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# Meeting the Challenge of Specialty Pharmacy Management

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Pharmaceutical Strategies Group

November 6, 2003



# Agenda

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- Specialty Pharmacy Impact
- Strategic Issues in Specialty Pharmacy Management
- Management Strategies / Outcomes
- A View Towards The Future



# Specialty Pharmacy Impact

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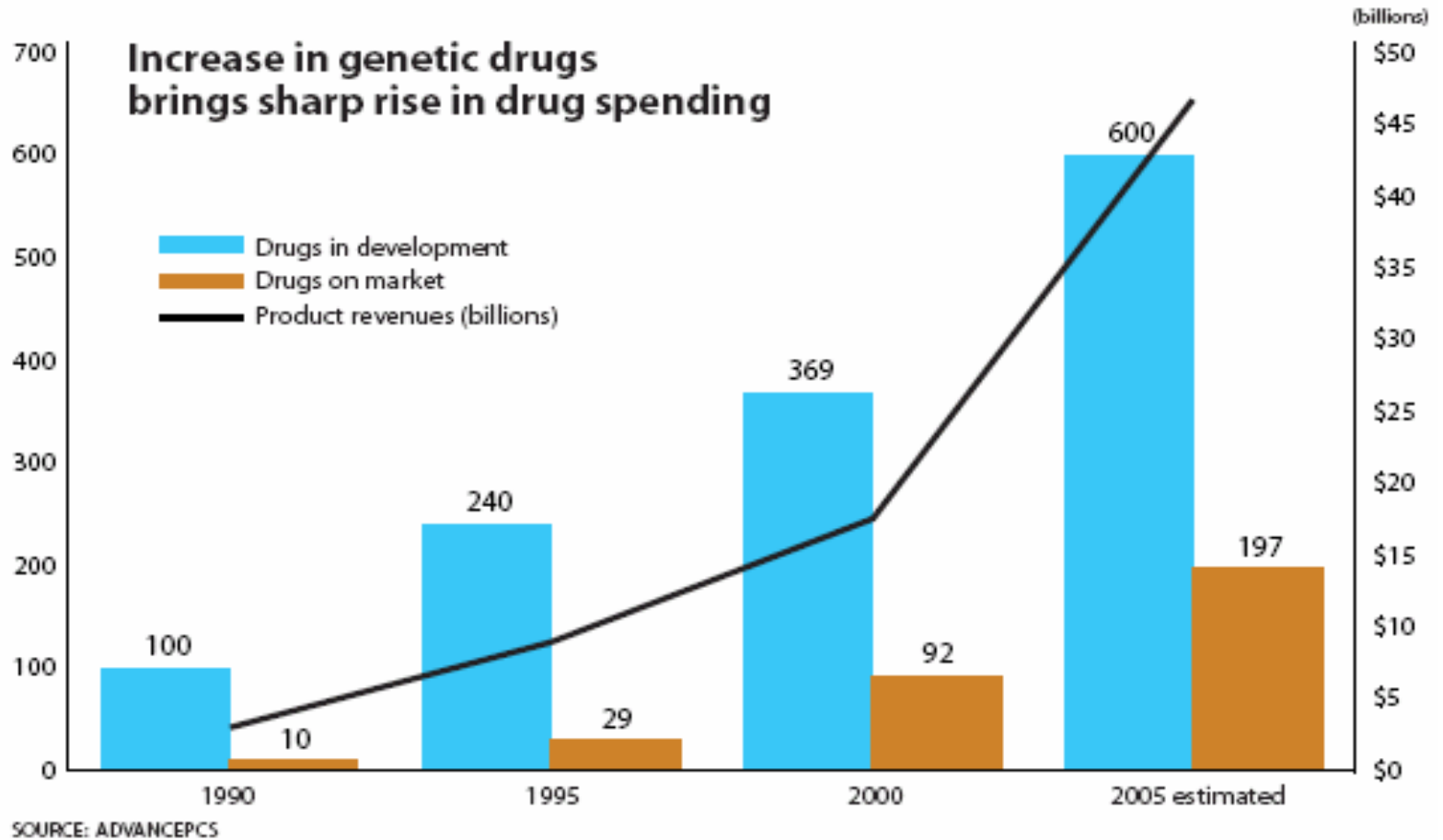
“The delivery of biotechnology products such as injectable or intravenously (IV) administered drugs, requiring special handling (i.e., refrigeration), combined with coordinated clinical services to assist patients and the physician implement a prescribed plan of care.”

