



Personalized Medicine: The Challenges Ahead

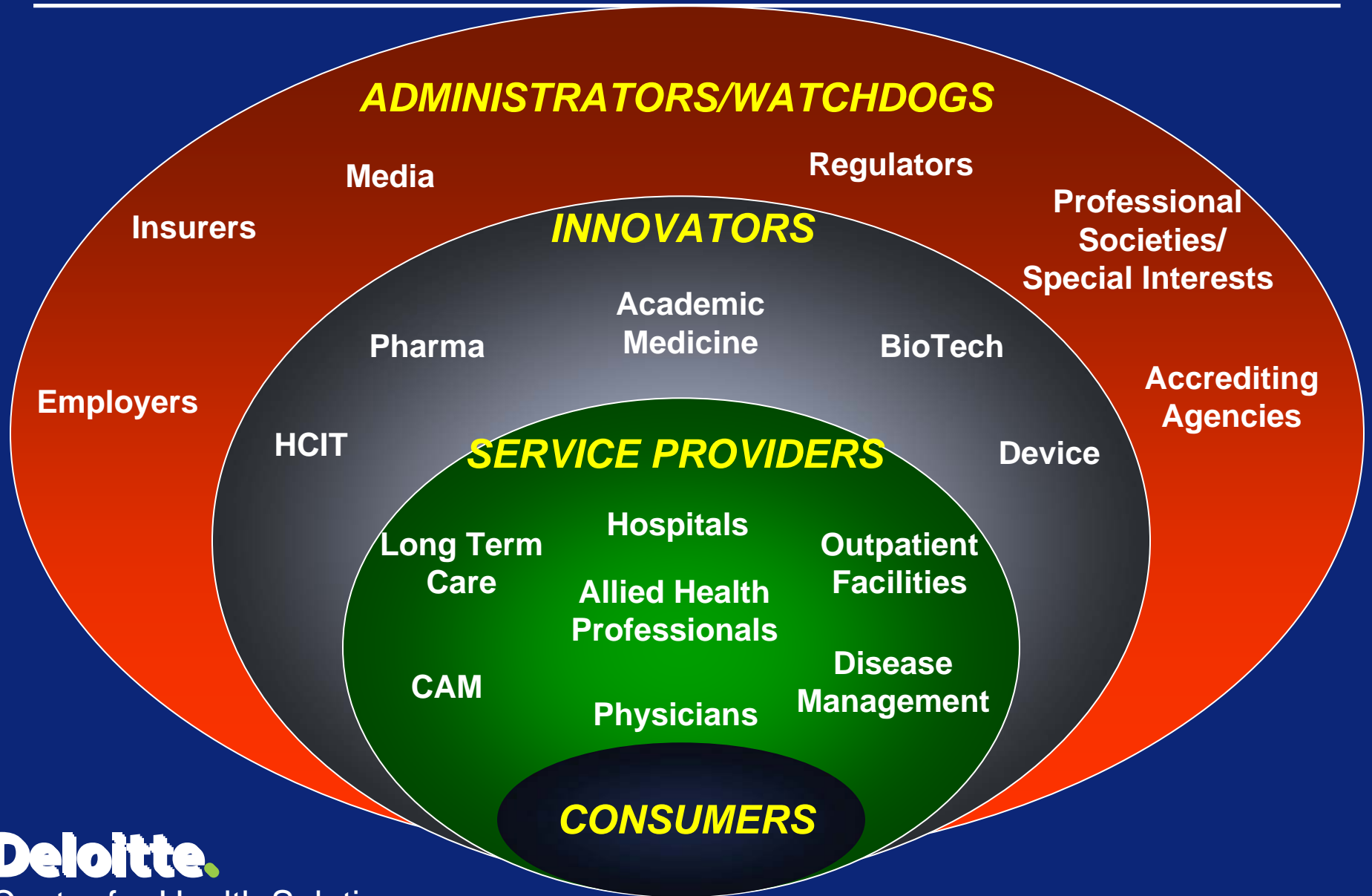
**Personalized Health Care National Conference
Columbus, Ohio
October 17, 2008**

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Deloitte Center for Health Solutions**



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Context: The U.S. health system is big, complex, fragmented, expensive



Context: Health costs are a major issue

- Fastest growing expense in household
- Fastest growing expense in government
- Fastest growing expense in corporate America

