



BERKELEY CENTER
FOR HEALTH TECHNOLOGY

Role of Competition in the US Pharmaceutical Market

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This Presentation



- Old views and new realities of the US market
- Payer strategies and impacts: utilization management, consumer cost sharing, price discounting



Traditional View of the US Market

1. Market authorization: Rigorous FDA review prior to launch, with little attention after launch.
2. Coverage and reimbursement: Lenient payer coverage criteria, with little demand for HTA; 'Free pricing' with only limited discounting
3. Physician prescription: High volumes and revenues, due to payment incentives favoring selection of most expensive products
4. Patient adherence: High adherence due to a culture of aggressive treatment and direct-to-consumer advertising



The US Market as a Field of Dreams

- The combination of rigorous pre-market review (a barrier to market competition), generous payer coverage, high physician prescription, and enthusiastic patient adherence generates strong revenues and profitability for innovative firms
- Profits earned in the US market support global industry R&D investment
- Roche/Genentech products have been first-in-class, best-in-class; the firm has earned half its global net revenues in this one market
- It's been a field of dreams



The New Reality of the US Market

1. Market authorization: FDA is moving to accelerated review, requiring less evidence prior to launch but more evidence after launch
2. Coverage and reimbursement: Payers are pushing back strongly on coverage criteria and demanding significant price concessions
3. Physician prescription: Utilization management and new payment methods from payers discourage choice of expensive drugs
4. Patient adherence: Utilization management and high cost sharing are reducing adherence and threatening outcomes



The Importance of Evidence Strategy

- The changing landscape is creating the demand for new evidence on performance, especially in competitive indications
- Roche/Genentech products now face competition in every therapeutic class. The firm enjoys a window of opportunity to transition from dependence on its Big Three oncology products and build strong positions with its newer products
- Its evidence strategy is central to its success
- This is true in all geographic markets, but of special importance in the US, due to the historical reliance there for global profitability



Payer Strategies



1. Tighter coverage criteria
2. Administrative controls on physician prescription
3. High consumer cost sharing to decrease patient demand
4. Increased pressure for discounts and rebates, reducing net prices and profits

Coverage Criteria

- Goal is to limit use of expensive drugs, encourage use of cheaper alternatives, and induce manufacturers to offer discounts
- Narrow formularies: more drugs excluded from coverage altogether
- Prior authorization: prescriptions denied where physician has not sufficiently documented the patient fits strict coverage criteria
- Step therapy: patients are required to 'try and fail' cheaper products before moving to more expensive options
- These trends are coming more slowly in oncology than in competitive indications such as MS, immunology



Payer Coverage Criteria Increasingly are More Restrictive than FDA Label and Clinical Guidelines

RESEARCH BRIEF

Variation in Private Payer Coverage of Rheumatoid Arthritis Drugs

James D. Chambers, PhD; Colby L. Wilkinson, BA; Jordan E. Anderson, BA;
and Matthew D. Chenoweth, MPH

Prior authorization criteria developed by 10 largest (by enrollment) private US health care payers:

Rheumatoid Arthritis:

- 69% are more restrictive than FDA label
- 33% are more restrictive than guidelines from American College of Rheumatology

Multiple Sclerosis:

- 46% are more restrictive than FDA label

- Am J Pharm Benefits. 2017;9(5):155-159
- J Managed Care & Specialty Pharmacy 2016; 22(10)

Systematic Literature Survey: Utilization Management Reduces Drug Use, with Adverse Outcomes

SYSTEMATIC REVIEW

The Effect of Formulary Restrictions on Patient and Payer Outcomes: A Systematic Literature Review

Yujin Park, PharmD; Syed Raza, MS; Aneesh George, MS;
Rumjhum Agrawal, MPharm; and John Ko, PharmD, MS

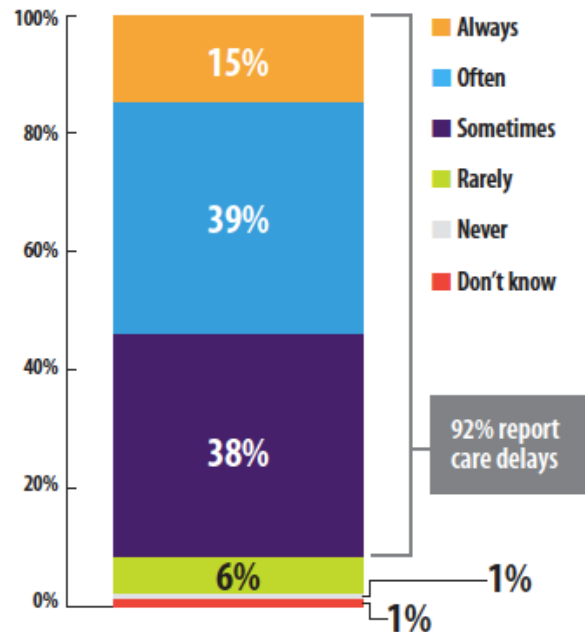
Systematic review of peer-reviewed articles (n=59) published 2005-18 on drug utilization management by US payers:

