



# Centric Ultra Orphan Conference

Reimbursement for Distribution Model Options

September 29, 2010



Providing Strategic and Tactical Solutions for the Commercialization, Distribution  
and Marketing of Pharmaceuticals, Medical Devices and Biologic Medications

# The Real Question...

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- Do different distribution models impact Payers inclination to:
  - Reimburse a given product
  - Reimburse a product at a given level
  - Place a product on a different reimbursement tier



# Specialty Care is Different

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- All about the patient
- Wrap around services
  - Reimbursement Support
  - Patient Counseling/Education/Training
  - Patient Registries
  - REMS
  - Physician Education
  - Patient Care Management





# Specialty Pharmacies are different

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- Purchase Product from Manufacturer Directly via 3PL, or from Wholesaler/ Specialty Distributors.
- Some SP's have 3PL and Specialty Distribution Capabilities
  - What is licensure structure (i.e. Pharmacy/ Distribution)
  - Do they fill an order vs. dispense a Prescription
- SP's can combine various services
  - Clinical Trial Distribution/Co-pay Support,
  - Patient Assistance Programs, Starter Kits, Sampling
- Provide Additional Payor Education: Particularly around new therapies at Case Management Level
  - Pipeline Awareness & Launch Programs that can streamline P&T processes.
- Many focusing on Infusion Capabilities





# What is the Distribution Model Impact?

*How do distribution models drive coverage*

- What drives the distribution model?
- What is the benefit to the stakeholders
  - Patient
  - Physician
  - Payer
- Does the payer really care....
  - ....or is it all about price?
- Does the product type/ category/ uniqueness impact the process?



# Needs/Requirements of Manufacturers



## EVERY PRODUCT IS UNIQUE & HAS DIFFERENT NEEDS

**Biotech/Some Pharma Companies are often “Virtual” in nature  
lacking operational and financial infrastructure**

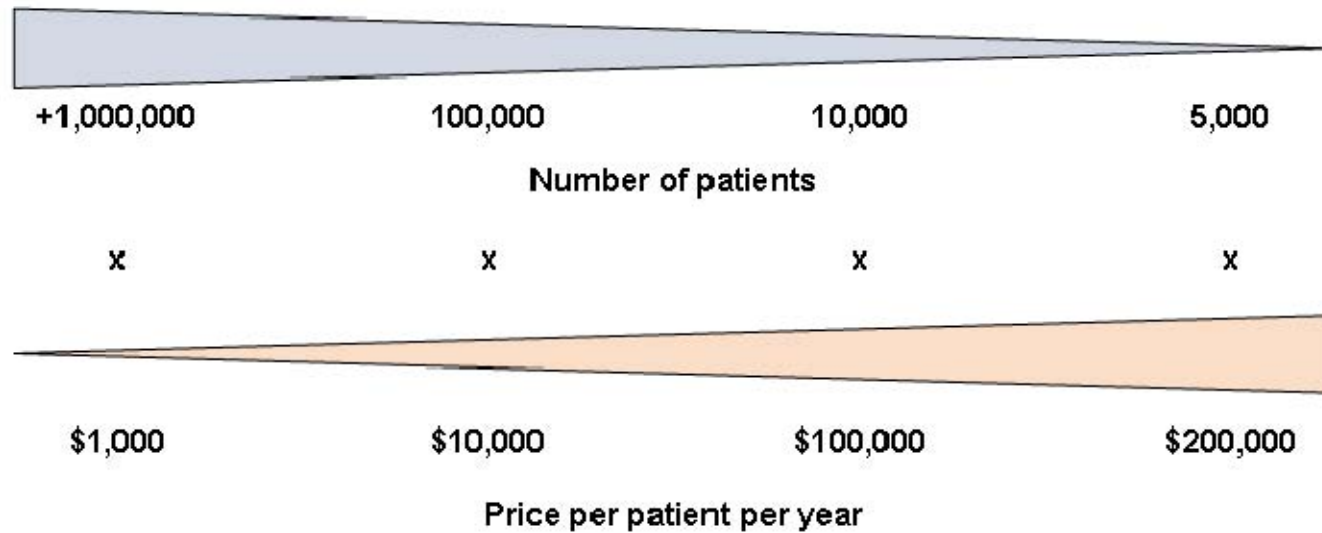
*Therefore they often look to outsource:*