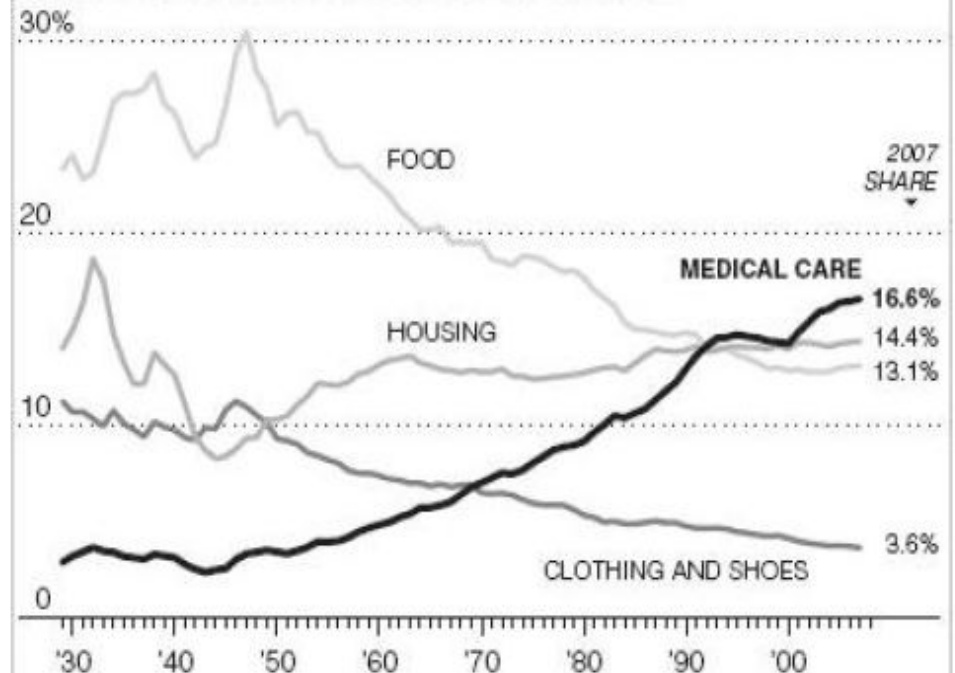
The New York Times

May 4, 2008

The Mounting Burden for Health Care

Spending on health care, which takes up more of consumers' income than housing, food or clothing, has risen significantly since 2000. As the economy slows and medical costs continue to rise, millions of people may be unable to afford care.

SHARE OF DISPOSABLE PERSONAL INCOME SPENT ON:



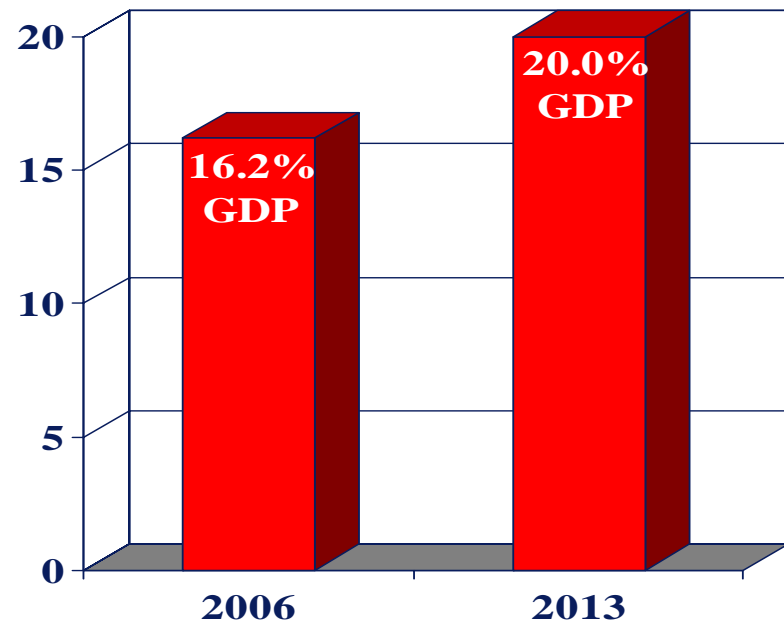
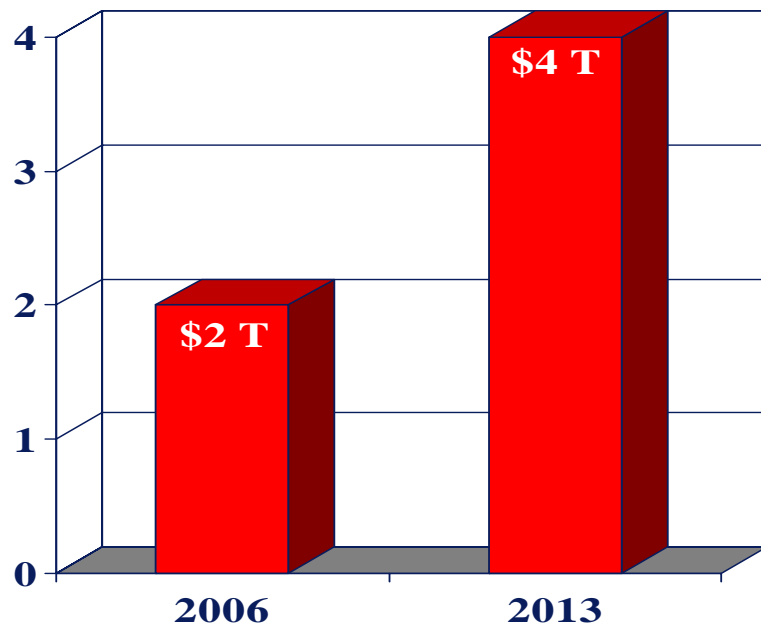
Sources: Bureau of Economic Analysis;
Deloitte Center for Health Solutions Analysis

