

Drug Discovery, Development and Commercialization, Winter 2013

Managed Markets and Sales Strategy

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Goals and Objectives

- The goals of this lecture are to:
 - introduce students to the general concepts of managed care within the framework of healthcare reform
 - understand the elements that go into development of managed markets sales strategy
- Upon attending the lecture, students should be able to:
 - *Discuss the key features of managed care with regard to commercialization of pharmaceutical products*
 - *Review the goals for a building a managed care sales strategy*

MANAGED MARKETS



What are Managed Markets Customers?

- Entities that play a key role in drug reimbursement and access
- Exert influence over drug choices of prescribers and patients through benefit and formulary design and management
- Can be public (government) or private (commercial)

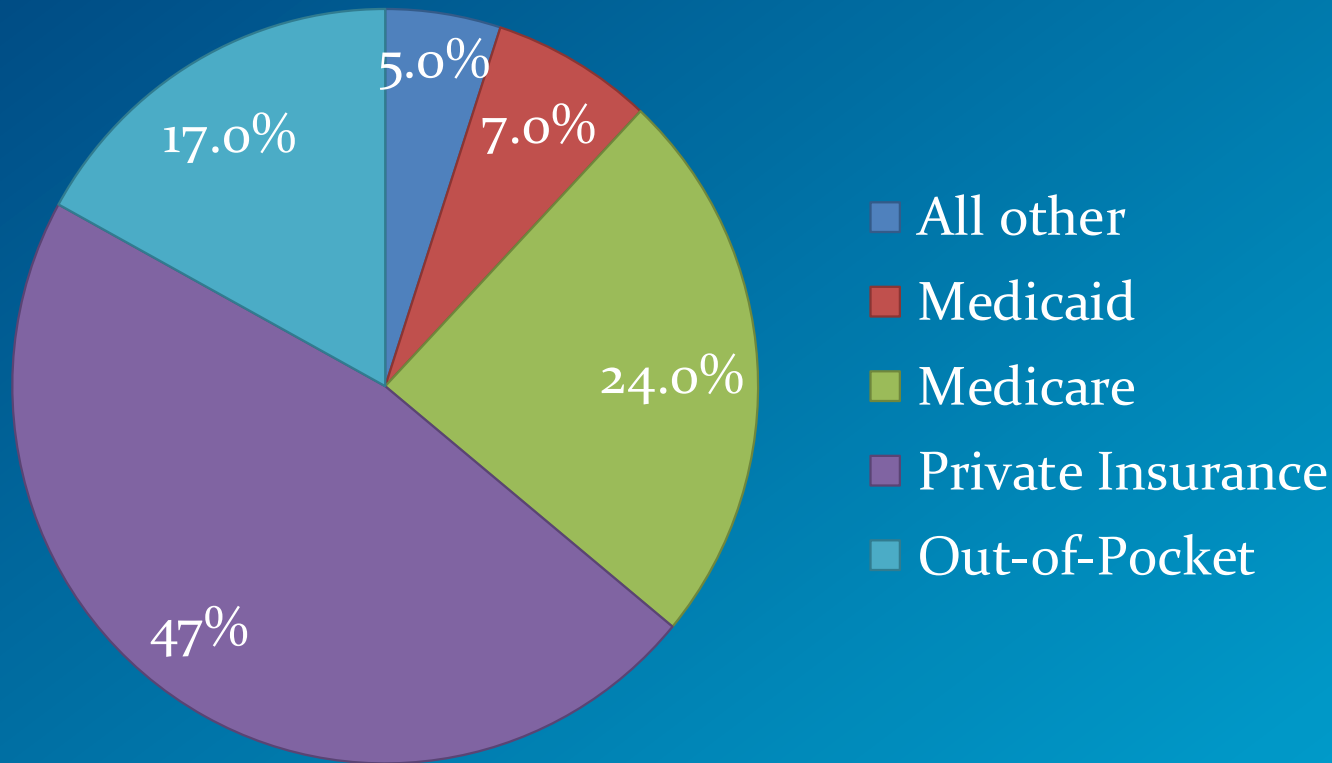
Largest Managed Markets Channels

Segment	Description
Commercial Plans (Private) <ul style="list-style-type: none"> Managed Care Organizations (MCOs) Pharmacy Benefit Managers (PBMs) 	<ul style="list-style-type: none"> Principal source of employee and some retiree coverage Provides coverage for 170+ million Americans Administer pharmacy and medical benefits on behalf of payers (employers, government)
Medicaid (Public)	<ul style="list-style-type: none"> Joint federal-state program that pays for medical assistance 55+ million low-income individuals Possible influx of over 24 million people into program under the Affordable Care Act (ACA)
Medicare (Public)	<ul style="list-style-type: none"> Federal health program for elderly and disabled individuals Expected increase of enrollees from 46 million to 78 million between 2010 and 2030 90% have some type of prescription drug coverage
VA/DoD	<ul style="list-style-type: none"> Roughly 30 million individuals eligible for health benefits