- ★ • Logistics
- Packaging and Labeling
- ★ • Customer Service
- ★ • Account Management (AP/AR)
- ★ • Reimbursement Support
- ★ • REMS/ Registry Programs
- ★ • Product Allocation Programs
- ★ • Patient Assistance Programs
- ★ • Sampling
- Field Sales
- ★ • Clinical Support to Patient
- ★ • Medical Affairs
- Marketing Development
- ★ • Literature Fulfillment
- Contract Sales and Marketing
- ★ • Other, Starter Kits, Gap

★ = LDN / SP('s) can provide assistance or manage



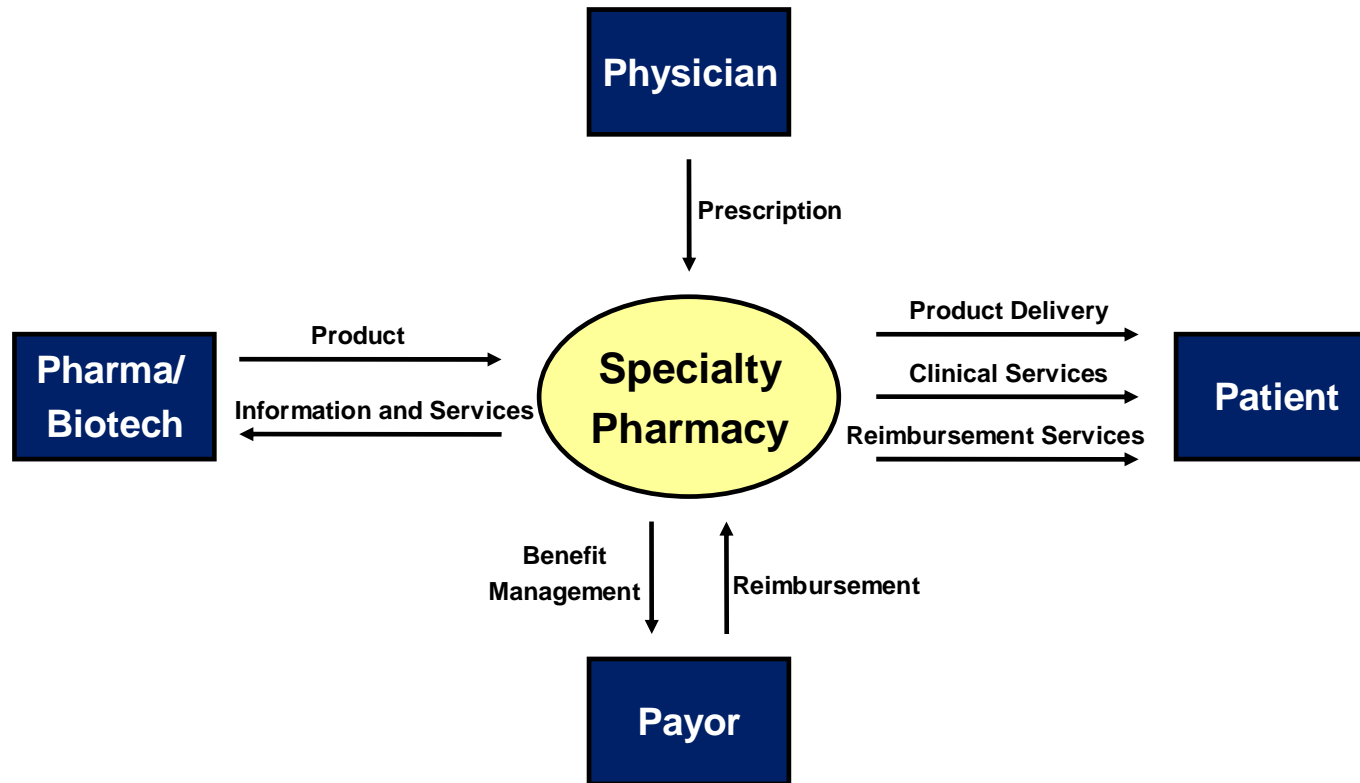
# The sliding scale of blockbuster sales: *Primary care drugs to ultra-orphan drugs*