THE NEW YORK TIMES

Deloitte

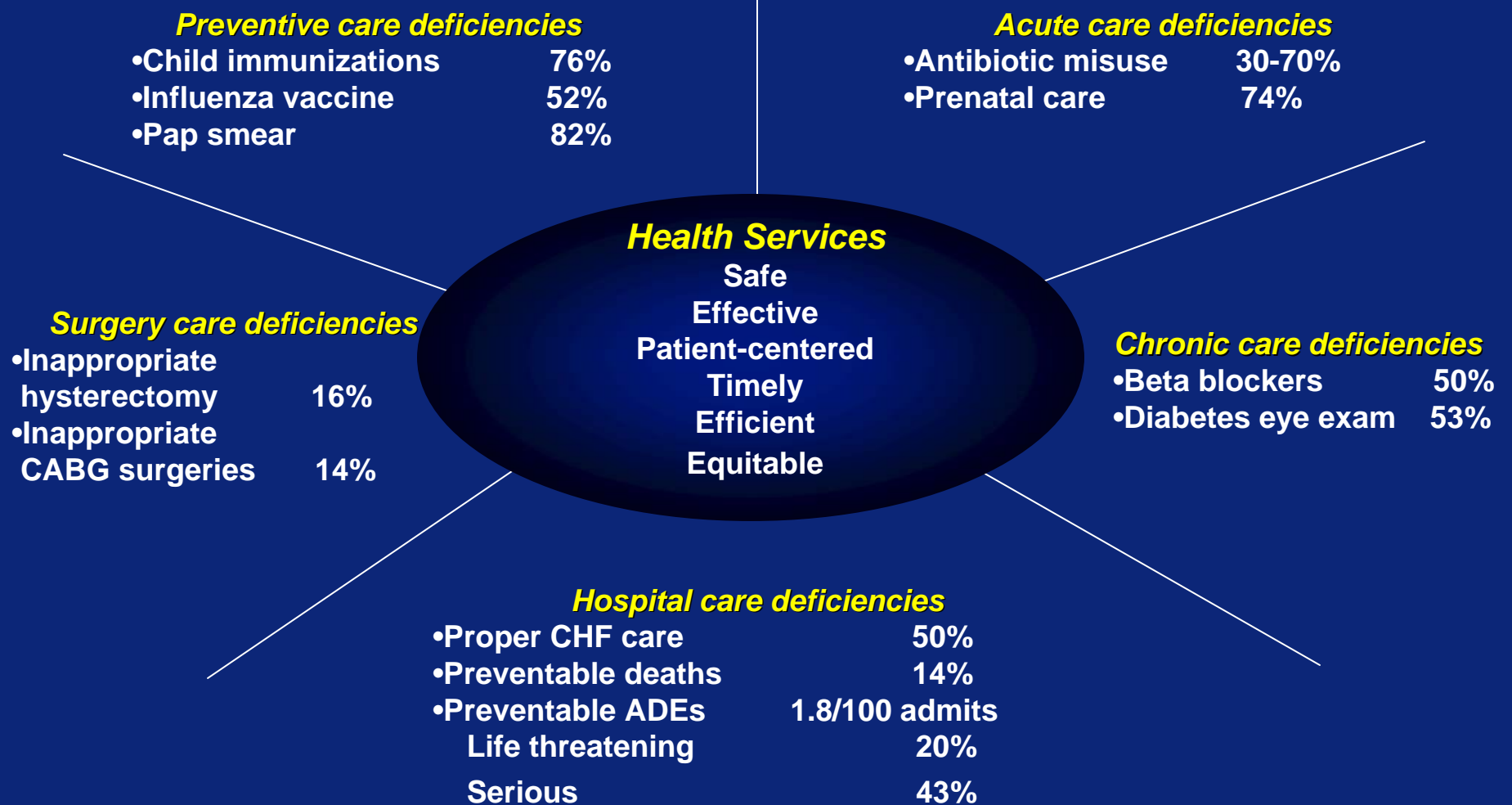
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And consuming the economy...



Spending on health care will double in 7 years

Context: suboptimal quality



Context: widespread non-adherence to evidence-based practice

McGlynn et al "The Quality of Health Care Delivered to Adults in the United States" NEJM June 26, 2003

<i>Condition</i>	<i>% Recommended Care Received</i>
Senile Cataract	78.7
Breast cancer	75.7
Prenatal Care	73.0
Low back pain	68.5
Coronary artery disease	68.0
Hypertension	64.7
Congestive heart failure	63.9
Cerebrovascular disease	59.1
Chronic obstructive pulmonary disease	58.0
Depression	57.7
Orthopedic conditions	57.2
Osteoarthritis	57.3
Colorectal cancer	53.9

