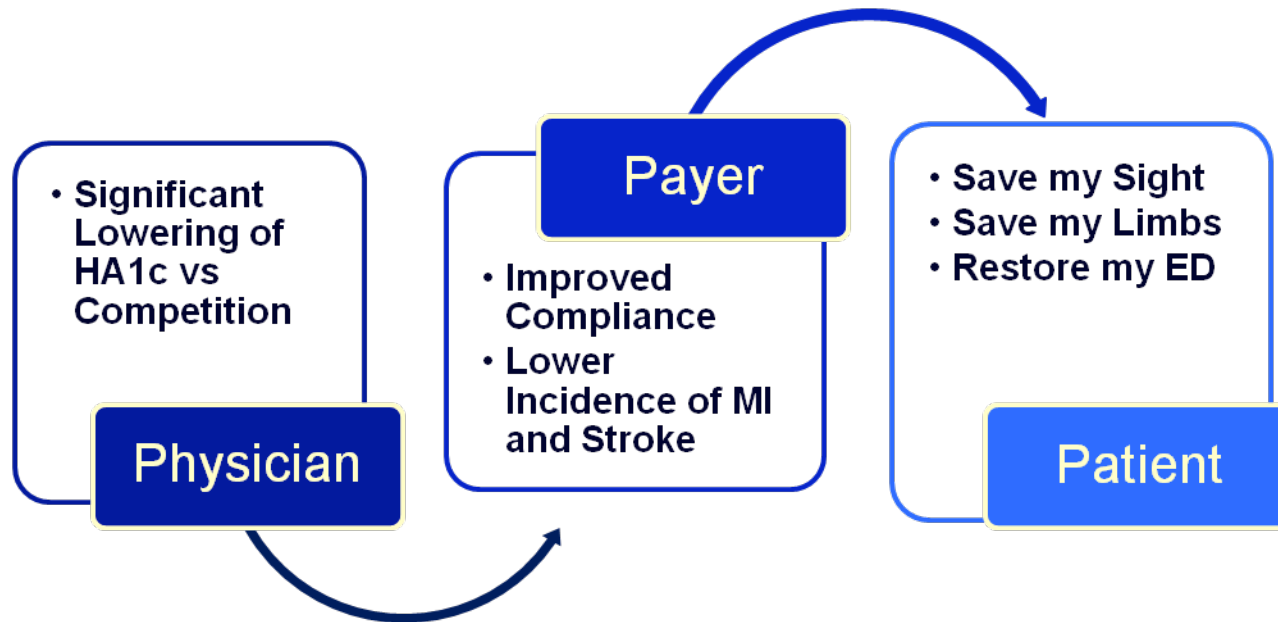
Putting It All Together—Stakeholders Want Different Things from New Drugs



