# Managing Biopharmaceuticals in the U.S.

## Public Policy and Market Strategy

**University of Paris-Descartes**
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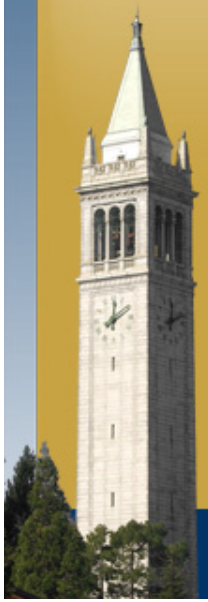
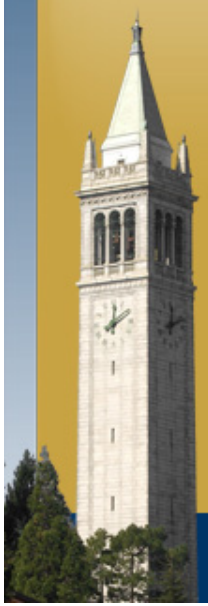
# OVERVIEW

- Public policy: Congress and Obama Administration
- Challenges to biopharmaceuticals in the US
- Small biotechnology firms
- Large biotechnology firms
- Market strategies for biotechnology and insurers
  - Immunology example: Rheumatoid arthritis
- Appropriate utilization
    - Care management, companion diagnostics
    - Benefit design and consumer cost sharing
- Distribution and physician practice economics
- Performance-based pricing



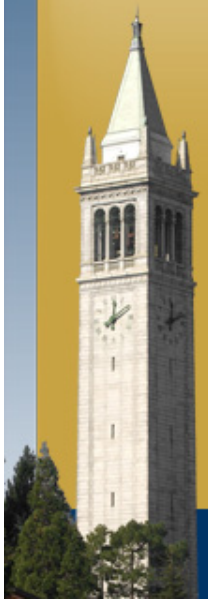
# Public Policy: Replacement of Market Forces

- Expansion of public insurance plans
  - Federal support for increased enrollment in state plans
  - New proposed national  public insurance plan
- Drug purchasing by public insurance plans
  - Mandatory discounts and rebates
- Cutting public payments for private plans
  - Encouraging Medicare enrollment to shift from private (Medicare Advantage) to public Medicare plan



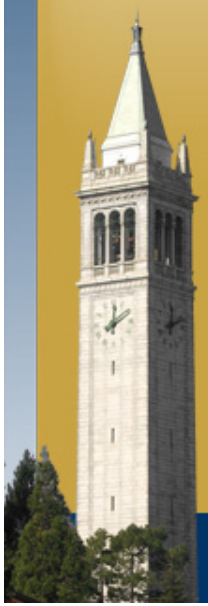
# Public Policy: Support for Market Forces

- Comparative effectiveness research
  - Therapies are equivalent until proven non-equivalent, or non-equivalent until proven equivalent?
  - Biologics as obvious candidates for testing
    - Lucentis and Avastin
    - Biologic therapies for rheumatoid arthritis, MS
- Regulatory pathway for biosimilars
  - Following the lead of the EU
  - Effects will be only long-term, not short-term, except for EPO, growth hormone, and a few others
- Continued support for employment-based insurance



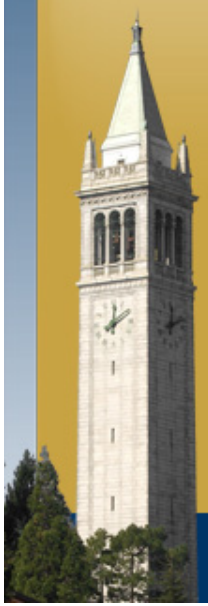
## Challenges to Biotechnology: Small Firms

- How to obtain continued financial investments:
  - Long pathway to product revenues
  - Retreat by venture capitalists (50% decline in 1Q09)
  - IPO window closed
  - Credit markets closed for debt financing
- Very low valuations: many valued at less than cash
- Acquisitions by larger biotech and by pharma
  - Large pharma is cash rich
  - Europharma has (had) strong(er) Euro
  - Acquisitions preferred over licensing
- Reverse merger or unwinding
- Overall: very widespread concerns over pipeline



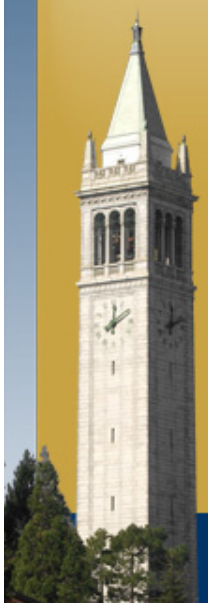
## Challenges to biotechnology: Large firms

- Some have strong product revenues (high prices, indication spread for oncology, immunology)
- Valuations mostly down, making them attractive acquisition targets: Genentech, Wyeth, Imclone
- Major challenge is from payers
  - Government
  - Consumers
  - Private insurers
- All these focus on unit prices, utilization, and expenditures (revenues) for biopharmaceuticals
- Huge pressure to reduce expenditures
- Most important are the private insurers



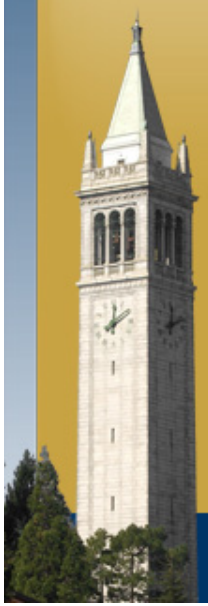
## Market Strategies: Biopharma and Insurers