Source: Salomon Smith Barney, May, 2001

Emphasis added.

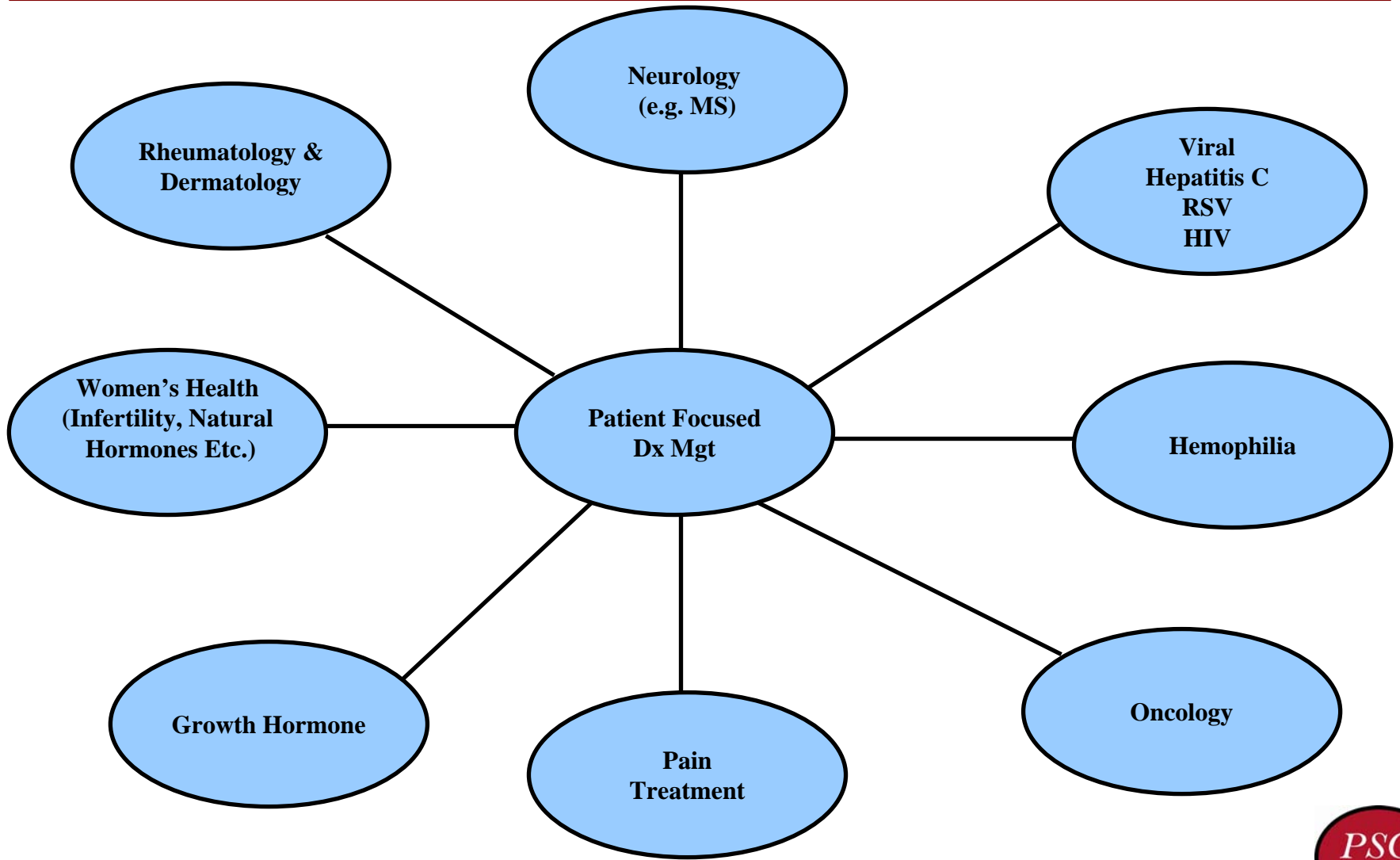


# Specialty Pharmacy Impact



# Specialty Pharmacy Impact

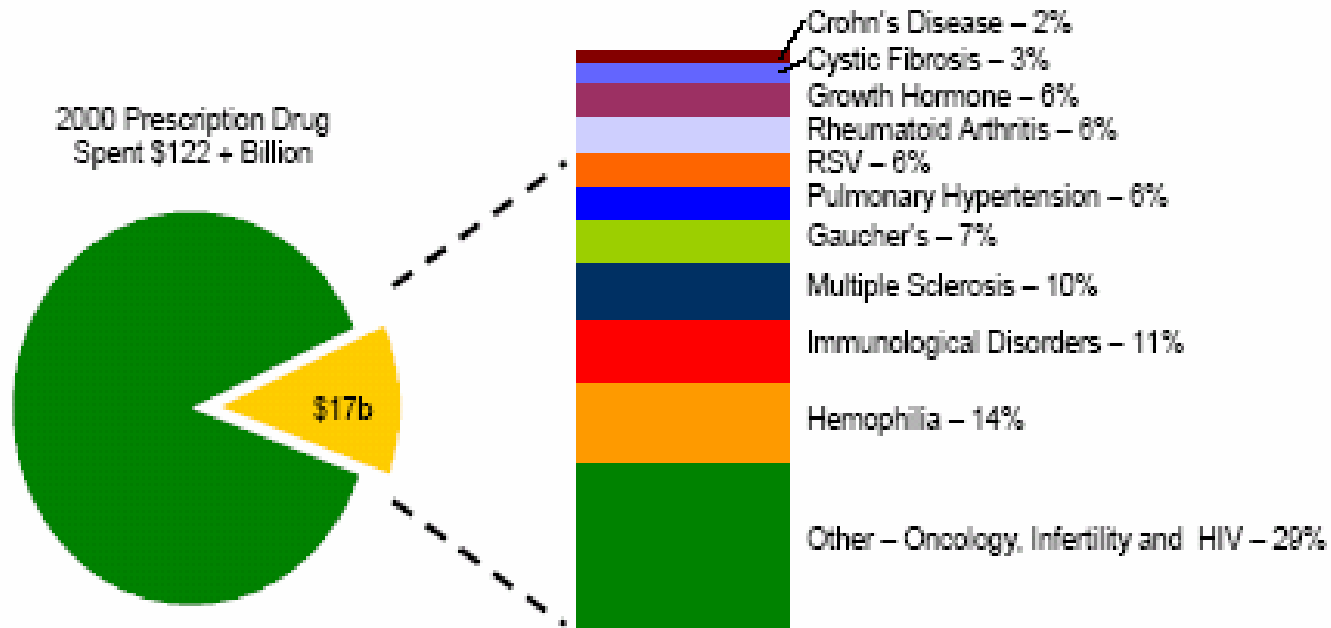
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# Specialty Pharmacy Impact

FIGURE 2  
SPECIALTY PHARMACEUTICALS MARKET

Of the \$122+ billion spent in prescription drugs, \$17 billion are spent on Specialty Pharmacy