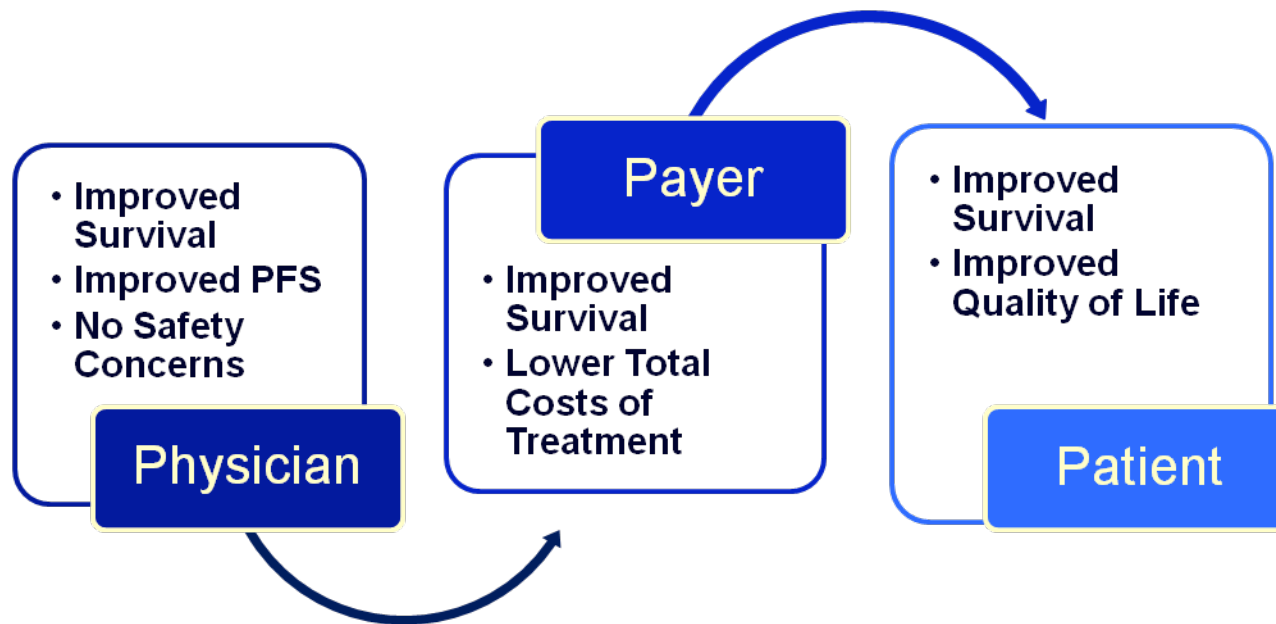
Example: Type II Diabetes



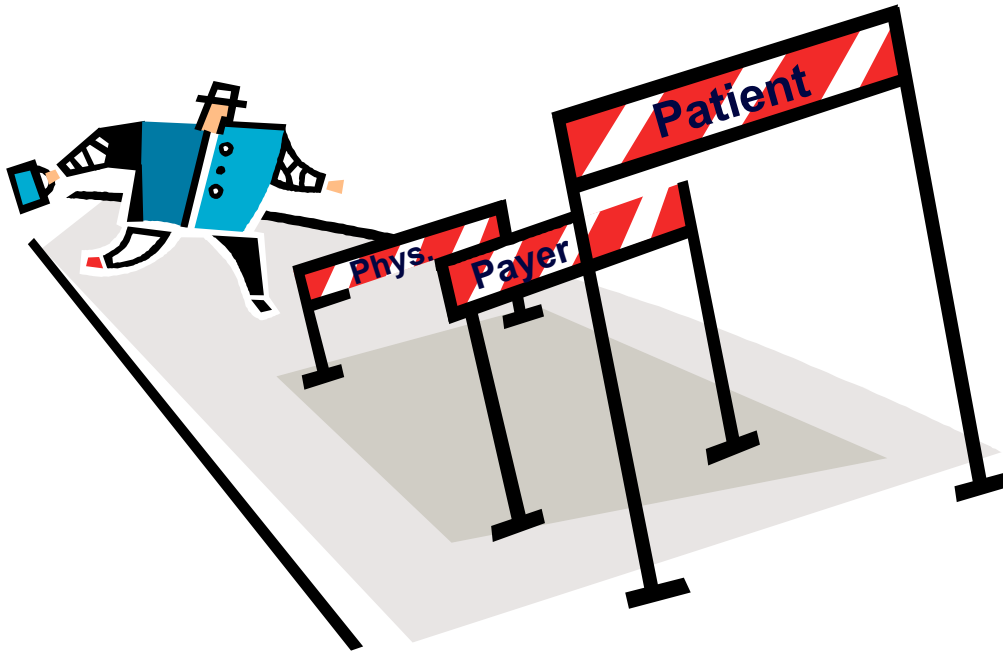
Example: Type II Diabetes



Example: Oncology



Shift Happens!