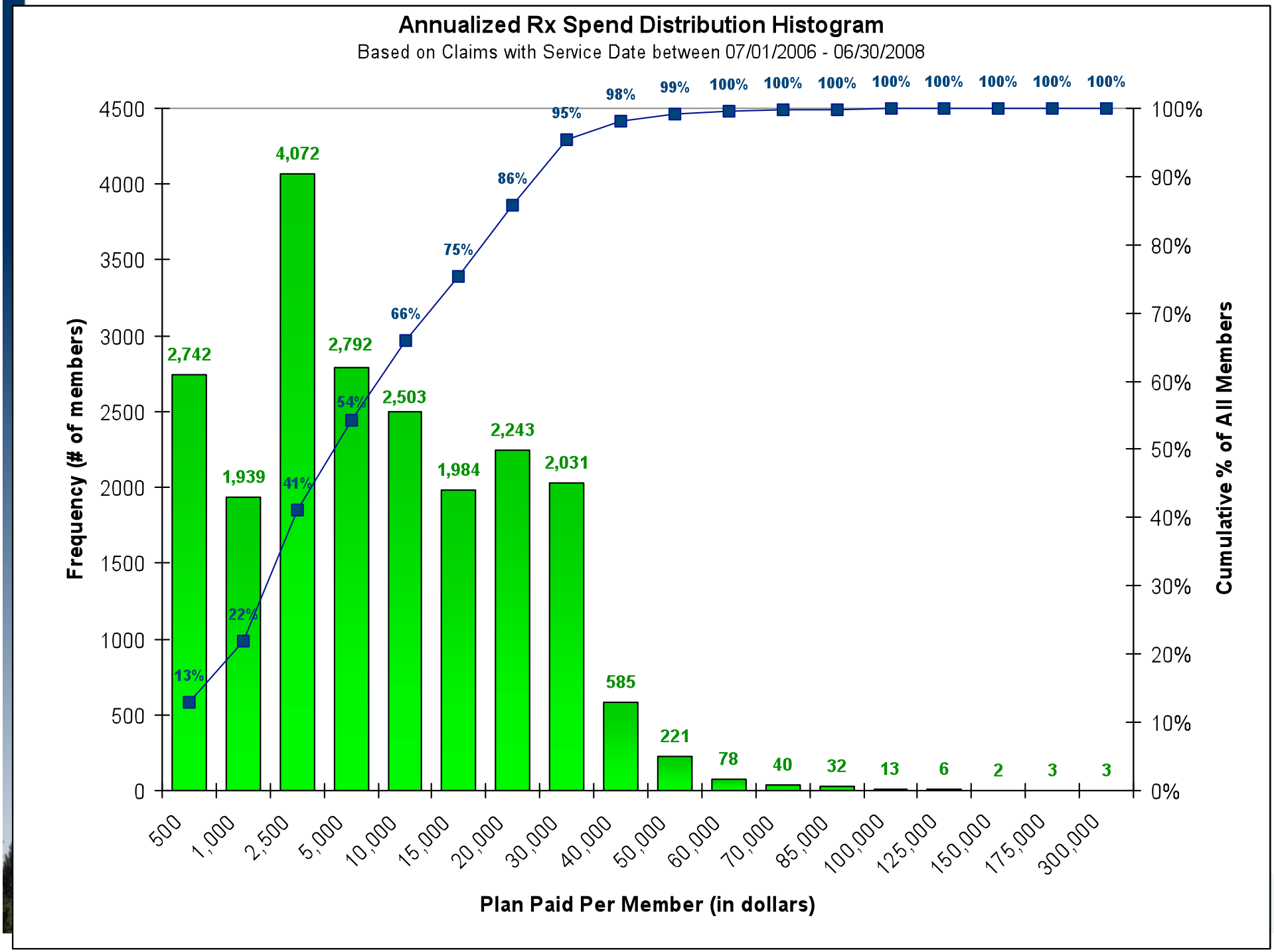
- Are manufacturers and insurers engaged in a zero sum game in the market?
  - Zero sum: your gain is my loss, and vice versa.
  - Manufacturers favor premium pricing, extended patent protection, coverage without restrictions, no financial barriers for patients, favorable reimbursement for physician practices
  - Insurers favor commodity pricing, biosimilars, prior authorization, consumer cost sharing, reduced payments for distribution through physician practices
- Can this be changed to a positive sum game?
  - We both gain overall from playing, even if our interests diverge at times (zero sum sub-games)



# A Positive Sum Game: Immunology

1. Enhancing appropriate utilization
   - Prior authorization and early intervention
   - Care management: safety monitoring and patient education
2. Benefit design and consumer cost sharing
   - Tiered formulary for specialty drugs
3. Distribution and physician practice economics
   - Specialty pharmacy and buy-and-bill
4. Performance-based pricing