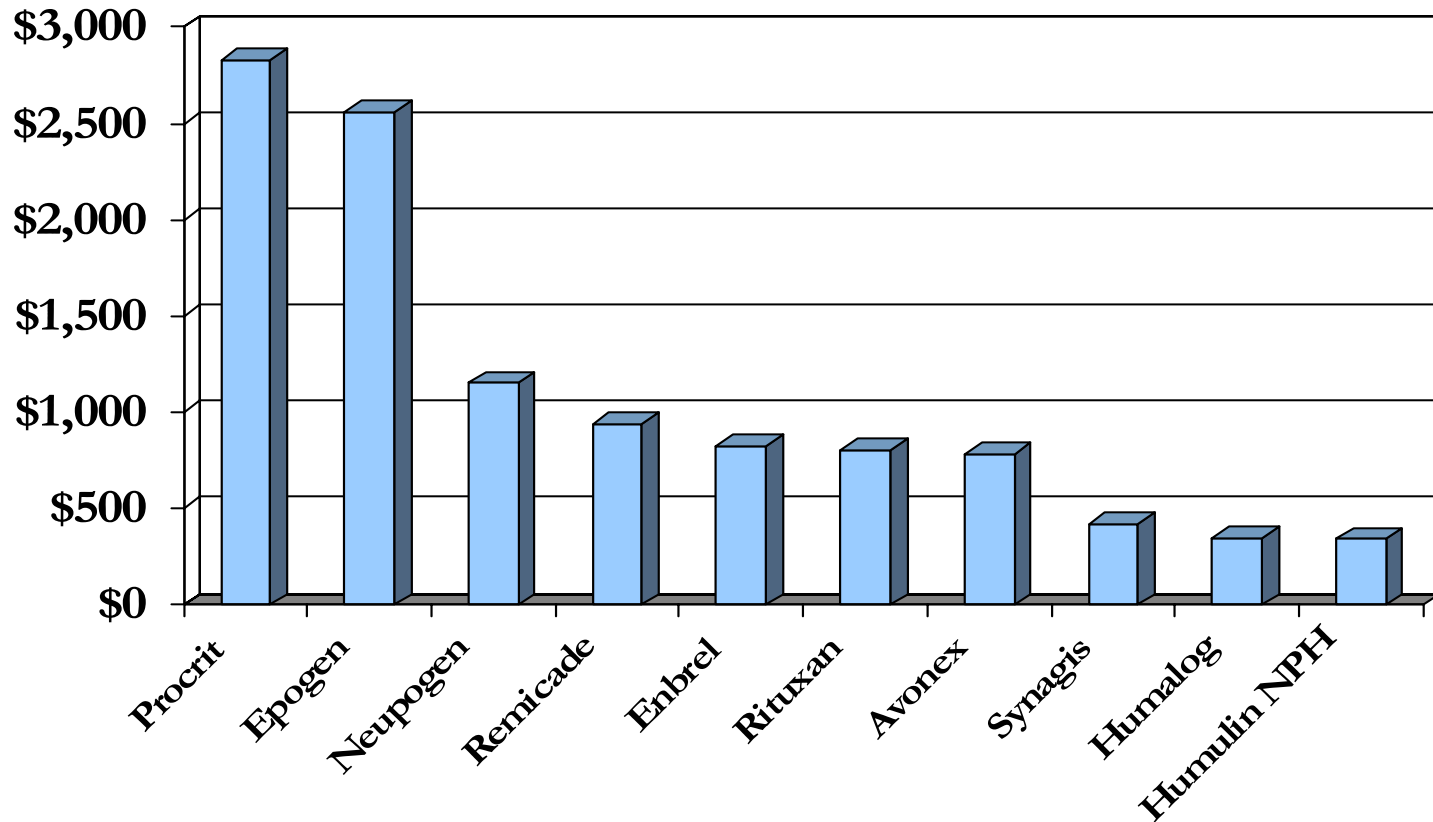


Sources: CMS, January 2002; Express Scripts Analysis, 2001.



# Specialty Pharmacy Impact

Leading Biotech Products Based on U.S. Sales, 2002 (in Millions)



Source: IMS Health 2002



# Specialty Pharmacy Impact

## 10 Products to watch in 2004

Drug	Disease	Estimated Launch	Estimated U.S. Market
CDP-571	Crohn's Disease	2004	> \$1 Billion
CDP-870	Rheumatoid Arthritis	2004	> \$1 Billion
Tarceva®	Lung Cancer	2004	> \$1 Billion
Xanelim®	Psoriasis	2004	> \$1 Billion
Antegren®	Multiple Sclerosis	2004	\$500 to \$999
Pemtumomab®	Cancer	2004	\$500 to \$999
Protein Kinase C-Beta Inhibitor	Diabetic Conditions	2004	\$500 to \$999
Raptiva®	Psoriasis	2004	\$500 to \$999
Meningitec®	Meningitis	2004	\$500 to \$999
HPV Vaccine	Cancer	2004	\$250 to \$500

