

Contracting and Distribution Strategies for Specialty Pharmaceuticals

January 25, 2006

Orlando, Florida

Dick Rylander

President BioPharmaceutical Strategies LLC



Personal Background

Dick Rylander

- 26 years with Parke-Davis/Pfizer
- 5+ years with Actelion Pharmaceuticals
 - Specialty distribution systems for Tracleer and Zavesca
 - Contracting
 - Managed Care
 - Pricing
 - Systems, IT and all backend development

Audience Member Background

Your name and company?

Snapshot of your background?

Workshop Flow

In this workshop we'll:

- 1) Identify the key players
- 2) Define the issues and challenges
- 3) Discuss approaches to solutions from the various players standpoints
- 4) If you will leave me your business card with your email address I will provide you a set of slides summarizing this workshop

What do you want to achieve today?

- What's the "1" thing you would come away with from today's workshop?

Marketplace Data

Let's take a few minutes to summarize the specialty drug marketplace...

- There are between 600 and 700 specialty drugs under development and the number will continue to grow
- There are over 40 disease states being targeted for specialty therapies

Marketplace cont'd

- In 2001 it is estimated that the US spent \$22 billion on specialty drugs
- In 2002 the expenditures rose to \$35 B
- In 2005 the cost had risen to \$55 B
- By 2030 the cost may reach \$1.7 trillion
- In 2005 specialty drugs accounted for about 24% of ALL drug expenditures
- By 2020 that could rise to 37% and by 2030 perhaps consuming 44% of all drug expenses

Marketplace cont'd

- There are about 200 specialty drugs on the market in the US
- Specialty drugs are used to treat about 3% of the general population
- **Monthly** cost per specialty drug averages over \$1000 with some as high as \$30,000
- Annual costs can range from \$10,000 to over \$500,000

Marketplace cont'd

- Specialty therapies are growing at 2x the rate of traditional ambulatory treatments
- Some 90-95% of specialty therapies are administered via injection
- Approx. 70% require administration or monitoring by a healthcare professional
- More and more specialty products are being moved from the medical benefit side to the pharmacy benefit

Marketplace cont'd

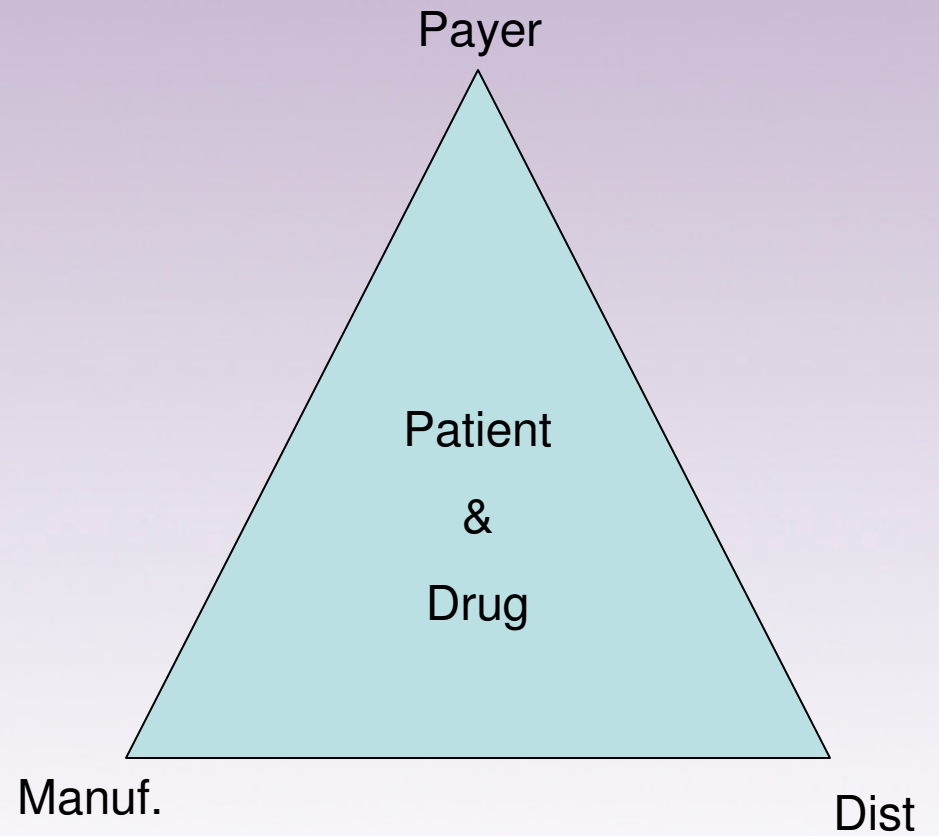
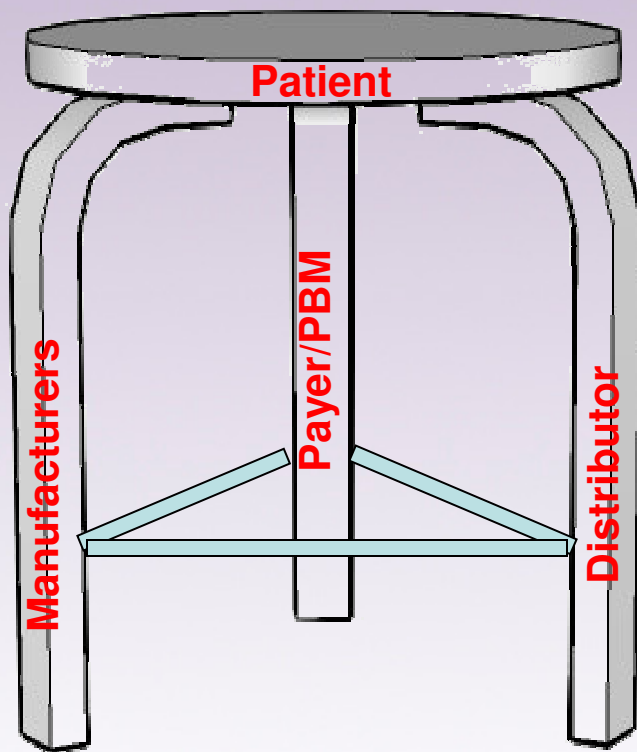
- More payers are moving specialty therapies into higher co-pay tiers which may reduce access and decrease use
- Medicare and Medicaid's can be a major factor in access and coverage