Annualized Rx Spend Distribution Histogram
Based on Claims with Service Date between 07/01/2006 - 06/30/2008
Frequency (# of members)
Cumulative % of All Members
Plan Paid Per Member (in dollars)
0
500
1000
1500
2000
2500
3000
3500
4000
4500
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%
2,742
1,939
4,072
2,792
2,503
1,984
2,243
2,031
585
221
78
40
32
13
6
2
3
3
13%
22%
41%
54%
66%
75%
86%
95%
98%
99%
100%
100%
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100%
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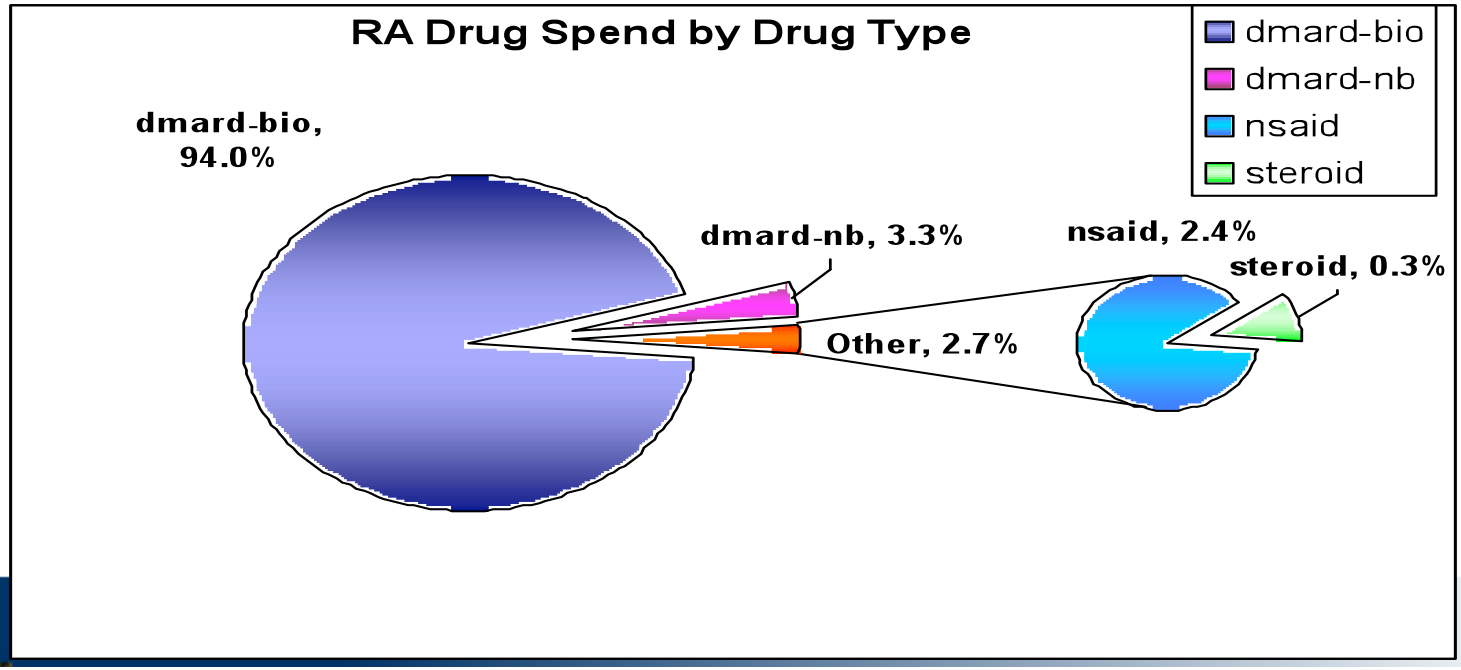
100%
100%
500
1,000
2,500
5,000
10,000
15,000
20,000
30,000
40,000
50,000
60,000
70,000
85,000
100,000
125,000
150,000
175,000
300,000

## Top RA Drugs Utilized Based on Paid

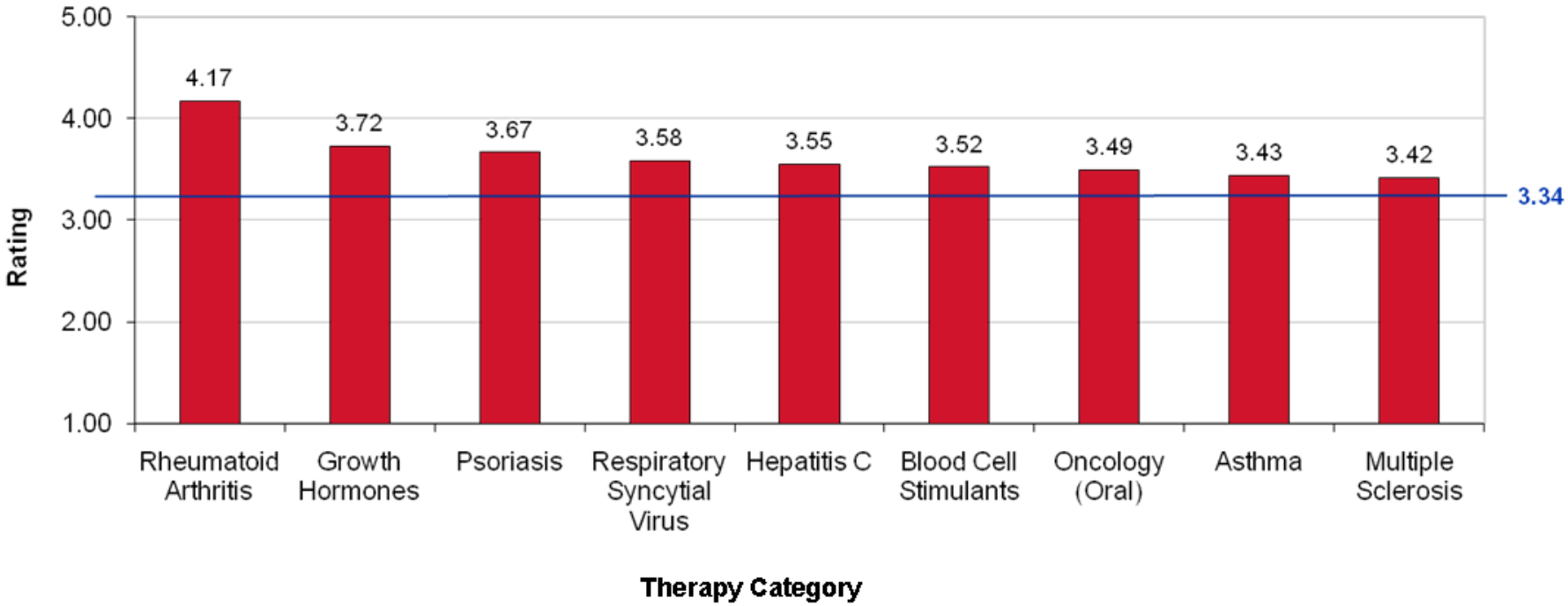
**Service Date between 7/1/2006 – 6/30/2008**