Source: Caremark TrendsRx 2003



# Specialty Pharmacy Impact

## National Disease Incidence and Specialty Spend Estimate

Medical Condition	National Incidence Rate	Spend Per Patient/Per Year	Estimated Number of Patients	Estimated SpecialtyRx Spend
Growth Hormone Deficiency	1:14,285	\$23,000	60	\$1,380,000
Hemophilia	1:25,000	\$150,000	70	\$10,500,000
Anemia - Blood Modifiers	1:1,333	\$10,000	750	\$7,500,000
Hepatitis C	1:1,075	\$25,000	793	\$19,825,000
Inmunoglobulin	1:14,285	\$36,000	70	\$2,520,000
Crohn's Disease	1:16,667	\$16,000	70	\$1,120,000
Multiple Sclerosis	1:2,000	\$15,000	700	\$10,500,000
Rheumatoid Arthritis	1:25,000	\$15,000	1,700	\$25,500,000
RSV	1:33,333	\$6,000	400	\$2,400,000
Gaucher's Disease	1:125,000	\$250,000	8	\$2,000,000
Infertility	1:5,882	\$12,000	170	\$2,040,000
Primary Pulmonary Hypertension	1:100,000	\$100,000	10	\$1,000,000
Other	1:1,916	\$18,000	522	\$9,396,000
<b>Total</b>			<b>5,323</b>	<b>\$95,681,000</b>
<b>Per Member Per Month (PMPM) at AWP</b>	<b>\$7.97</b>			
<b>Actual Client Population</b>	<b>1,000,000</b>			
<b>SpecialtyRx Spend at AWP</b>				
Estimated Pharmacy (PBM)	\$23,061,000	24%		
Estimated Major Medical	\$72,620,000	76%		
<b>Total Estimated Current SpecialtyRx</b>	<b>\$95,681,000</b>	<b>100%</b>		

Source: Estimates provided by Regence Blue Shield at the IIR Specialty Drug Conference, 2003



# Specialty Pharmacy Impact

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## Is Specialty Pharmacy Just for Orphan Diseases?.....Hardly

- Asthma impacts > 17 million Americans (> 7 million with allergic forms)
  - Xolair<sup>®</sup> is a first in class therapy for moderate to severe cases
  - Costs will exceed \$10,000 per patient per year
- Rheumatoid arthritis impacts > 2 million Americans
  - 3 new biologics can significantly improve functioning, may slow disease progression, and improve quality of life
  - Cost in excess of \$14,000 per patient per year
- Psoriasis impacts > 4 million Americans
  - Amevive<sup>®</sup> can significantly improve quality of life
  - Cost of therapy is > \$10,000 per treatment cycle
  - Repeat courses may be utilized in clinical practice
  - Significant patient and provider demand will fuel growth

Sources: MHS Drug Trends Report 2003



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# Strategic Issues in Managing the Specialty Pharmacy Benefit



# Strategic Issues In Specialty Pharmacy Management

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- Specialty pharmacy goals:
  - Provide a reliable source for hard to find injectables
  - Provide access to professionally trained staff on a 24 hour basis
  - Integrate specialty medications with other medications for a robust drug utilization review and patient safety profiling system
  - Design & deploy a comprehensive patient education strategy on how to best manage the disease, achieve desired outcomes, minimize negative consequences, etc.



# Strategic Issues In Specialty Pharmacy Management

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- Specialty pharmacy goals cont.
  - Achieve competitive pricing
  - Create a streamlined & more accurate claims processing system
  - Eliminate inappropriate utilization
  - Enhance predictive modeling
  - Improve outcomes reporting, including pharmacoeconomic impact assessments



# Strategic Issues In Specialty Pharmacy Management

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- Will it be voluntary or mandatory?
  - This decision will impact every other implementation step
  - Many plans implement a voluntary period, followed with a mandatory conversion
  - Some plans implement the program voluntarily for a portion of the provider panel, while making it mandatory for the remainder of the network