- 90% of studies find formulary exclusions, prior authorization, and step therapy to reduce drug use and spending
- Some reductions in drug spending were offset by increases elsewhere
- 10/12 studies using clinical endpoints report adverse outcomes

Physician Views of the Impact of Prior Authorization on Patients

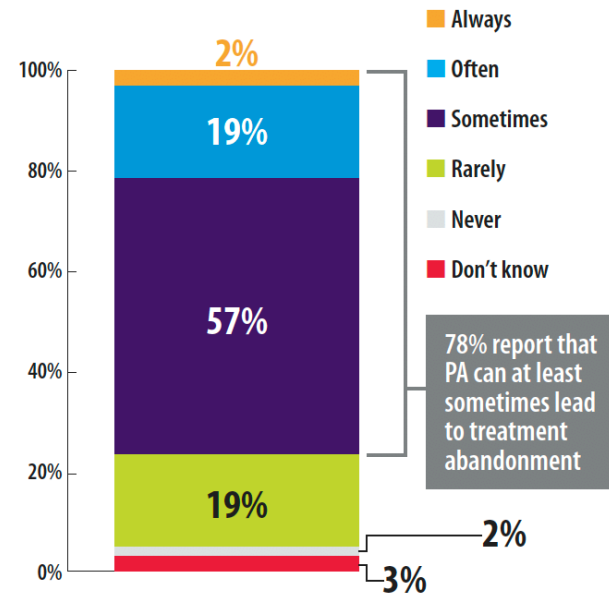
Care delays associated with PA

Q: For those patients whose treatment requires PA, how often does this process delay access to necessary care?



Abandoned treatment associated with PA

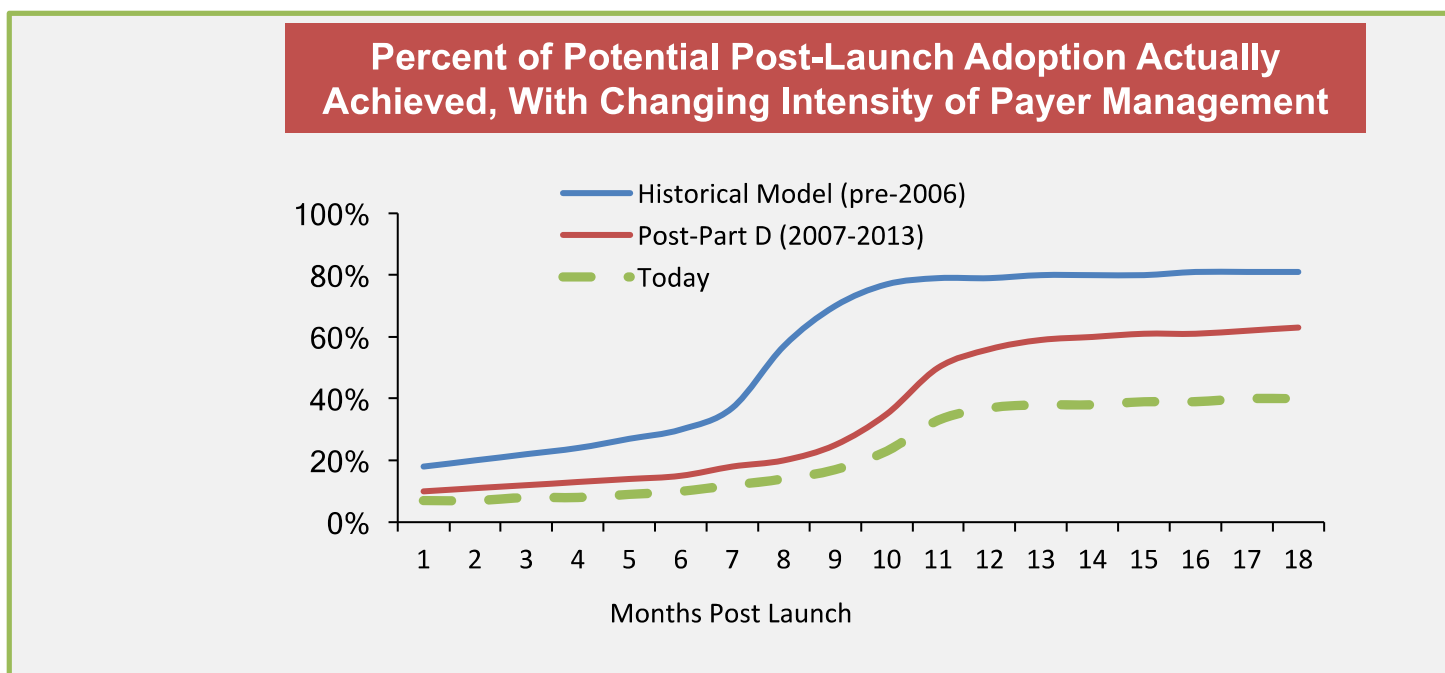
Q: For those patients whose treatment requires PA, how often do issues related to this process lead to patients abandoning their recommended course of treatment?