| Drug | Paid | % of Paid | Mbrs | % of Mbrs |
|---|---|---|---|---|
| REMICADE | $ 89,736,667 | 32.4% | 2861 | 12.8% |
| ENBREL | $ 85,261,154 | 30.8% | 4172 | 18.7% |
| HUMIRA | $ 61,731,384 | 22.3% | 2987 | 13.4% |
| ORENCIA | $ 11,423,856 | 4.1% | 831 | 3.7% |
| RITUXAN | $ 10,818,816 | 3.9% | 528 | 2.4% |
| CELEBREX | $ 4,015,979 | 1.5% | 3055 | 13.7% |
| METHOTREXATE | $ 3,213,967 | 1.2% | 12283 | 55.1% |
| LEFLUNOMIDE | $ 2,766,610 | 1.0% | 2532 | 11.4% |
| HYDROXYCHLOROQUINE | $ 1,381,051 | 0.5% | 5627 | 25.2% |
| KINERET | $ 990,552 | 0.4% | 71 | 0.3% |



# Highest-Priority Therapy Categories

*On a scale from 1 to 5, where 1=lowest priority and 5=highest priority, rate the priority to manage each drug category.*




Mean=3.34



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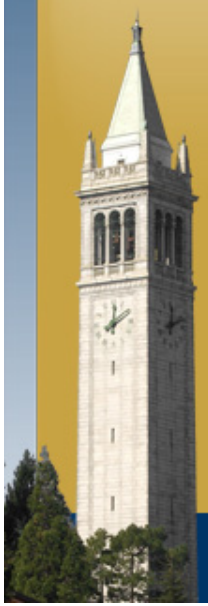
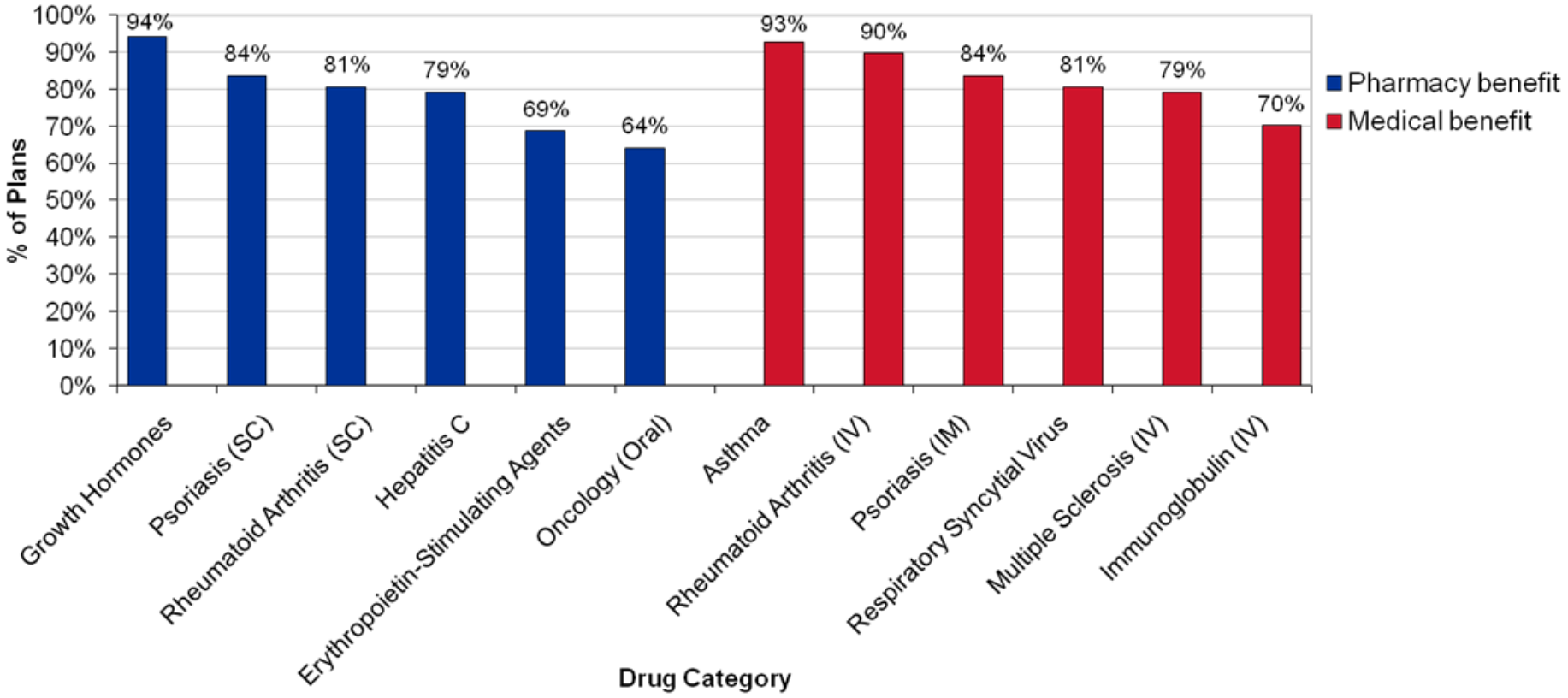
# Enhancing Appropriate Utilization: Patient Identification

- The basic trade: manufacturers agree to help insurers contain use within evidence-based appropriateness, while insurers agree to help manufacturers identify patients who would benefit but are currently not on drug
- Cooperation on guidelines for appropriate use
  - FDA label, off-label: prior authorization
  - Severity: step therapy v. early intervention
  - Leapfrog over step therapy for early responders
- Companion diagnostic for early identification of patients who would benefit from treatment?