# Strategic Issues In Specialty Pharmacy Management

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- Will all providers be required to use the service?
  - Oncology is an issue for many plans
  - Reimbursement adjustments are common, though not at 100% offset
  - At some point, it becomes an issue of parity
  - Rx Director, 400k + Health plan in NY
    - “Count on losing some physicians from your network after you implement a mandatory specialty distribution contract. Physicians who rely on their own markup of specialty products may discontinue their relationships with MCOs”

Source: “How Health Plans Should Deliver High Cost, Low Volume Biotech Drugs”, May 21, 2003 Webcast, AIS Health



# Strategic Issues In Specialty Pharmacy Management

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- Over what period of time will the program be phased in?
  - Most recommend at least one year for successful implementation
  - Many have transitioned over more than one year to ensure that appropriate communication plans, operational processes, financial underwriting changes, etc. are in place
  - Overall implementation could include a voluntary implementation window, followed by a gradual implementation to a mandatory system



# Strategic Issues In Specialty Pharmacy Management

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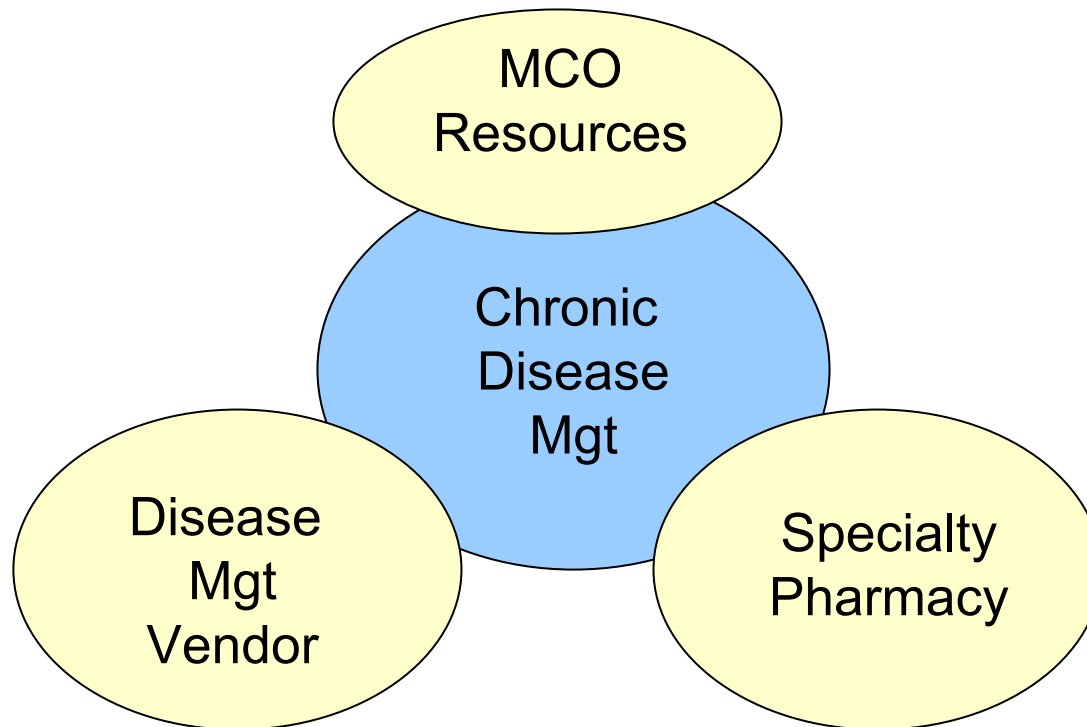
- What services will your specialty pharmacy (ies) provide?
  - Negotiated discounts & distributive services
  - Member reimbursement support
  - Data integration services
  - Disease monitoring / management
  - Utilization management
  - Member education



# Strategic Issues In Specialty Pharmacy Management

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- Who's in charge of UM / DM?
- Will it vary by disease state? (e.g. Asthma vs. Gaucher's disease)