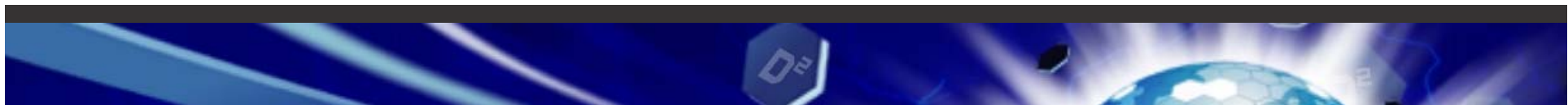
**MANY NICHE PRODUCTS WILL REQUIRE A REMS COMPONENT. IT WILL COST PHARMA A TREMENDOUS AMOUNT OF MONEY TO MANAGE LARGER SP NETWORKS.**



# Specialty Pharmacy Overview



<ul style="list-style-type: none"> <li>▪ Hemophilia/ VonWillebrands</li> <li>▪ Gaucher's Disease</li> <li>▪ Growth Hormone Deficiencies</li> <li>▪ Multiple Sclerosis</li> <li>▪ Hepatitis C,B,A</li> <li>▪ Pulmonary Hypertension</li> </ul>	<ul style="list-style-type: none"> <li>▪ Cystic Fibrosis</li> <li>▪ Fertility/ Hormone Therapies</li> <li>▪ Immune Disorders: IVIG, Alpha</li> <li>▪ Respiratory Syncytial Virus</li> <li>▪ Hemopoietics/ Colony Stimulating Factors, ESRD</li> </ul>	<ul style="list-style-type: none"> <li>▪ Rheumatoid/ Osteoarthritis</li> <li>▪ AIDS/ HIV</li> <li>▪ Transplant</li> <li>▪ Oncology</li> <li>▪ Dermatology/ Psoriasis</li> <li>▪ Asthma/ Diabetes/ Opth <b>(newer entrants)</b></li> </ul>
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# The Changing look of SP Revenues



Specialty Pharmacy Revenue Streams		
Sources	% of 2008 Revenues	% of 2010 Revenues (proj)
Distribution	41%	31%
Service Fees	37%	46%
Manufacturer rebates/discounts	17%	18%
Patient Copays	5%	5%

Source: Health Strategies Group, Specialty Pharmacy Management, August 2009



# Specialty Services to Manufacturers: Why Use SP's or Have Limited Distribution Networks?



## Control Inventory

- Channel, Returns, Lot #s, Serialization
- **Proper Forecasting: Manufacturing, Financial**
- Protect from Speculative Buying/IMA Agmnts

## Data/ Reporting

- Control from market dynamics
- **Greater Detail/ ICD-9, PA, etc.**
- **Greater Frequency**
- **Remote Real-time Access: Purchasing, Pharmacy Director, Reps**
- HIPAA Challenges Today

**REMS**

## Consistent Patient Services

- Reimbursement Support, Payment Plan Options
- 24/7/365 Services
- **Refill Reminder/ Compliance & Persistency (C&P) Programs**
- Nursing Coordination
- Ancillary Supplies

## Allow Multiple Billing Options

- Medical, Pharmacy or Variation

## Managed Care Access

- **Quick Backdoor Contracting/Product Specific**

## Case Management Support Patient Advocacy

- PA Processing
- Clinical Appeals
- Financial Appeals (100% Copay, 50% Deductible, etc.)

