Specialty Pharmacy Overview

Brian Burke – VP National Accounts

9/14/2012
“Specialty Pharmacy is the practice of dispensing complex therapies delivered by expert healthcare practitioners to patients with chronic and acute illnesses. This model coordinates condition-specific core services designed to improve patient access and achieve optimal clinical outcomes*”

*As defined by Charter Members of National Coalition of Specialty Pharmacies, October 2008
What Makes a Drug a “Specialty”?:

- More than just saying “It’s a biologic”
- Targets a disease with a small-to-medium population
- Serious unmet medical needs
- Includes one or more of the following features:
  - Usually a large-molecule injectible
  - Increasingly, small-molecule oral drug
  - Coverage under the medical benefit but increasingly under the pharmacy benefit
  - Primarily prescribed and administered by a specialist
  - Often requires special handling (express or overnight shipping), refrigeration and storage
  - Requires disease-management services (e.g., patient education, monitoring, co-pay assistance, etc.)
- High Cost (over $1,200 per month)
Factors Determining Classification as Specialty Pharmacy by Plans

On a scale of 1-5, where 1 = no impact at all and 5 = extreme impact, please rate the impact each factor has in determining whether a drug category is classified as “specialty pharmacy.”

- High cost: 80% impact in 2010, 84% in 2011
- Requires special handling: 62% in 2010, 68% in 2011
- Treats rare disease: 46% in 2010, 49% in 2011
- Limited distribution: 49% in 2010, 63% in 2011
- Requires ongoing assessment of response: 47% in 2010, 47% in 2011
- Requires patient administration training: 37% in 2010, 38% in 2011
- Requires monitoring of side effects: 32% in 2010, 42% in 2011
- Drug has an FDA mandated REMS: 29% in 2010

*Average minimum monthly cost to meet the high cost criteria was $1,200 in 2010 and $1,154 in 2011

**New selection in 2011

EMD Serono Specialty Digest, 8th edition
Specialty Product Disease States Defined

- ALS
- Alzheimer's
- Arthritis
- Asthma
- Blood Modifiers
- CMV
- COPD
- Crohn’s Disease
- Cystic Fibrosis
- Dialysis
- Enzyme Replacement
- Growth Hormone
- Hemophilia
- HIV/AIDS
- Infertility
- IVIG
- Mental Health
- Multiple Sclerosis
- Oncology
- Psoriasis
- Rheumatoid Arthritis
- RSV
- Osteoporosis
- Transplantation
- Viral Hepatitis

Armada Health Care
Specialty Pharmacy Services Defined

• Patient Services
  – 24/7 Patient Support
  – Registry Capabilities
  – Educational Services
  – Reimbursement Support/ Benefit investigation/Prior Authorizations/Foundation Support
  – Compliance Initiatives
  – Outcome monitoring

• Coordination of Care with Providers

• Clearly Defined Business Model
  – Physician Relationships / Referrals
  – Differentiated by Marketing Services

Armada Health Care
Specialty Pharmacy Services

Value Proposition

Pre Launch

Drug Development ≈ $1.3 Billion

Launch

Market Access: Rebate Accrual $$$
Product Marketing: Agency $$$
Sales Force: Salary, Training, Travel $$$

Continuum of Care

“An ounce of prevention is worth a pound of cure”
Benjamin Franklin
### Patient

**Service Expectations**
- Comprehensive Patient Care
- 24/7 Nurse or pharmacist on call
- Benefits Investigation/PA
- Overnight delivery to home or office
- Temperature controlled packaging
- Online support groups

### Physician

**Service Expectations**
- Clinical extension of office
- Compliance management
- Customized dose delivery
- Reimbursement coordination
- Coding and billing assistance

### Payor

**Service Expectations**
- Competitive pricing
- Customized programs (at group level)
- Seamless, dedicated account management and transition
- Marketing and sales support