Caremark's 2006 Report

- Q1-Q3 2005 biotech/specialty comprised 20.8% of the Book of Business (BoB)
- Biotech/specialty grew from 5.9% of gross cost to 8.5%
- In 2006 the three (3) categories they watched most closely were:
 - PAH
 - MS
 - RA

Why are specialty drugs more expensive?

- ✓ Narrow indications
- ✓ Small treatment populations (Orphan?)
 - ✓ Development costs spread over smaller #'s
- ✓ Higher service requirements (Infusion?)
- ✓ Special handling (refrigeration and shipping)
- ✓ Reimbursement challenges
- ✓ Prior-Auth's
- ✓ Safety issues (with special reporting?)
- ✓ Intensive patient monitoring



Players

- Manufacturer – Sales and Marketing
- Distributor –
 - Pharmacy (Specialty or Retail/Chain)
 - Wholesaler (if non-specialty)
 - Payer/PBM – If integrated
- Payer/PBM – Approval, Payment



Top Issues & Challenges

- Define
- Address from the 3 sets of needs:
 - Manufacturer
 - Distribution (SPD; Wholesaler or Payer)
 - Payer/PBM
- Goal: Identify common challenges and ways to address them so we come up with a win-win-win

Questions

- What is specialty distribution?
- Why does it exist?
- What are the challenges of specialty distribution?
- What are the relationships between the parties? (Manuf. – Dist – Payer)

Discussion Issue's?

- When does specialty distribution make sense?
- What types of contracts between the various parties?
- How do you set up working relationships?
- Impact of generics moving forward?
 - Will there be generic biotech therapies?
- Is the line between pharmacy, distributor, payer, and PBM blurring? (Integration)
- Impact of the demise of AWP?

Workshop Q&A

- The following slides will:
 - List each issue and discussion comments
 - They are NOT in any specific order
- These were the issues the attendees raised and wanted feedback on.

Why have limited distribution?

- ✓ Using a checklist place a + in the column of either pharmacy or specialty depending on your assessment of which one has the advantage for the particular challenge.
- ✓ This list is relatively comprehensive but should be adjusted as necessary.

Limited Distribution Checklist

Issue or Challenge	Retail	Spclty
Ability to obtain payer approval/coverage		
Ability to work with patients on co-pay		
Handling, supporting and reporting of AE's/SAE's		
Patient education and support services		
Timeliness of delivery and support		
Disease expertise		
Data gathering and sharing		
Appeal handling process and success		
Ancillary services (testing, in-home nursing, etc.)		

How do you determine the number of Specialty Pharmacy's?

- Are you going to handle the administration of relationships in-house or farm it out?
 - If in-house how many relationships can you handle?
- How many SP's do you need to cover the payer plans that impact your product (including State Medicaid's)?
- Will you have a patient assistance program and if so will an SP(s) handle it?
- Is the volume of sales (and thus profit) large enough to keep your SP's "healthy" or will it be small they can't afford to provide support and services?
- Bottom line? What is the smallest number of SP's that have the expertise and services, at prices you can work with, that will help you meet or exceed your target?

Why choose fewer than more specialty pharmacies?