## Disease State Management Programs

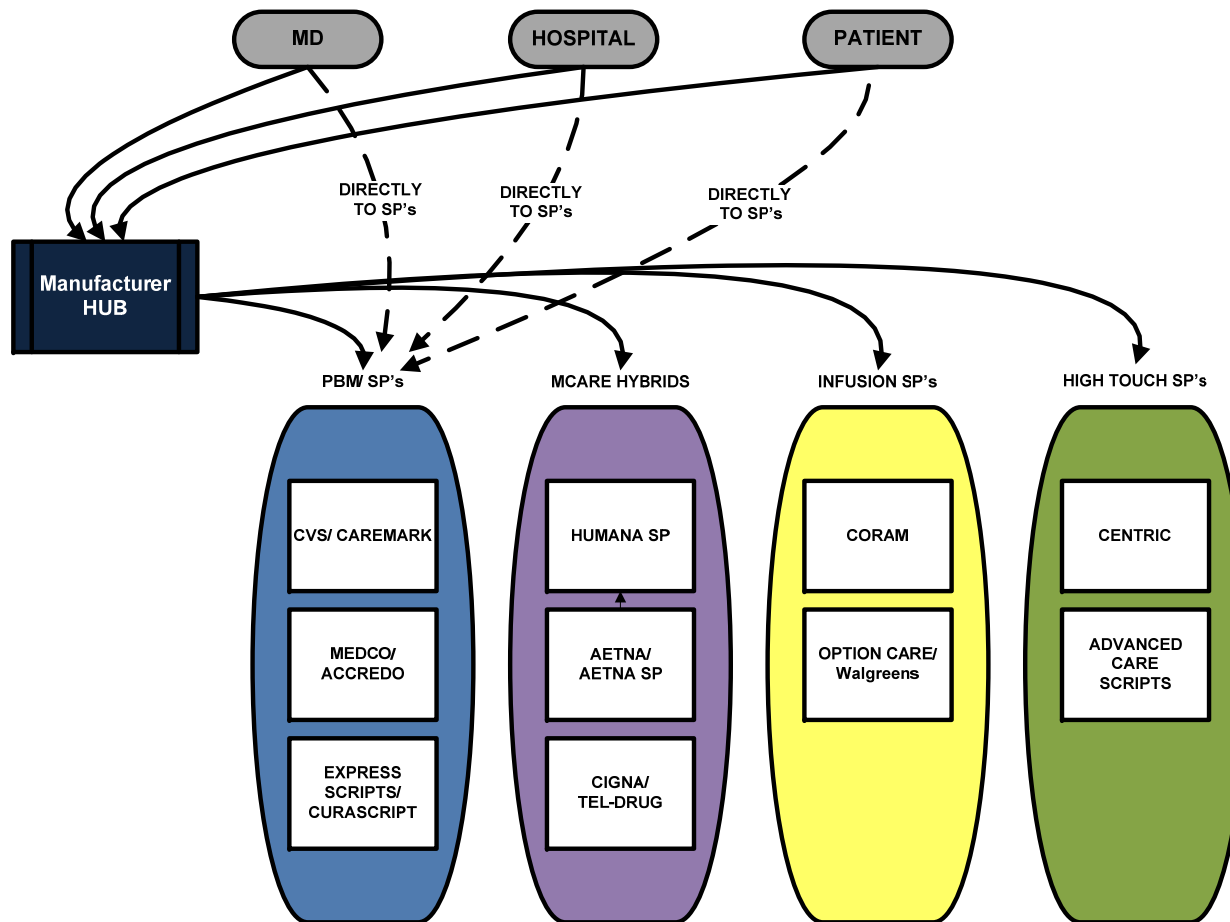
- Track Pharmacy and Medical for ROI Story
- Manage "Global" Patient Costs
- **Niche/ Custom Management Programs**

## FDA/ Clinical Programs

- **FDA Mandated Process or Data Capture**
- **REMS/ RiskMAP**
- High Side Effect Product Profile/ Process and Data Capture/ Risk Avoidance