Total does not equal 100% due to rounding.

Source: 2017 AMA Prior Authorization Physician Survey

More Intense Prior Authorization, Step Edits, and Consumer Cost Sharing Are Slowing Physician Prescription and Patient Adherence after Launch



Source: QuintilesIMS, Payer and Managed Care Insights, Novartis

Price Negotiations Reduce Net Prices

Net price growth for protected brands is forecast to be 2-5% through 2021

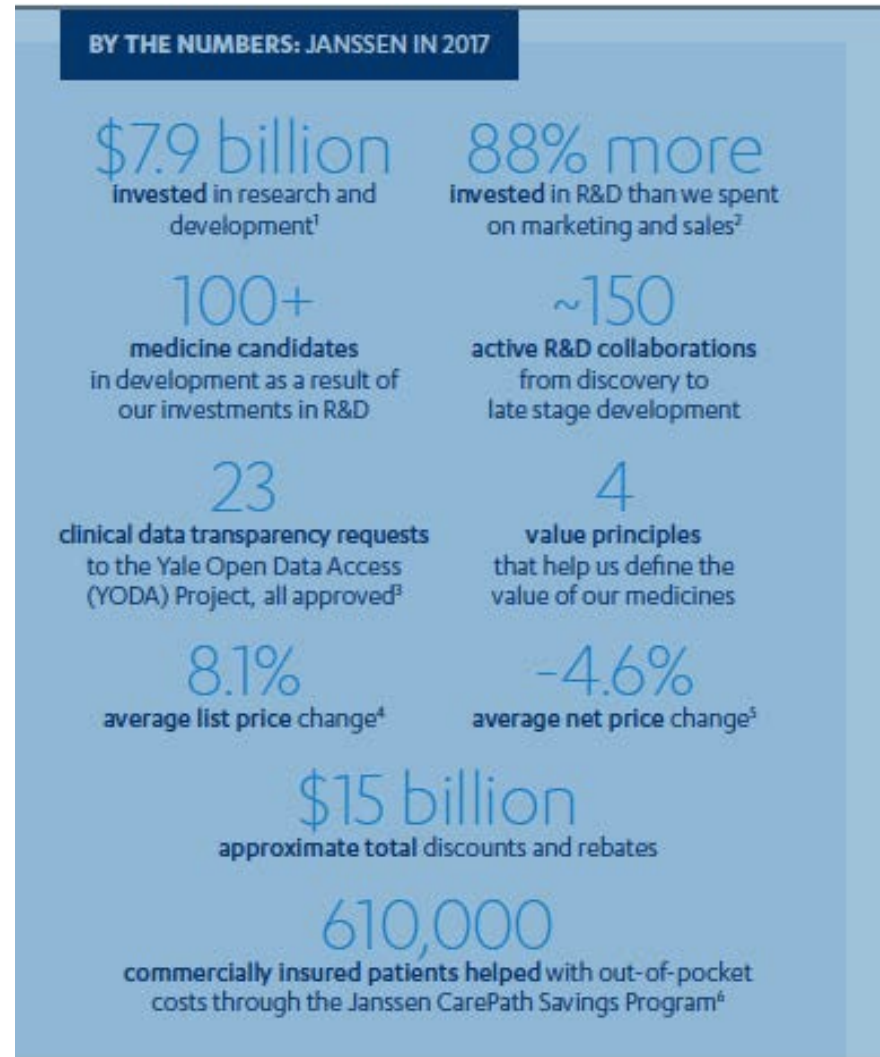
Protected Brand Invoice and Net Price Growth



Source: QuintilesIMS, National Sales Perspectives, QuintilesIMS Institute, Mar 2017

Some Major Pharmaceutical Firms Report Negative Net Price Increases

- Janssen (J&J) reports list price increases (across portfolio) of 8%, but net price changes (after rebates) of negative 5%



Eternal Vigilance

- The US market no longer features free pricing and unmanaged patient access
- Global firms cannot rely on profits from the US market to cover investment in R&D unless they adapt their product and pricing strategies
- These new strategies require evidence tailored to the demands by FDA, payers, physicians, and patients





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