# Prior Authorization Required by Drug Category

*Indicate which of the following therapeutic classes/products require PA for coverage under each benefit.*




**Compare and Contrast**

Compared to the 2007 data, the 2008 survey data identified:

- Higher use of prior authorization for psoriasis and lower use of prior authorization for self-administered multiple sclerosis therapies



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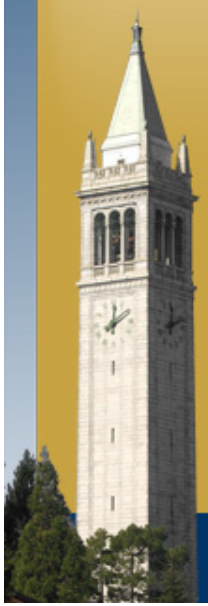
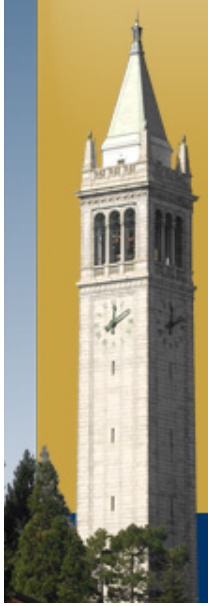
# Prior Authorization for RA in Private Insurance

- Criteria for coverage and payment to physicians and pharmacy
  - Diagnosis of RA made by specialists, not physician generalist
  - Drug authorization for RA (on-label use)
  - Step therapy: patient must have failed on 6 month of MTX + NSAIDs
  - During that time period, patient must have:
    - No decrease in number of swollen or painful joints,
    - No decrease in pain or disability,
    - No improvement in global assessment that includes patient activity/functional assessment, OR
    - Radiographic evidence of disease progression
  - OR patient cannot tolerate MTX due to documented side effects



## Enhancing Appropriate Utilization: Care Management

- All patients using high-cost and potentially toxic biologics should be in care management (CM)
- The basic trade: Insurers agree that a major goal of CM is to maintain continuance of therapy (as is often appropriate) by resolving financial barriers, adverse effects, convenience problems.
- Manufacturers agree that goals of CM also include safety monitoring, identifying patients who should discontinue therapy.



# Accordant DM program

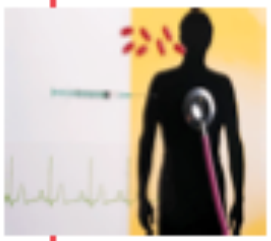
## What Can Members Expect from the Accordant Program?

- Introductory telephone phase call from AHS nurse
- Condition-specific assessment calls
- A personal Disease Management nurse
- Individualized interventions and condition-specific education
- Assistance with coordination of care and resource needs
- Physician (PCP and specialist) notification/interaction
- Monthly newsletters on general wellness and condition-specific topics (alternating monthly) and other educational material as needed
- Access to disease-specific communities at www.accordant.com
- 24/7 access to nurse specialists

Call Center is staffed Monday through Thursday, 8 AM to 10 PM EST.

CVS CAREMARK Accordant

## Disease Management Intervention Strategies

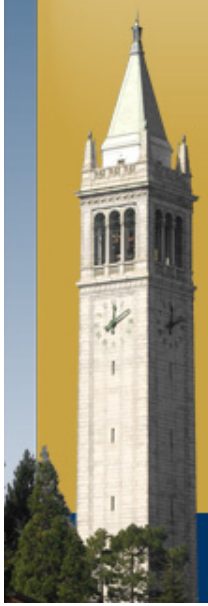


- Promote Better Self-Management Skills
  - Access, Education, Communication, Compliance
- Prevent Disease Complications
  - Risk Stratify, Assess, Monitor, Refer
- Promote Drug Safety
  - Education, Monitoring, Compliance, Interactions/Contraindications
- Enhance Participant's Ability to Cope
  - Psychosocial, Advance Directives, Community Resources
- Promote "Stay Healthy" Behavior
  - Wellness/Prevention
- Provide Care Coordination