Today's Environment

- US health care spending reached \$2.7 trillion in 2011
 - Prescription drug spending: \$263 billion (+2.9%)
 - 3.9% growth over prior year
- Affordable Care Act
 - Most influence will not be seen until 2014, with 3 notable exceptions:
 - 2.7 million dependents moved to their parents' plan
 - Extended and increased pharmaceutical manufacturer rebates for various Medicaid plans
 - Required manufacturers to provide a 50% “discount” on brand-name prescriptions to Part D enrollees in the “doughnut” hole

2011 Prescription Drug Spending by Payer Type (\$263 b)



1. All other includes Children's Health Insurance Program, DoD, Department of Veteran's Affairs worksite health care, other private revenues, Indian Health Service, workers' compensation, general assistance, maternal and child health, vocational rehabilitation, other federal programs, Substance Abuse and Mental Health Services Administration, other state and local programs, and school health.

2. Out-of-pocket expenditures equals cash-pay prescriptions plus copayments and coinsurance.

Source: Pembroke Consulting analysis of National Health Expenditure Accounts, Office of the Actuary in the Medicaid and Pharmaceutical Sciences, January 2013



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Role of the Account Manager

- Work cross-functionally to develop a compelling value proposition for managed markets customers
- Develop a robust contracting strategy
- Determine how to allocate resources within and across managed market channels
- Secure formulary access
- Ensure sales forces are prepared to be successful within this environment (pull-through v push-through)
- Develop relationships with decision-makers

Considerations of a Managed Markets Strategy

- What is the access goal?
- What are the key channels/ accounts?
- What is the product's value proposition?
- What are appropriate contracting strategies?

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Access is Defined in Terms of Formulary Position

Tier	Co-Pay	Comments
I	Lowest	Typically generics
II	Slightly higher	Preferred brands
III	Highest set co-pay	Non-preferred brands
IV	Usually a set % of cost	Biologics and specialty products
Non-formulary	Patient bears all costs	

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Not all Accounts are Created Equal

- Account/ Channel importance is assessed by:
 - Target population of drug
 - Drugs for elderly -> Medicare & Commercial plans with large Med D populations
 - Inpatient drugs -> Hospitals and Integrated Health Systems
 - Broad populations -> National and regional/local Commercial plans
 - Size of plan
 - Total covered lives
 - Covered lives in relevant demographic
 - Controls that the account has in place to drive utilization
 - Co-pay differentials
 - Prior authorizations and step edits
 - Generic utilization rates

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What is a Value Proposition?

- A unique value (value-add) that a product offers to its customers
- In drug development and marketing, the value proposition asks the question, “What incremental benefit is provided over other alternatives and at what cost?”

Value Proposition - Factors to Consider

- Relationships with customers are a very important when all things are equal (reputation, flexibility, integrity, knowledge)
- Developing and communicating a value proposition requires a customized approach which focuses on understanding of your customer's needs, the roadblocks they face, and what is important to them

Product Value Proposition Example: Ilaris® Compared to Arcalyst ®

- FDA approved for cryopyrin-associated periodic syndrome (CAPS)
- Ilaris benefits:
 - Convenient dosing regimen (q 8 wks vs q wk)
 - Few injection-site reactions reported
 - Favorable safety profile, no antibodies detected
 - Cost-effective

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Ilaris offers a new standard of convenient care for CAPS patients with proven efficacy and tolerability



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How are Contracting Strategies Determined?

- Many factors must be considered; however, there are 2 key questions:
 - What is the cost of contracting to the company? (i.e. rebate level required for desired formulary position)
 - What is the benefit of contracting (i.e. the expected share gain due to better access and reimbursement)
- The company must determine the return on investment associated with the contract, balancing pricing concessions against the probable impact of the formulary position

SALES STRATEGY



So Now You Have Access.... What Next?

Sales Strategy

- Looks at the optimum deployment of human and financial resources
- Driven by the marketing strategy for the product, as well as the company's portfolio strategy

Relationship of Sales and Marketing Strategy

Marketing Strategy

- What can we achieve through promotion of this product?
- What is the product's potential?
- Who are our customers?
- What is our positioning in the target market?
- What key messages do we need to deliver to drive adoption?