### Pharma/Manufacturer

**Service Expectations**
- Broad distribution
- Special handling/temperature control
- Overnight delivery
- Patient and office assistance
- Direct patient interaction
- Reimbursement coordination
- PAP/REMS execution

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**Specialty Pharmacy Services Value Proposition**

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**Armada Health Care**
## Drug Access Challenges: Manufacturers and their “Intended” Vision

<table>
<thead>
<tr>
<th>Category</th>
<th>Services</th>
</tr>
</thead>
</table>
| REMS Management                 | • Physician Registry  
                                    • Patient Registry  
                                    • Pharmacy Registry                                                   |
| Reimbursement Support           | • Benefits Verification  
                                    • Prior Authorization & Appeal  
                                    • PAP                                                                    |
| Patient Education and Support   | • Welcome Calls  
                                    • Product Education  
                                    • Late to Fill Calls                                                   |
| Distribution                    | • Controlled  
                                    • No Leakage  
                                    • 867/852 Data                                                        |
| Data                            | • Dispensing Data  
                                    • Intervention Data  
                                    • Outcomes Data                                                       |

Pharmacies must be equipped with the tools to meet these requirements.
For Every 100 Prescriptions Initially Written, Only 15 to 20 Prescriptions are Continued After the Initial Supply

For every 100 prescriptions written by a physician, how many prescriptions are...

- Originally filled by the patient? 50 to 70
- Picked up by the patient? 48 to 66
- Taken according to the physician? 25 to 30
- Refilled by the patient? 15 to 20

Factors Impacting Adherence and Persistency to Therapy Regimen

<table>
<thead>
<tr>
<th>Social and Economic Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Poor socioeconomic status</td>
</tr>
<tr>
<td>• Illiteracy</td>
</tr>
<tr>
<td>• Unstable living conditions</td>
</tr>
<tr>
<td>• Cost of medication</td>
</tr>
<tr>
<td>• Cultural beliefs</td>
</tr>
<tr>
<td>• Family dysfunction</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Health Care Team/System</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Poor patient-provider relationship</td>
</tr>
<tr>
<td>• Poor medication distribution systems</td>
</tr>
<tr>
<td>• Overworked HCP</td>
</tr>
<tr>
<td>• Lack of incentives</td>
</tr>
<tr>
<td>• Lack of knowledge on managing adherence</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Characteristics of the Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Level of disability</td>
</tr>
<tr>
<td>• Severity of symptoms</td>
</tr>
<tr>
<td>• Rate of progression and severity of the disease</td>
</tr>
<tr>
<td>• Comorbidities</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Disease Therapies</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Complexity of regimen</td>
</tr>
<tr>
<td>• Duration of therapy</td>
</tr>
<tr>
<td>• Previous treatment failures</td>
</tr>
<tr>
<td>• Side effects</td>
</tr>
<tr>
<td>• Injection anxiety</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Forgetfulness</td>
</tr>
<tr>
<td>• Treatment anxiety</td>
</tr>
<tr>
<td>• Low motivation</td>
</tr>
<tr>
<td>• Lack of understanding of health risk</td>
</tr>
<tr>
<td>• Disbelief in diagnosis and/or treatment</td>
</tr>
</tbody>
</table>

Aging World Population:

• Over 500 million or about 8% of people (worldwide) are over age 65
• The elderly population is expected to grow to more than 1 billion by 2030; this will account for 13% of the world population*
• The most rapid increase in the elderly population is in developing countries

Source: United Nations Department of Economic and Social Affairs
*U.S. State Department
Specialty Products are available for more than 30 disease states

In 2008, 197 Biotechnology drugs on the market in the US*

19% of which were Infused Products*

Through 2012, the top three specialty disease states, inflammatory conditions, MS and cancer, will account for two-thirds of specialty drug spend under pharmacy benefits^
Specialty Pharmacy Overview: Yesterday