CVS CAREMARK Accordant

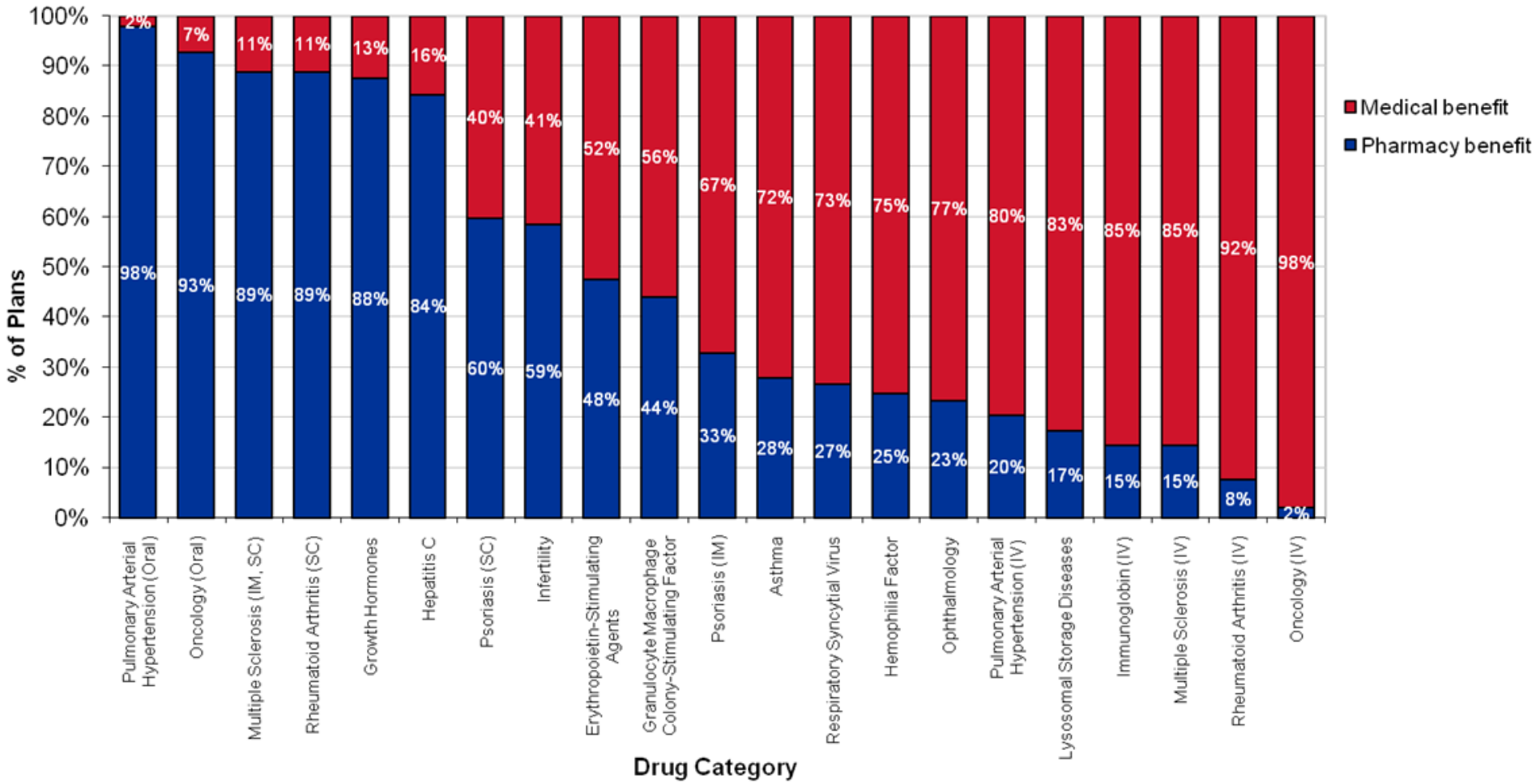
## Benefit Design: Cost Sharing

- Consumers must be conscious of the cost of care, and cost sharing can guide appropriate choices
- But some patients avoid effective and cost-effective treatments due to cost-sharing
- “Value-based insurance design” (VBID) shifts cost -effective drugs to “tier” with lower cost sharing
- VBID for immunology biologics?
  - Complications: benefit design and cost share differ between office administered infused drugs (e.g., Remicade, Rituxan) v. self-administered injected drugs (e.g., Enbrel, Humira)



# Benefit Coverage of Specialty Pharmaceuticals by Drug Category

*Indicate the benefit under which each drug is typically covered for your most common benefit structure.*



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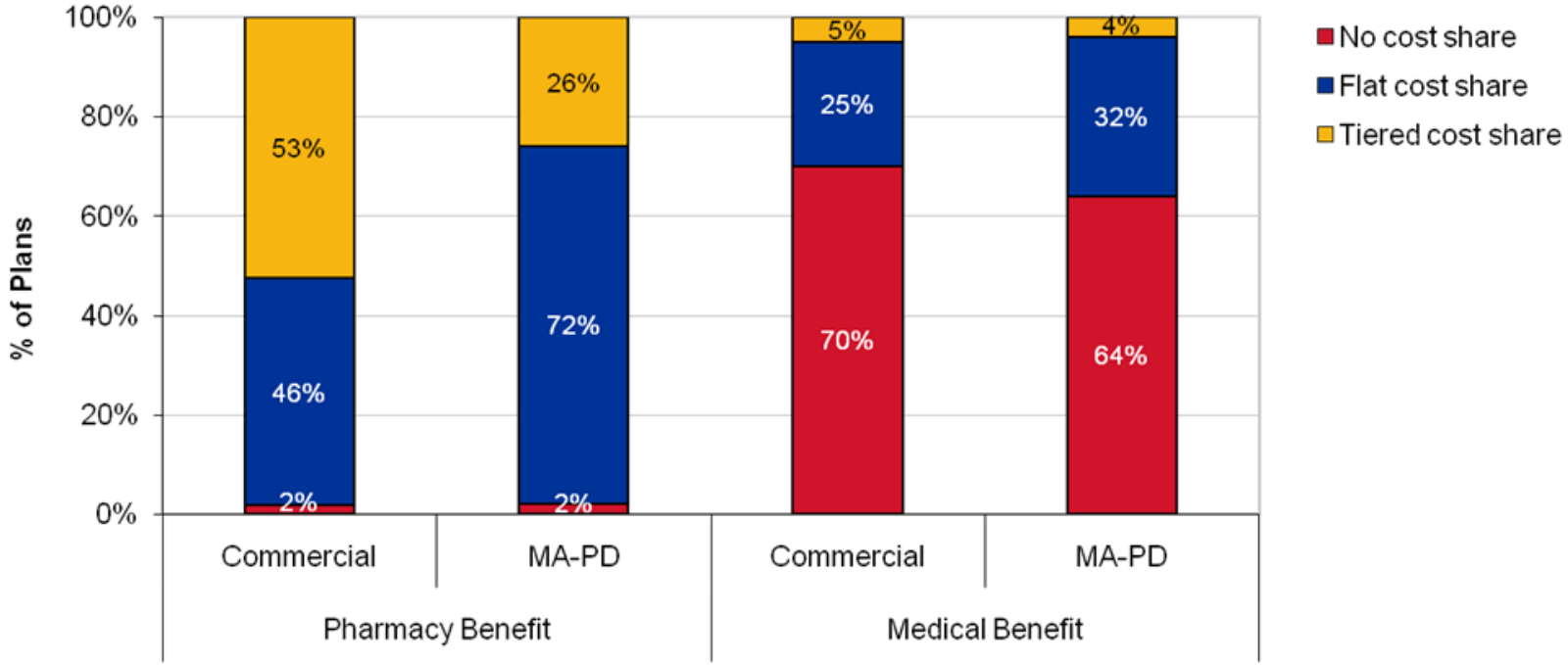
# Pharmacy and Medical Benefit Cost Share Methods