<i>Condition</i>	<i>% Recommended Care Received</i>
Asthma	53.5
Benign prostatic hyperplasia	53.0
Hyperlipidemia	48.6
Diabetes mellitus	45.4
Headache	45.2
Urinary tract infection	40.7
Community acquired pneumonia	39.0
Sexually transmitted diseases	36.7
Dyspepsia/peptic ulcer disease	32.7
Atrial fibrillation	24.7
Hip fracture	22.7
Alcohol dependence	10.5

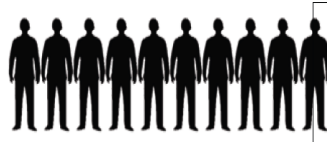


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Efficacy and safety suboptimal

Reduced Safety

Just in hospitals: about 6.7% of patients (2.2 million) experience serious adverse drug reactions



Serious adverse drug reactions in even smaller percentages of treated populations have led to the withdrawal of several drugs from the market

Baycol Fen-Phen Lotronex

“Are good drugs going to the wrong people?”

Propulsid Tysabri Vioxx

Reduced Efficacy

PATIENTS CAN RESPOND DIFFERENTLY TO THE SAME MEDICINE

HYPERTENSION DRUGS ACE Inhibitors	10-30%	
HEART FAILURE DRUGS Beta Blockers	15-25%	
ANTI-DEPRESSANTS	20-50%	
CHOLESTEROL DRUGS Statins	30-70%	
ASTHMA DRUGS Beta-2-agonists	40-70%	
Percentage of the patient population for which any particular drug is ineffective		

Brian Munroe, Presentation to the 2005 FDA Science Forum April 26, 2005

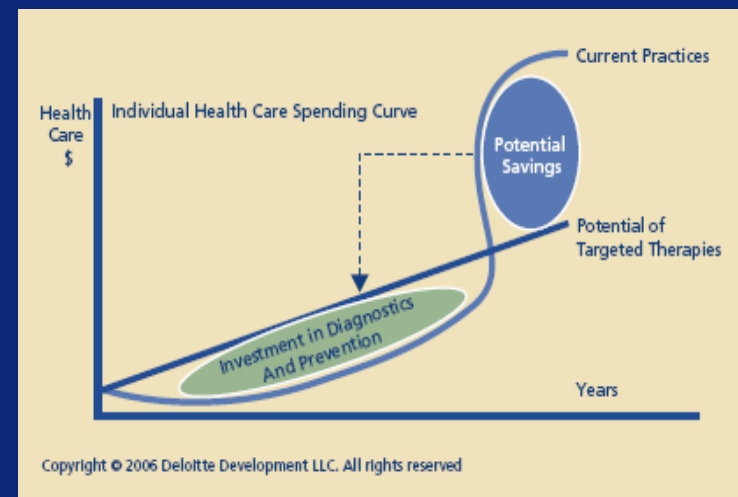
http://www.personalizedmedicinecoalition.org/communications/TheCaseforPersonalizedMedicine_11_13.pdf

Context: Three big issues but costs trump everything else!!



Benefits of Personalized Medicine Undisputed...

- ☑ Advanced screening for disease
- ☑ Improvements in the drug discovery and approval process
- ☑ Avoidance of serious adverse drug reactions
- ☑ Better, safer drugs and vaccines
- ☑ More powerful medicines
- ☑ More accurate methods of determining appropriate drug dosages
- ☑ Increased patient satisfaction and compliance
- ☑ Decrease in the overall, lifelong costs of health care, including shorter, lower-cost, end-of-life expenditures
- ☑ Improved outcomes and quality of life



The PM Promise: Disruptive Innovation

Personalized Medicine will create a new care paradigm



Predictive Care:

Using genetic data we will be able to understand what therapies will best suit individuals



Personalized Care:

Care is provided based upon the likelihood that the specific individual will respond to treatment

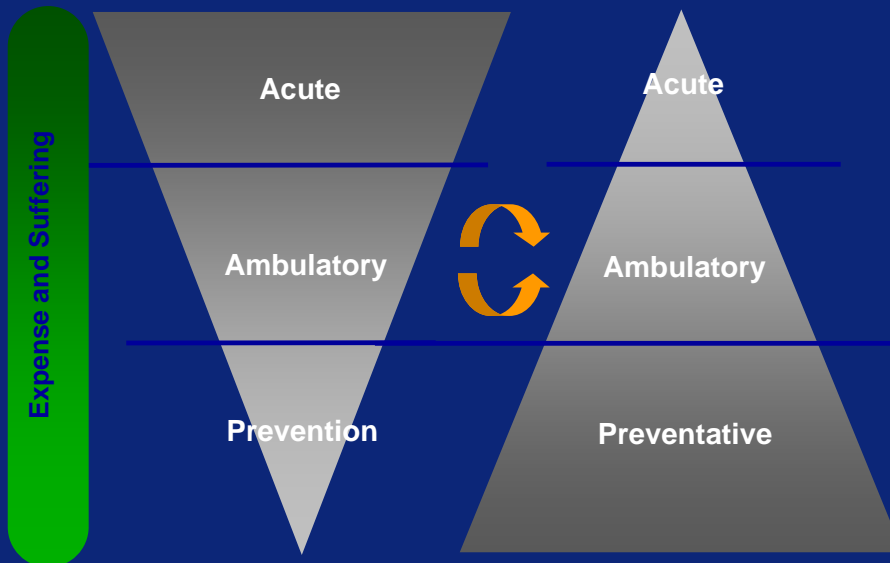


Preemptive Care:

Early diagnoses will allow for treatment before disease presents in patients

The Curative Care Paradigm: Focus on Treating When Ill

The Preemptive Paradigm: Focus on Preventing Illness



Personalized Medicine and Health Parity

Population-based medicine can disadvantage certain populations. Care may be effective for certain groups and not others. Genetically targeting therapies can provide equally effective and efficacious care for all.