- ≥ $100 billion spent in 2010
- Less than 2% of the population represented 20% of the total drug spend
- In 2010, six of the top 20 therapeutic classes were specialty
- In 2010, seven of the top 20 drugs were specialty products
- 150+ FDA-mandated Risk Evaluation Mitigation Strategies (REMS)...ever increasing
• 2011-2012 US Pharmaceutical Market
  – Specialty is the fastest growing segment and is expected to grow at a rate of 20% to 23.5% annually*
  – It is estimated that specialty spend will climb to more than 40% of total drug spend by 2030**
  – The specialty category is receiving high attention due to the high cost of drugs
    • “Nine medicines now cost more than $200,000 per year”^^
    • Average annual percent change in manufacturer prices for widely used specialty prescription drugs remains high in 2010= 9.2%”^^

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*Curascript 2009 specialty drug trend report. **Source: IMS 2008 Health Year in Review
## Limited Distribution Specialty Products

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Drug</th>
<th>Manufacturer</th>
<th>Drug</th>
<th>Manufacturer</th>
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<th>Manufacturer</th>
<th>Drug</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actelion</td>
<td>Tracleer, Ventavis, Zavesca</td>
<td>Bayer</td>
<td>Mirena, Nexavar</td>
<td>Novartis</td>
<td>Exjade, Visudyne</td>
<td>Organon</td>
<td>Implanon</td>
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<tr>
<td>Astra-Zeneca</td>
<td>Iressa, Synagis</td>
<td>Biomarin</td>
<td>Kuvan</td>
<td>Orphan Medical</td>
<td>Xyrem</td>
<td>Rare Disease Therapeutics</td>
<td>Orfadin</td>
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<tr>
<td>Biogen idec</td>
<td>Tysabri, Rituxan</td>
<td>Celgene</td>
<td>Revlimid</td>
<td>Questcor</td>
<td>Acthar Gel</td>
<td>Shire</td>
<td>Elaprase</td>
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<tr>
<td>BMS</td>
<td>Erbitux</td>
<td>Gilead Sciences</td>
<td>Letairis</td>
<td>Serono</td>
<td>Zorbtive</td>
<td>United Therapeutics</td>
<td>Remodulin</td>
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<tr>
<td>Endo</td>
<td>Supprelin LA</td>
<td>Genzyme</td>
<td>Cerezyme, Fabrazyme, Myozyme</td>
<td>Tercica</td>
<td>Increlex, Somatuline</td>
<td>ZLB Behring</td>
<td>Vivaglobin</td>
</tr>
<tr>
<td>Genentech</td>
<td>Avastin, Herceptin, Xoliar, Lucentis, Nutropin, Raptiva,</td>
<td>GSK</td>
<td>Tykerb</td>
<td>Pfizer</td>
<td>Inlyta</td>
<td>Alexion</td>
<td>Soliris</td>
</tr>
</tbody>
</table>

Source: Armada Health Care internal data base.
Oncology makes up 40% of the specialty pipeline

A shift to oral chemotherapy agents is one of the major trends in specialty

- Oral drugs make up 35% of the oncology pipeline
- By 2013, the percentage of oral oncology drugs will reach 25%, up from 10% in 2009

Specialty Product Pipeline

New Molecular Entities and Supplemental Indications in Phase III Development

- New Molecular Entities: 53% Traditional, 40% Specialty
- Supplemental Indications: 47% Traditional, 60% Specialty

*EMD Serono Injectables Digest™ 4th Edition*
Specialty Manufacturer Pipelines
Specialty Pharmacy Pipeline: Deep Dive

Orphan drug: Rare diseases affecting less than 200,000 U.S. people

- Potential 25 to 30 million patients across the U.S.
- Research & Development is actively encouraged through the National Institute of Health’s rare and neglected disease initiative and the U.S. FDA

<table>
<thead>
<tr>
<th>Category</th>
<th>#</th>
<th>Category</th>
<th>#</th>
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<tbody>
<tr>
<td>Eye Disorders</td>
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<td>Other</td>
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<td>Cardiovascular</td>
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<td>Transplantation</td>
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<td>Blood disorders</td>
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<td>Autoimmune</td>
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<td>Infectious Disorders</td>
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<td>Gastrointestinal</td>
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<td>Cancer</td>
<td>107</td>
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</table>
Specialty Pharmaceuticals: Evolving Customer
Armada Membership Profile