*Describe the most common share methodology for specialty drugs covered under each line of business.*



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# Employer Trends 2000-2008

Among Covered Workers with Three, Four, or More Tiers of Prescription Cost Sharing, Average Copayments and Average Coinsurance, 2000–2008

| | 2000 | 2001 | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 |
|---|---|---|---|---|---|---|---|---|---|
| **Average Copayments** | | | | | | | | | |
| First-Tier Drugs, Often Called Generic | $8 | $8 | $9 | $9* | $10* | $10 | $11* | $11 | $10 |
| Second-Tier Drugs, Often Called Preferred | $15 | $16* | $18* | $20* | $22* | $23* | $25* | $25 | $26 |
| Third-Tier Drugs, Often Called Nonpreferred | $29 | $28 | $32* | $35* | $38* | $40* | $43* | $43 | $46* |
| Fourth-Tier Drugs | ^ | ^ | ^ | ^ | $59 | $74 | $59 | $71* | $75 |
| **Average Coinsurance** | | | | | | | | | |
| First-Tier Drugs, Often Called Generic | 18% | 18% | 18% | 18% | 18% | 19% | 19% | 21% | 21% |
| Second-Tier Drugs, Often Called Preferred | NSD | 23% | 24% | 23% | 25% | 27% | 26% | 26% | 25% |
| Third-Tier Drugs, Often Called Nonpreferred | 28% | 33% | 40% | 34%* | 34% | 38% | 38% | 40% | 38% |
| Fourth-Tier Drugs | ^ | ^ | ^ | ^ | 30% | 43%* | 42% | 36% | 28% |

SOURCE:

Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2000–2008.

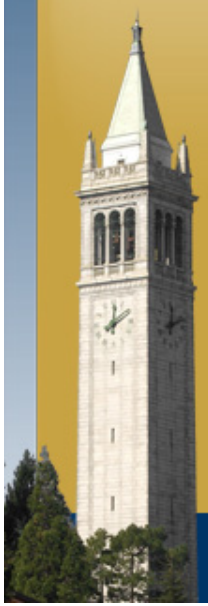
* Estimate is statistically different from estimate for the previous year shown (p<.05).

^ Fourth-tier drug copayment or coinsurance information was not obtained prior to 2004.

NSD: Not Sufficient Data.

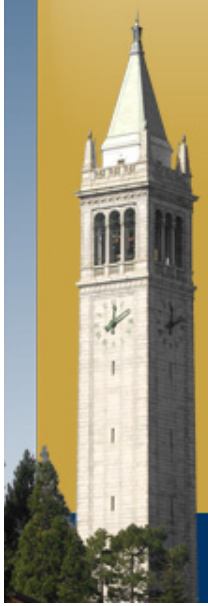
# Consumer Cost Sharing: The Basic Trade

- Insurer places a drug in tier with minimal cost sharing if:
  - The patient is an appropriate candidate (according to coverage criteria, prior authorization, companion diagnostic), **and**
  - The patient cooperates with care management program, **and**
  - The drug is obtain through appropriate distribution channel (e.g. specialty pharmacy) and physician practice, **and**
  - The drug is priced based on performance (see below)
- Otherwise, drug is placed in tier with high cost sharing



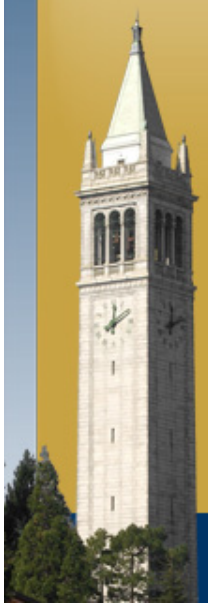
## Distribution and Physician Practice: The Basic Trade

- Manufacturer cooperates with insurer in moving practices from markups to specialty pharmacy (and/or B&B without big markup), good data capture, coordination of office administration with care management program.
- Insurer agrees not to design reimbursement and consumer benefits that discriminate against office administered drugs, and to raise professional fees to replace drug markups.