What is a disruptive innovation?

Dr. Clay Christensen

According to [Clayton Christenson](#), Harvard Business Professor and author of *The Innovator's Dilemma* and *The Innovator's Solution*, a **disruptive innovation is a technology, process, or business model that brings to a market a much more affordable product or service that is much simpler to use. It enables more consumers in that market to afford and/or have the skill to use the product or service. The change caused by such an innovation is so big that it eventually replaces, or disrupts, the established approach to providing that product or service.**

Health care exists along a spectrum: from judgment/specialist-based medicine to a simpler rules-based medicine. Most health care today is concentrated at the specialist end of the spectrum, **creating a situation that not only excludes many who need the care but also resists any downward pressure on costs. "The opportunity for change lies in the simplicity and diagnostic power of rules-based medicine"**, says Harvard Business School Professor Clayton Christensen.

Providing solutions patients want and see as better alternatives is the driver for disruption to occur. Christenson states that an innovation will be disruptive if it provides the consumer with a more affordable and simpler way to get the job done that the consumer wants/needs done. What enables those disruptions to surface is one or more changes in the technology, process, and business models of health care that can change everything from the cost equation, to pricing structures to distribution and delivery channels, to who provides the service, to who is in control of the decision-making.

This competition seeks to identify those changes that are examples of or have the potential to become disruptive innovations in health and health care.



Challenges

1. Lack of widespread consumer support

Consumers want change and innovation: they are increasingly dissatisfied with the status quo

- 44% of consumers (including 36% of Medicare enrollees) say they would be comfortable with the accuracy, safety, and quality of care offered in a retail clinic that is staffed by a nurse practitioner.
- Slightly more (45%) say they would be comfortable if the nurse practitioner uses a computer-based system that enables him/her to access electronic patient records, check for drug and allergic interactions, confirm treatment recommendations, etc.
- Nearly half (48%) of consumers say they would be comfortable if the nurse practitioner is affiliated with a doctor's office.