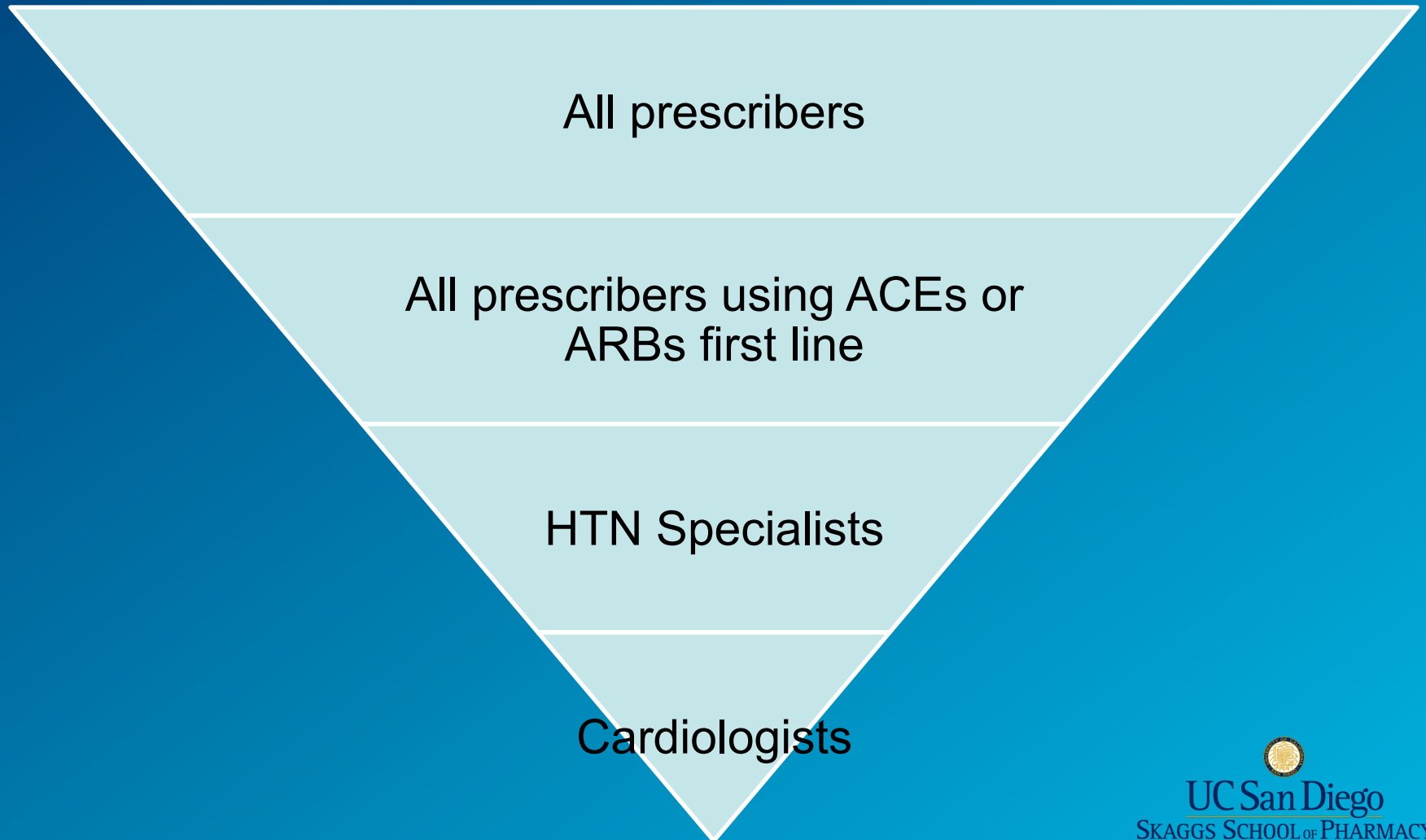
Sales Strategy

- What is the optimal approach for executing the sales component of the marketing strategy?
- What is the optimal selling process (or model) based on product potential and customer mix?
- How many representatives do we need to reach key target customers?
- How should we structure the sales force?
- How should the sales force be trained?

Sales Targeting

- Identification of key physician targets – factors:
 - Total prescriptions (TRx) and new prescriptions (NRx) written
 - Accessibility
 - Relationship with company and industry in general
 - Effect of managed care formularies on the ability to prescribe a drug
 - Adoption sequence
 - Tendency use a wide palette of drugs
 - Colleague influence
 - Specialty

Sales Targeting for a New Anti-hypertensive



BRINGING IT ALL
TOGETHER.....

Case Example - Xolair®

- Launched in 2003 by Genentech and Novartis for moderate to severe allergic asthma in patients 12 years of age and older
- Monoclonal antibody requiring subcutaneous injections every 2-4 weeks

Xolair® Challenges

- First commercially available biologic for a disease typically treated by primary care physicians
 - Novel and highly targeted mechanism of action required that the science be communicated clearly
- Injectable less convenient than preexisting products
- Supplied as a lyophilized powder which had to be reconstituted over 20 minutes
- High price point (~\$400/vial) and chronic use
 - Most patients required 2-3 vials, one or two times monthly

What Did We Do?

- Targeted to allergists and pulmonologists (which created other issues....)
- Deployed a Medical Science Liaison force in 2001 (2 years prior to launch) to establish relationships with these physicians and establish the unmet clinical need
- Needed to “take the science to the payers”
 - Close collaboration of medical and account management
- Companies chose to market almost exclusively to managed care plans and specialty prescribers, not DTC

What Did We Do?

- Established a single point-of-contact insurance support line for physicians and patients to assist with prior authorizations
- New sales function was established to work with front office staff
- Sales deployed the “total office call”

What Happened?

- 6 months post-launch, Xolair® was being prescribed by 30% of the target physician population; upwards of 60% within 18 months
- In 2005, *MedAdNews* named Xolair® a top 10 product in terms of its full first-year sales
- By 2006, Xolair® generated US sales of \$425 million; now a billion dollar product worldwide

Questions