- If you choose only “1” all your eggs are in “1” basket...if something goes wrong you’re in trouble
- If you choose too many none of the SP’s can make enough money to make it worth doing
- Oversight has a cost and value. How many people will you need to manage each relationship and what will that cost?
- Can you find the expertise and services you need in fewer? If so how few?
- What are the costs from each SP and who gives the value you the most value?

Specialty vs. Retail – Which is best?

Which offers the best mix for your drug?	Retail	Spclty
Is it a mass market drug or niche? (i.e. 200,000 pts/yr + vs. 200,000 or less)?		
Is there special support needed?		
Is shipping and handling a challenge? (refrigeration)		
Is insurance coverage routine or does it require effort?		
Are there likely to be a lot of coverage/payment appeals?		
Are AE's or SAE's a potential issue with reporting?		
Is inventory quantity or dating an issue?		
Is cost an issue that impacts stocking and co-pay?		

Exclusive network +’s/-’s

Pro’s

- ✓ Manufacturer may have better overall control
- ✓ Control of inventory (less outdated goods)
- ✓ Data tracking and reporting is more timely and accurate
- ✓ Support services can be defined and monitored
- ✓ AE/SAE tracking and reporting control
- ✓ Removal of layers (wholesalers) reduces costs
- ✓ Performance incentives can be tuned to support the brand goals
- ✓ Compliance and persistence programs can be developed, implemented, monitored and assessed.

Exclusive network +’s/-”s

Con’s

- ✓ Payer may not work with the SP and thus access may be reduced
- ✓ Costs could be higher if special handling and services are expensive
- ✓ Payer may impose out-of-network charges to the patient
- ✓ Prior-Auth or other access barriers may be put in place
- ✓ If vertically integrated the payer may request/require “their” SP be used

How do drugs get from manufacturer to patients?

- Specialty
 - Manufacturer to warehouse
 - Limited # of SP's allowed to purchase
 - Shipped by warehouse to SP
 - SP warehouses
 - SP ships to patient upon insurance approval and co-pay settlement
 - Many use next day or 2nd day delivery
 - Patient receives drug
 - SP contacts the patient on refill cycle



How do drugs get from manufacturer to patients?

- Retail
 - Manufacturer sells to wholesalers
 - Wholesalers sell to pharmacies
 - Pharmacies stock or custom order
 - Pharmacy fills Rx
 - Patient comes to store to pick up
 - Pharmacy contacts patient on refills or waits for patient to call

Where will specialty pharmacy be in 3 years?

- More consolidation
- Infusion and SP distinctions will blur
- SP's will increasingly become part of major payers and plans
- Growth will continue at 20% or more per year based on the flow of new therapies
- Specialized services will continue to increase
- They will be “data sophisticated” with tracking, reporting and integration a key strength

How do we define “optimal” relationships?

- It's a matter of perspective
- Each of the three (3) segments has a different set of needs and views:
 - Manufacturer
 - Payer
 - Distributor (SP, Retail Pharmacy, etc.)
- Partnership successes are based on finding common ground that meet as many needs of all parties as possible
- Suggestion: Sit down with each of the potential partners and have a series of discussions on the issues/challenges and possible solutions
 - Then negotiate up-front

Rebates – Role and Use in Specialty?

- Rebates has a connotation that may be negative in some minds
- Rebates are required by State Medicaid's (15.1% or more)
- Discounts are required by the VA/DOD (24%)
- Incentives can be tied to performance metrics for commercial relationships
- With SP's consider:
 - Straight payment for defined services on a PM/PM
 - Special incentives based on meeting or exceeding certain defined goals (sales, units, etc.)

Office Infused Issues – RA Example

- When will a self-administered therapy be chosen vs. an office infused?
- Using RA as an example:
 - Factors affecting the decision may include:
 - Drug fee for the office?
 - Service fee for the office?
 - Therapeutic impression by MD?
 - Is there a step therapy guideline?
 - What are the members benefits (med vs. phcy)?
 - Quality of Life issues?
 - Control and compliance issues?



What can be done to improve communication between plans and manufacturers?

- Provide as much advance information as soon as possible
- Provide studies, comparisons, anticipated pricing, etc.
- Identify who in an organization is the key contact and work with them
- Identify advocacy groups and work with them in advance
- Work with sponsors of large group plans early
- How soon is soon?
 - 12 months in advance

What does the demise of AWP lead to?

- Most moving to ASP
- Contract will be written (re-written) to use ASP + % vs. the old AWP - %
- More likely quarterly price changes
- Smaller price changes more frequently
- Possible use of WAC +
- Reduce profit margins for distributors

Summary

- Specialty Pharmacy is “the” growing segment of distribution
- Growth is projected at 20%+ for the foreseeable future
- Designing and setting up processes and procedures for specialty products is challenging and requires detailed work
- The flow of new products will bring this area into the public light and increased scrutiny