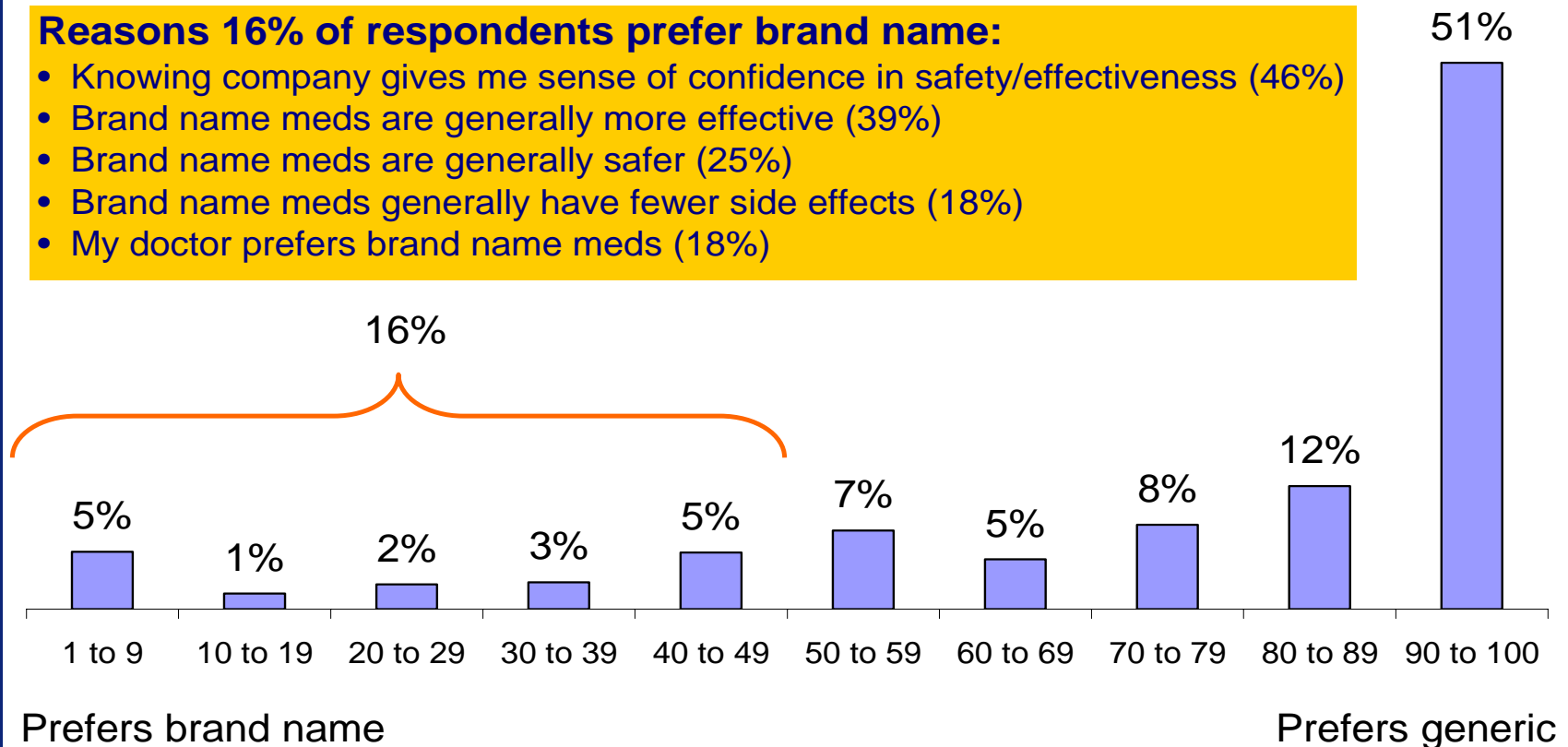


Costs of therapeutics matters to consumers

Preference for Brand Name vs. Generic Medications

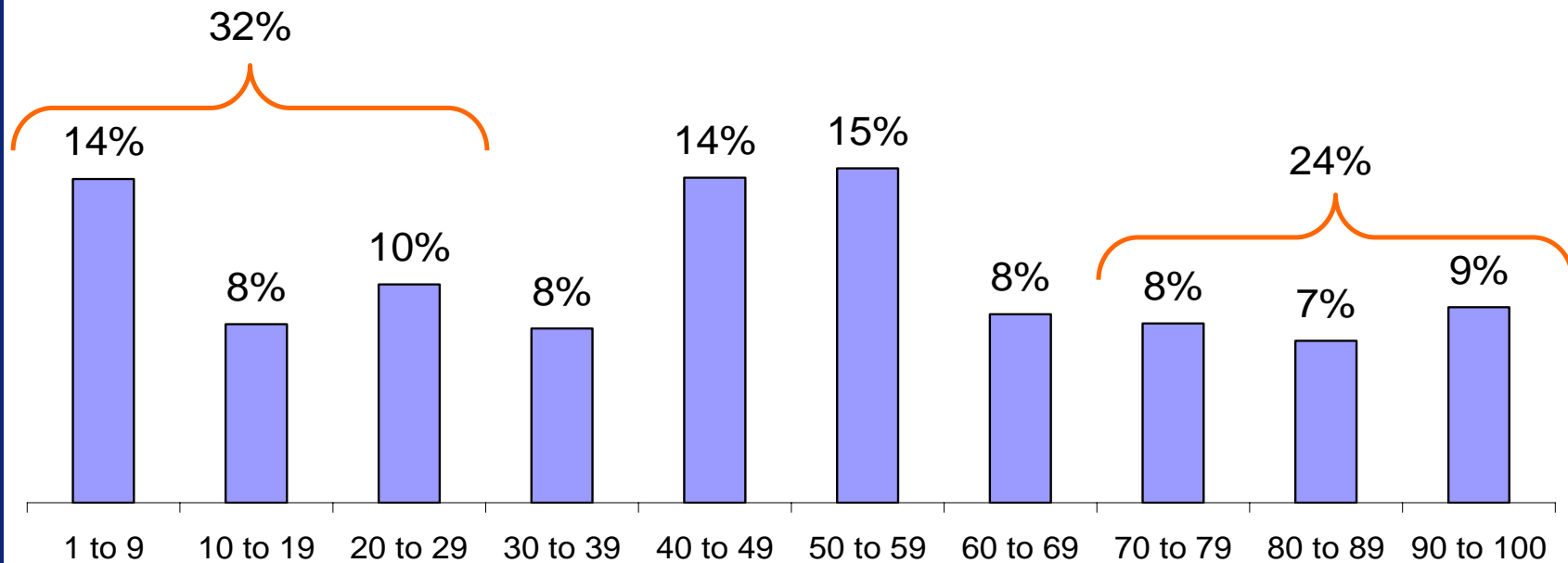
Reasons 16% of respondents prefer brand name:

- Knowing company gives me sense of confidence in safety/effectiveness (46%)
- Brand name meds are generally more effective (39%)
- Brand name meds are generally safer (25%)
- Brand name meds generally have fewer side effects (18%)
- My doctor prefers brand name meds (18%)