# Traditional Model # 1: Contained Access



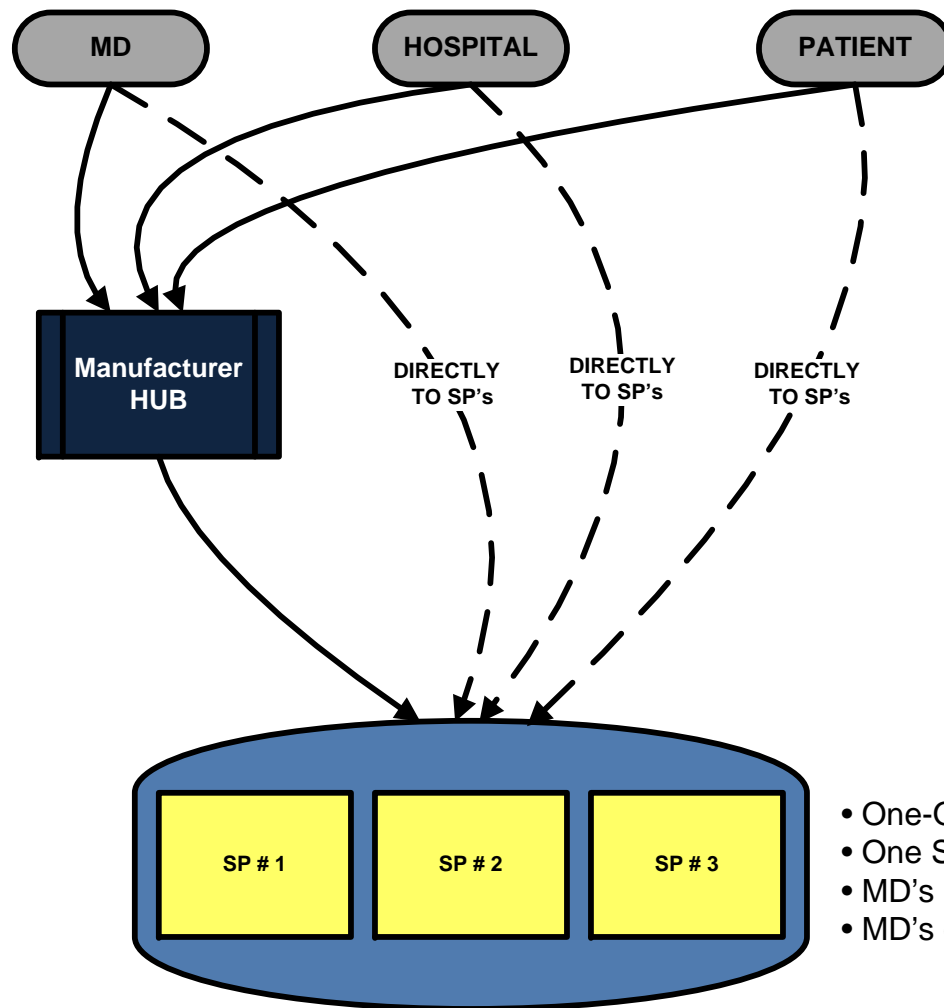
PROS
Quickest Access To Lives
All Perform Consistent Services
Payors Have Options for Coverage
Pts Have Greater Choice: Rx vs MM

CONS
More Accounts to Manage
More Data to Aggregate
More Complexity to Contracting
Inconsistent Data from SP's
More A/R to Manage
More Inventory to Manage
Low Focus from SP if Low Margin

- One-Off Drop Shipments can be made to “exceptions” as needed
- One Specialty Distributor./ Wholesaler will lower costs globally
- MD's can send to HUB or SP's/ Data will be aggregated
- MD's could acquire products and buy and bill or get product from SP via Rx