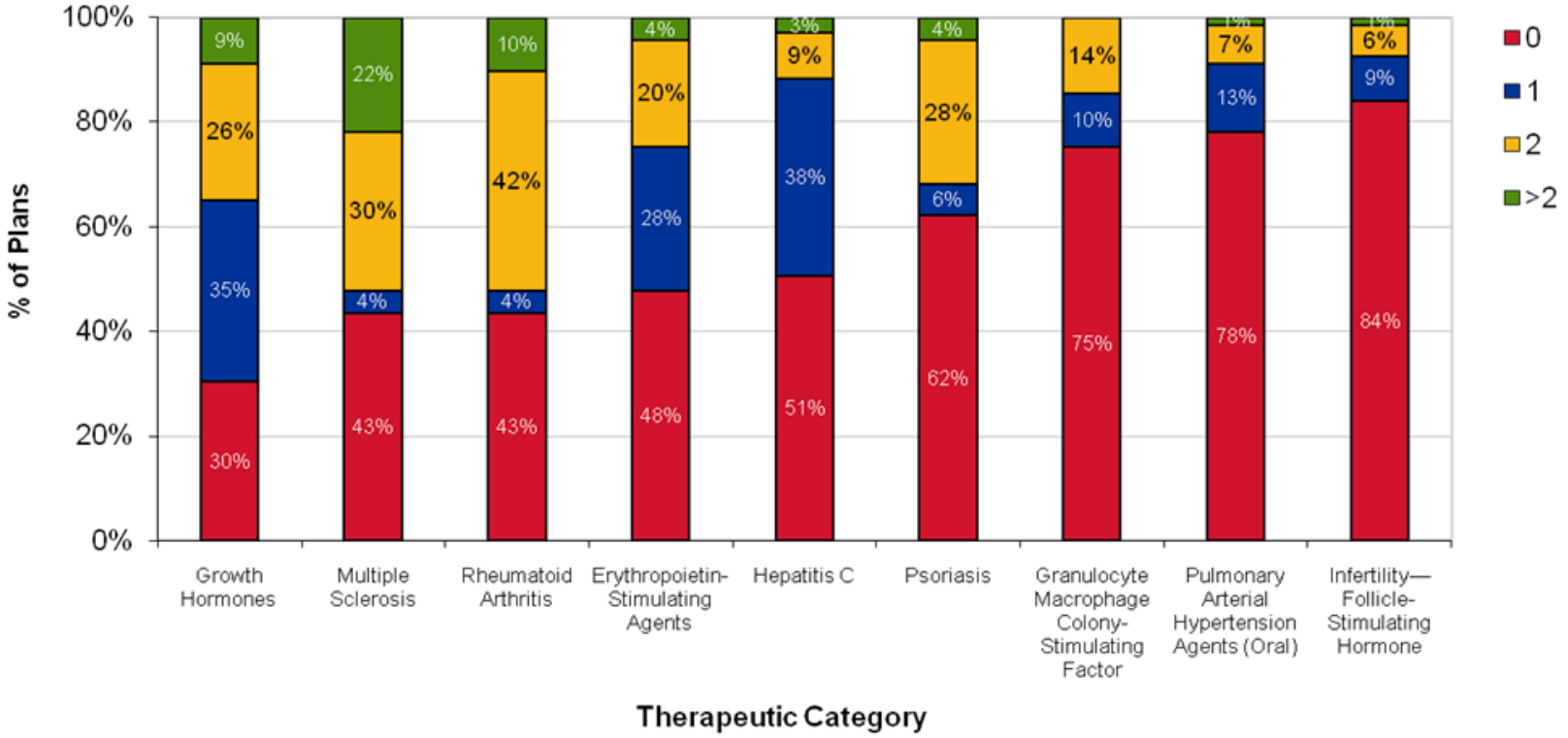
## Performance-based Pricing

- Manufacturer's preference: list price, based on reference product price plus differentiator (V=R+D)
  - V=Value-based price
  - R=Reference product price
  - D=Difference between new and reference drug
- Without therapeutic substitution, manufacturer wins
- With widespread therapeutic substitution, insurer wins
- With limited but growing substitution, is there a trade?



# Number of Preferred Products by Therapeutic Category

*Indicate the number of preferred products for each of the following therapeutic classes/products.*



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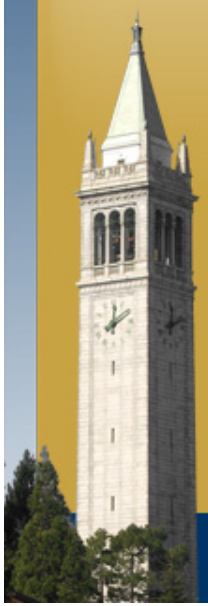
# Performance-Based Pricing

- Performance-based price: P=R+D+E
  - P: performance-based price
  - R: reference price of lowest cost therapeutic equivalent, using comparative effectiveness studies to determine equivalence
  - D: difference between new and reference drug, updated with new evidence on efficacy, safety, patient experience
  - E: efficiencies from cooperation: criteria for appropriate use, care management, consumer cost sharing, distribution, physician practice support, data capture and analysis



## Conclusion and summary

- Public policy is wavering between replacing and supporting market forces in health care
- Biopharma industry is under pressure
- Areas of potential cooperation: biotech/insurers
  - Patient identification and care management
  - Value-based insurance design and cost sharing
  - Distribution and physician practice support
  - Performance-based pricing
- Immunology as current example
- Oncology as most important sector to watch