Consumer “demand” for improved efficacy varies widely

Treatment Preference If Had a Serious But Not Life-Threatening Illness

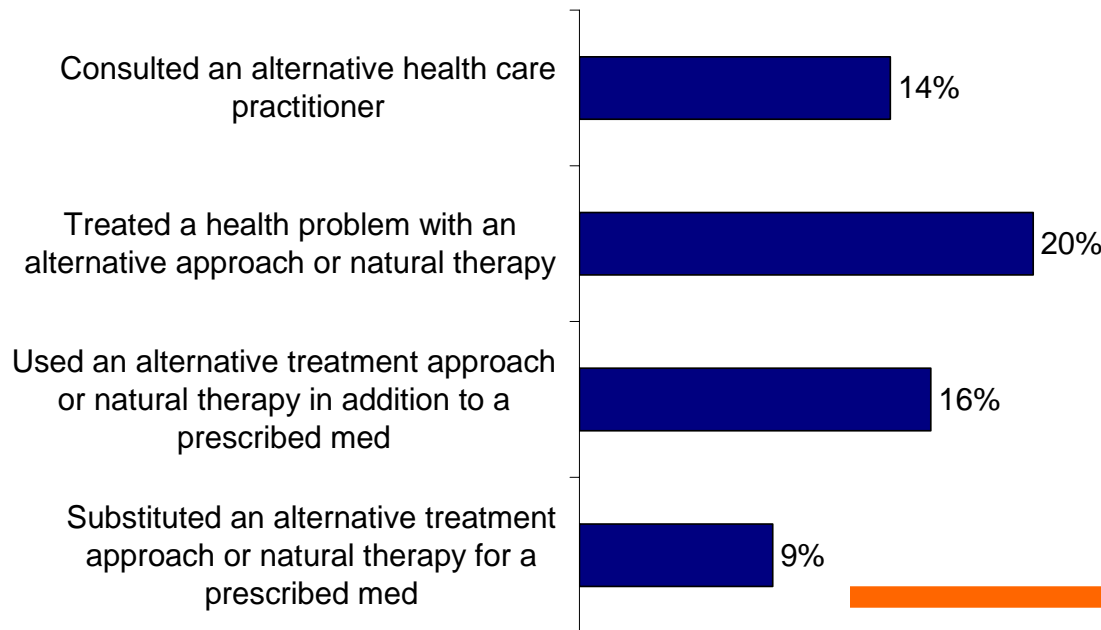


Standard treatment that has a 75% chance of working

Innovative treatment that seems to have greater chance of working but has been tested with fewer patients

Use of non-conventional therapeutics is increasingly popular

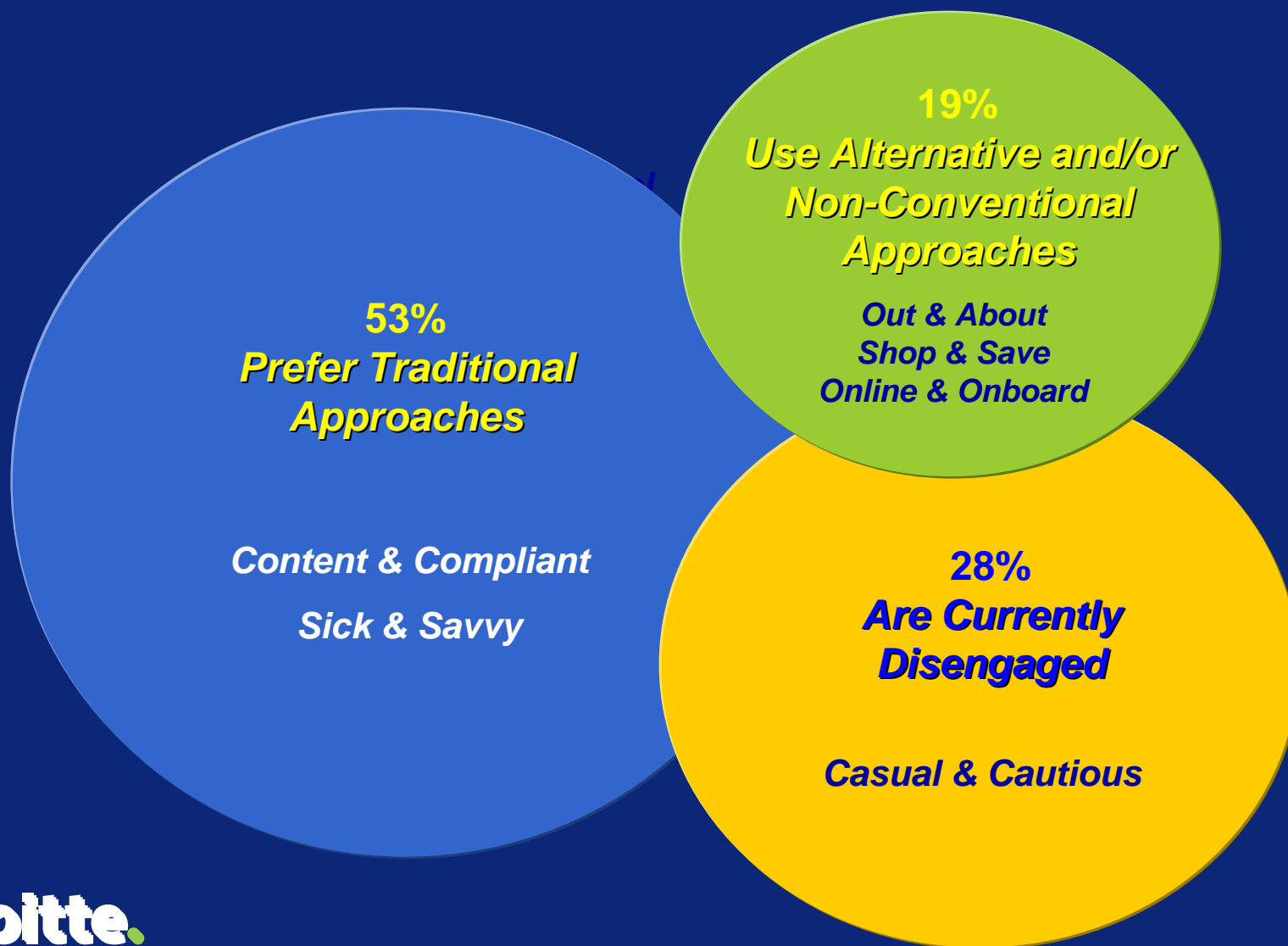
Use of Alternative Practitioners, Approaches, and Therapies in the Last Year