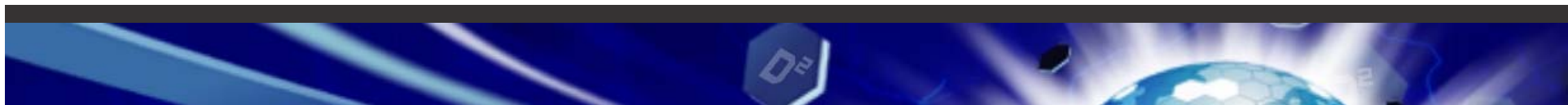
# Traditional Model # 2: Limited Access



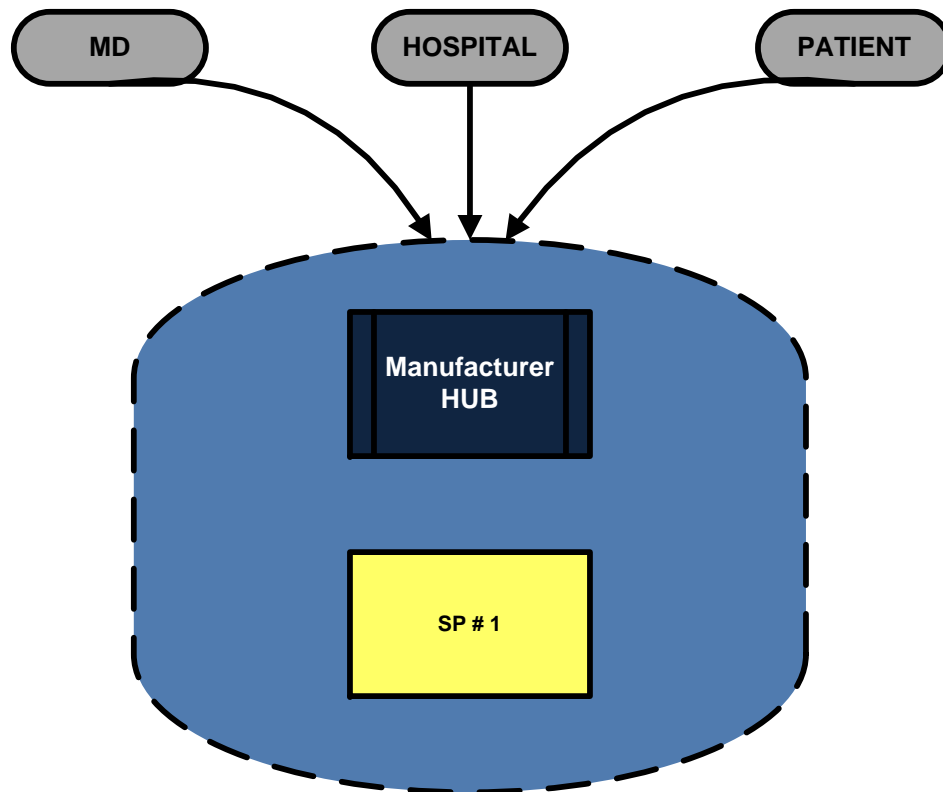
PROS
Access to 75% of Lives
Smaller Act Mgmt Needed
Easier Inventory Mgmt
Consistent Services
Moderate Cost Savings
Moderate Financial Responsibility

CONS
Irritation to SP's not in Network
Irritation to Payors/ SP not in Network
Must be High Margin to get Attention

- One-Off Drop Shipments made to “exceptions” as needed
- One Specialty Distributor./ Wholesaler will lower costs globally
- MD's can send to HUB or SP's/ Data will be aggregated
- MD's could acquire products and buy and bill or get product from SP via Rx



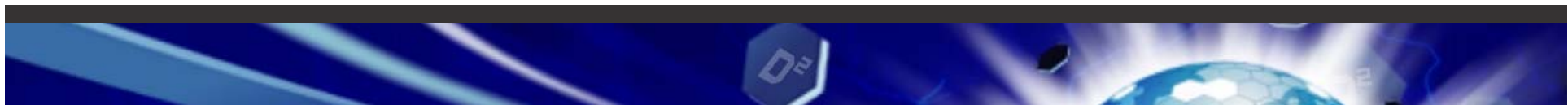
# Traditional Model # 3: Controlled Access



- One-Off Drop Shipments can be made to “exceptions” as needed
- One Specialty Distributor./ Wholesaler will lower costs globally
- MD’s can send to HUB or SP (could be same entity)
- MD’s could acquire products and buy and bill or get product from SP via Rx

PROS
Easy Inventory Control
Least Overhead/ Act Mgmt
Best Data
Orphan Story: High Cost, Low Pt Pop
Easiest Contracting
Highest Level of Control

CONS
Initial Perception/ Closed
Payor Contracting/ LOA Variability
Service Issues/ Resolution Needed
Eggs in One Basket





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# THE IMPACT ON REIMBURSEMENT



# Coverage in the US Market

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- It's all about patient access
  - PBM owned SP's
  - Payer owned SP's
  - Regional providers with key payer relationships
  - One-off contracting structures
  - Limited exclusive distribution models





# Validation to Payer Market

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- Specialty Drugs are different
  - High cost of drug
  - High cost of patient care
  - Potentially...higher cost if *lack of patient care*
- Payers have a budget too...
  - If clinical data is not compelling payers will either
    - Not cover (if this is an option with their customer base)
    - Will cover but at significant (50%) coinsurance
  - If in a competitive category then...
    - Payers will evaluate cost competitiveness





# What do payers want?

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Where is the market going relative to reimbursement?