Old Paradigm

- ◉ Prove safety, efficacy to FDA
- ◉ Focus on Physicians Promoting Clinical Benefits

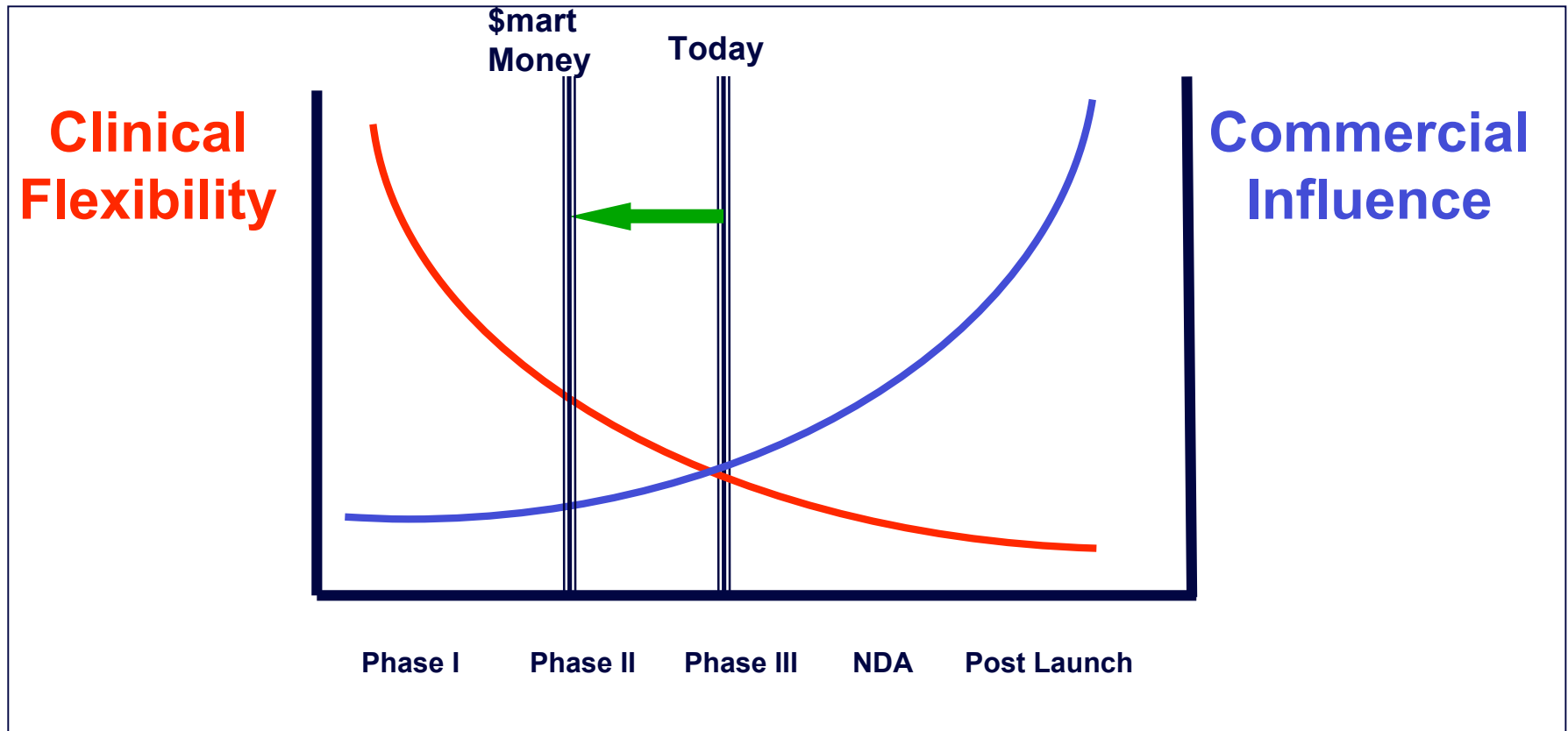
Current Paradigm

- ◉ Prove safety, efficacy to FDA
- ◉ Differentiation Message to Physicians Plus Reasonable Formulary Access
- ◉ Convince payers to reimburse it
- ◉ Get consumers to ask for the medication via DTC

Future Paradigm

- ◉ Prove safety, efficacy to FDA
- ◉ Communicate treatment benefits to all stakeholders
 - ◉ Get physicians to prescribe
 - ◉ Get Payers to Reimburse
 - ◉ Get Patients to be willing to Pay Co-Payment
- ◉ Label Drives the Message of Differentiation and Incremental Value

You Need to Plan for Commercial Success Early and Probability of Success Will be Critical to Prospective Partners!





Understanding Your Customers: The Key to Driving and Deriving Product Value

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