Consists of the nation’s leading local, regional and national Specialty Pharmacy Providers providing comprehensive prescription services and disease state management programs for specific chronic conditions

<table>
<thead>
<tr>
<th>Specialty Pharmacies</th>
<th>Home Infusion/Home Health</th>
<th>Retail Chains /Independents</th>
<th>Clinics/ IDNs/ Outpatient Pharmacies</th>
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<tr>
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<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Independent</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>
**Specialty Pharmacy “Players”**

### Traditional Customer

1. “Closed Shop” specialty pharmacy  
   - Large public companies  
   - PBM owned  
   - Independent  
   - Chain owned separate location  
2. Full contract loads  
3. Generally have access to limited distribution products  
4. Have physician/payer sales force  
5. Developed internal dispensing system  
6. Armada provides complimentary services  
7. Armada provides typical “GPO” services  
8. Armada collects daily dispensing data specialty products  
9. Armada provides contracting opportunities
New Specialty Customer

1. SP patients are ambulatory
2. More products are accessible to “Open Access” pharmacies
   - 35% of oncology pipeline are oral drugs
3. Still a fair # of limited distribution products
4. Trend towards greater pharmacy access from payers
   - i.e. Union Plans
Retail Customer

1. Increased access to patients
2. Basic patient services
   - “Face to face” pharmacist time
   - “Point of sale” messaging
3. Limited, but growing access to manufacturer discounts
4. Lack of access to limited distribution products
5. Lack of patient outreach capabilities
6. Limited resources for complicated P/A process
Specialty Pharmaceuticals: Evolving Contracting Strategies
Marketing Teams DO NOT Want to "Restrict Access"

Patients are Ambulatory, but Product must be mailed to your house???????
Program Descriptions

• Armada and Manufacturers jointly develop programs for our customer base

• Compensation for These Programs Are
  – C&P Based - Fee for Service
  – Rebates
  – Discounts (off invoice)

• In all cases – “Back-end Services” are needed
The Opportunity:
*Armada’s Program helps to decrease time to fill for patients awaiting administration of drug*

- Armada’s ASPN personnel receive prescriptions and map them to the most appropriate pharmacy as determined by
  - Patient needs
  - Billing expertise
  - Payer accessibility

- Participating pharmacies are paid
  - Base rebate for participation and data
  - Additional rebates are paid based on “time to fill”
**Member Benefits:**

- **4% upfront discount** on products
- Track patient compliance with ReachRx OTM

**Eligibility Criteria:**
Pharmacies must have specific capabilities, including (but not limited to):

- Provide comprehensive Hepatitis services to patients (on own, or Armada Call Center)
- Utilize Armada’s ReachRx OTM system to manage patient compliance
- Customer service team available 9 a.m. to 5 p.m., Monday through Friday and at least one representative proficient in Spanish
- Provide 24/7 (including holidays) nursing and pharmacist support to patients
ANTI TNF Program Highlights

The Opportunity:
Armada’s ANTI TNF Program helps to increase patient compliance and adherence via multi-channel communications, at key points during therapy.

• Armada Call Center representatives complete Outbound phone calls at critical points in a patient’s therapy, including:
  
  • **New to Therapy/ Welcome Call:**
    • Welcome patient to therapy
    • Confirm diagnosis
    • Review side effects of therapy
  
  • **Late to Refill Call:**
    • Target patients who are ‘late to refill’ their prescription
    • Determine issues with therapy or side effects
    • Discuss importance of compliance
  
  • Armada completes a Direct Mail campaign in support of the Outbound call campaign, including:
    • Welcome Letters
    • Unable to Reach Letters: Targets patients who we are unable to reach via phone.
Open Discussion & Questions