- Payer are looking at new products differently than in the past
  - Active Comparative Data
  - EU/NICE Model coming into play
  - Genetic Testing as necessary element to engage or continue on therapy
    - Herceptin (Herc2 Test)
  - Questions to answer
    - Does testing lead to a better qualified patient?
    - Does testing lead to a better result for patients?

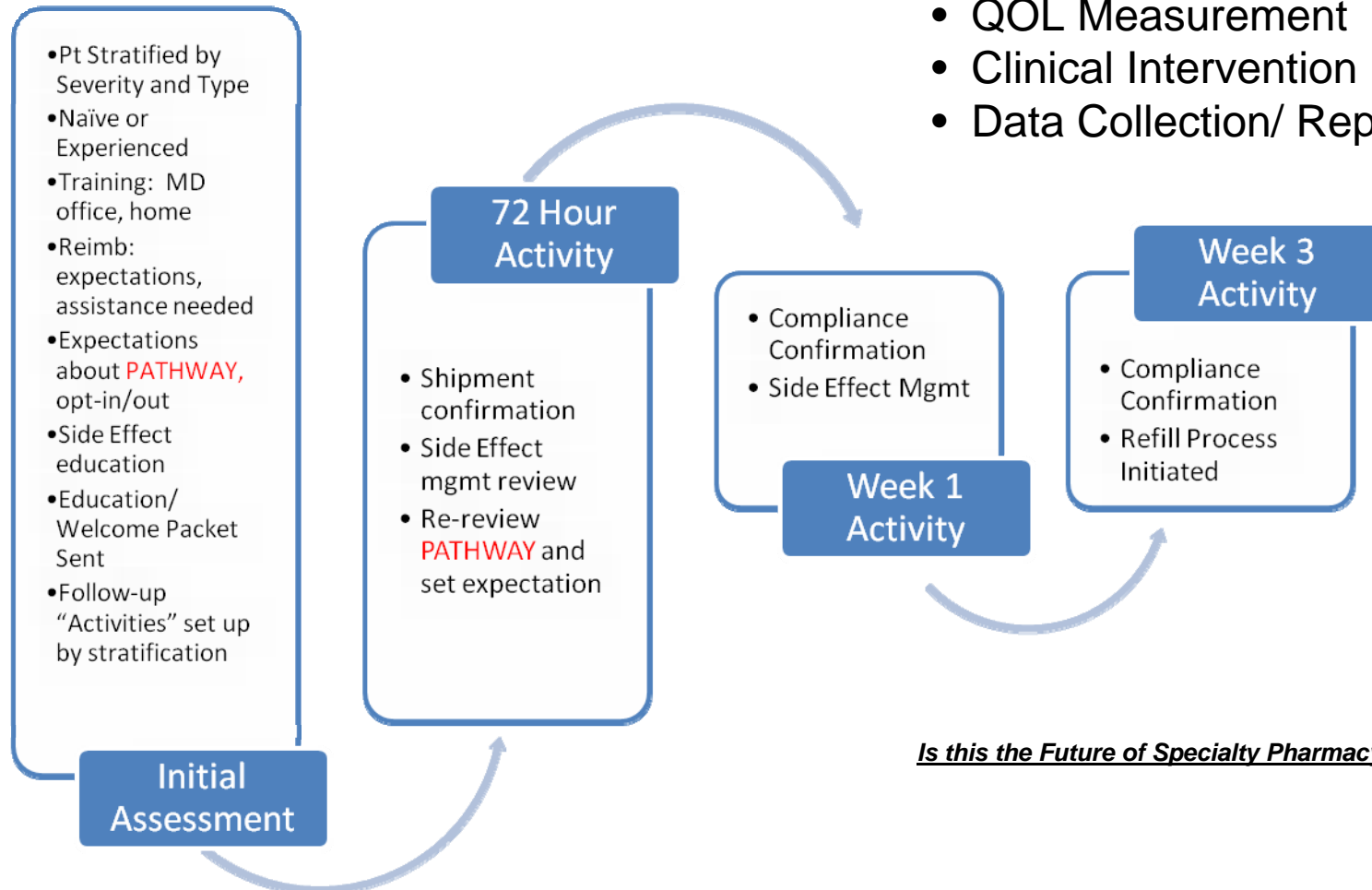


# Custom Pathways with New Technology



## ■ Custom/ Niche Programs

- Structured Activities
- Medication Adherence
- QOL Measurement
- Clinical Intervention
- Data Collection/ Reporting