- 50% wanted to try alternative first
 - 42% prefer alternative / natural therapies
- 23% said alternative cost less than Rx
- 22% said Rx wasn't working

Only 2 out of 3 using alternatives say their doctor knows

And 1 of 5 consumers believes the system is not geared toward “healthy” therapeutics and actively seeks alternatives



Challenges

1. Lack of widespread consumer support
2. Lack of health plan coverage

The Health Plan Dilemma

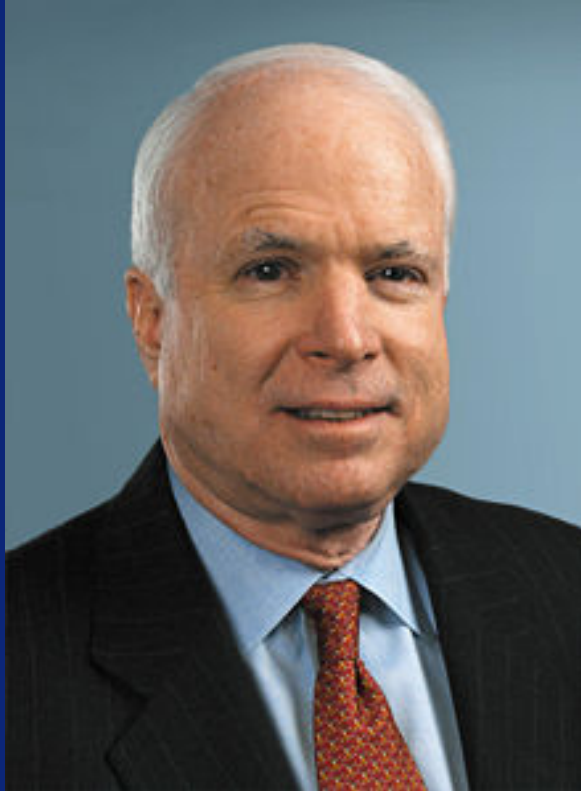
- Increased transparency
- Increased regulatory oversight
- Decreased leverage with employers
- Decreased operating margins
- Increased necessity to “retail” insurance

So for a commercial plan, what's the rationale to cover a more expensive, but more efficacious diagnostic or therapeutic?

Challenges

1. Lack of widespread consumer support
2. Lack of health plan coverage
3. **Lack of supportive public policies**

Context: the new President will inherit the challenge of reform at a difficult time



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Direction: Innovation in the US system will involve response to five changes: cost reduction is common to all

Improved quality
Comparative effectiveness
Evidence-based personalized medicine

Reduced demand
Coordinated care—Preventive,
Chronic, Acute, Long Term

Leveraged Information technology
EMR-PHR Connectivity
Community-based

Changed incentives
Value-based purchasing
Episode-based payments

Engaged consumers
Guided self-care management
Financial participation

Public Policy & Private Sector Innovation

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Policy Challenges for PM

- FDA funding priorities and scope of surveillance
- CMS cost controls for Medicare, Medicaid
 - *Implementation of e-prescribing & comparative effectiveness*
 - *Implementation of episode-based payments*
- IP ownership in emerging markets
- NIH funding & prioritized research agenda

Three major challenges

1. Lack of widespread consumer support
2. Lack of health plan coverage
3. Lack of public policy momentum

Our view

- ✓ We believe conditions are favorable for *disruptive innovations to play a prominent role* in the US healthcare system.
- ✓ We believe health costs will be the driver.
- ✓ We believe advances in technology, consumerism, and public policy changes will *advance momentum* for personalized diagnostics and therapeutics.
- ✓ We believe *public-private collaboration* will be necessary..

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