***Is this the Future of Specialty Pharmacy?***

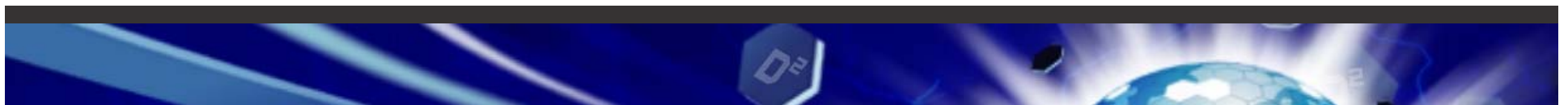


# Where should manufacturers focus

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- Distribution channel doesn't matter if the manufacturer has the right arguments to:
  - Support coverage of the product
  - Support the right care model for the patient
  
- Manufacturers should provide to payers to enhance their reimbursement position:
  - Cost of Drug
  - Cost of Side Effects
  - % of positive Patient Outcomes
  - Anticipated Adverse Events
  - Uniqueness relative to mechanism of action (i.e. Copaxone)





# Custom Distribution Models

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What should a custom distribution model deliver?

- What does a payer get for coverage of a \$50K – \$100K drug therapy
- Help the patient the Value of Drug Therapy
  - What is the *Importance of Compliance?*
- Understanding of the best pathway to maximize patient care.
  - Assistance in *physician education*
- Ability to collect all data across all services provided to the patient.
  - Measuring outcomes
  - Measuring a meaningful impact (longer life, less hospitalizations, more workdays etc.)



# Does distribution impact reimbursement?

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- Does it matter? Or....
- It doesn't matter at all?
  
- Custom distribution models should be built to enhance the offering to the market
- Custom models do not impede reimbursement if they support a sufficient care model





# Payer expect

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- Proof of clinical data
- In a competitive category head to head testing
- Will move to more Pathways within specialty categories
  - Oncology (ahead in this area)
  - Expanding to other categories
    - Hep C
    - RA
    - MS
    - IVIG
    - Diabetes (Disease Management)





# What should we expect

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- Payers will accept limited/ exclusive distribution
  - Validation by the manufacturer that the product and/or patient requirements justify a unique model
  - The service provider works with the payer Case Management/Clinical Staff to:
    - Identify the right patient
    - Provide the right level of care
  - The distribution model:
    - Provides consistent quality service
    - Is cost effective in that it provides
      - Right Drug, Right Patient, Right Time
  - The Manufacturer...
    - May have to consider risk sharing contracting model with the payer...guaranteeing the intended results in alignment with the clinical trial results





**Thank you for your time today.....**



# Dean Erhardt, MBA

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## Principal

- Express Scripts: PBM, Specialty Pharmacy, Manufacturer Services Organization (PAP, Sampling, HUB's, Direct Programs)
  - Vice President: Specialty Pharmacy Benefit Management
    - Development of specialty benefit design structure
  - Senior Director Specialty Distribution Services
    - Included Pharma distribution and support programs including direct programs, Phoenix Sampling and the largest PAP distribution in the US
- Cardinal Health: Wholesaler; Director of GPO's, IDN's, National Accounts
- US Healthcare: HMO/PPO Organization; Director of Sales and MD recruitment/credentialing
- BA in Marketing from the University of Oklahoma
- MBA from the Keller Graduate School of Management
- Consultation:
  - Academic: NACDS/ White Paper, CBI PAP and various Specialty Conferences
  - Pharma: 50+ Companies
  - Other: Pharma Contracting, Operational Reviews, Diligence, Pharma Services
  - BA in Marketing from the University of Oklahoma; MBA, Keller Graduate School of Management