# Strategic Issues In Specialty Pharmacy Management

Stakeholder	Pros	Cons
<b>Patient</b>	<ul style="list-style-type: none"> <li>•Reimbursement support</li> <li>•Access to additional clinical resources</li> <li>•Availability of home delivery</li> </ul>	<ul style="list-style-type: none"> <li>•Minimizes importance of retail pharmacy</li> <li>•Could cost more out of pocket, depending on plan design</li> <li>•Operational processes could confuse patient and / or delay care</li> </ul>
<b>Provider</b>	<ul style="list-style-type: none"> <li>•No need to hold expensive inventory</li> <li>•Reimbursement support</li> <li>•Convenience of one supplier</li> </ul>	<ul style="list-style-type: none"> <li>•No ability to generate revenue</li> <li>•Operational process could be cumbersome</li> </ul>
<b>Health Plan</b>	<ul style="list-style-type: none"> <li>•Better coordination of care</li> <li>•Better understanding of data</li> <li>•Potential for reduced costs</li> </ul>	<ul style="list-style-type: none"> <li>•Potential for provider disruption</li> <li>•Potential for member complaints</li> <li>•Shift services to more favorable reimbursement environment (e.g. hospital, home health, etc.)</li> </ul>
<b>Manufacturer</b>	<ul style="list-style-type: none"> <li>•Reduction in number of contracts / orders to manage</li> <li>•Potential for increasing product use (reimbursement support)</li> </ul>	<ul style="list-style-type: none"> <li>•Limitations on product use via managed care strategies</li> <li>•Potential for price erosion via price reductions demanded via contracting process</li> </ul>



# Strategic Issues In Specialty Pharmacy Management

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- What will the communication plan entail?
  - Provider panel
    - Program goals
    - Implementation timelines
    - Operational issues
    - Help line
  - Members
    - Program goals
    - Implementation timelines
    - Where benefits are impacted (change in copay / co-insurance)
    - Help line



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# Management Strategies / Outcomes



# Management Strategies / Outcomes

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## View from Tom Morrow, MD (Matria Healthcare)

“Health plans have used management techniques centered on limiting access to an entire category or increasing the cost sharing to the member. These techniques include:

- Requiring prior authorization;
- Requiring first use of nonbiologics;
- Blocking off-label use;
- Establishing a higher tier or a percentage copayment; and
- Using a specialty pharmacy company (SPC) as the supplier with payment going straight to the SPC from the MCO”.

Source: Managed Care, September 2003



# Management Strategies / Outcomes

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## Xolair®

Plan	Excluded / Postponed Coverage
HealthPartners	Non-formulary decision reached by P&T in September, 2003
Anthem	Excluded until 12/20/2003
Wellpoint	Decision postponed

### More common approach:

Prior authorization required

- Moderate to severe
- Failure on other therapies
- Many require positive allergy skin test

Source : Drug Cost Management Report, Oct 24, 2003



# Management Strategies / Outcomes

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- Fusing Competition Into the Market
  - Numerous therapeutic treatment groups now have multiple options
  - Some examples:
    - RA, Growth Hormone, MS, etc.
  - Important clinical distinctions:
    - Are the agents “therapeutically equivalent”
    - What about side effect profiles?
    - How will “non-preferred” agents be made available for medical necessity?



# Management Strategies / Outcomes

Example of a Specialty Preferred Drug List (AETNA)

Therapeutic Category	Preferred Products
Antineoplastics / Antivirals	Intron-A®, Peg-Intron®, Rebetrol® /Rebetron®
Growth Hormones	Humatrope®, Nutropin®, Nutropin AQ® Protropin®
Hematopoietic Agents	Aranesp®, Neulasta®, Procrit®
LHRH	Lupron®, Zolvadex®
Multiple Sclerosis	Avonex®, Betaseron®, Copaxone®
Osteoporosis	Forteo®
Rheumatoid Arthritis	Remicade®

Source: Specialty Pharmacy, Stakeholders Strategies and Markets, AIS Health, 2003



# Management Strategies / Outcomes

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- BCBS Florida
  - Mandatory state-wide program covering 100 drugs
  - Selected Option-Care as its specialty pharmacy vendor
  - BCBS FL claims their approach has saved 30-40%
  - Limited public data on:
    - Reductions in provider panel
    - Improvements in patient care
    - Impact on overall member satisfaction



# Management Strategies / Outcomes

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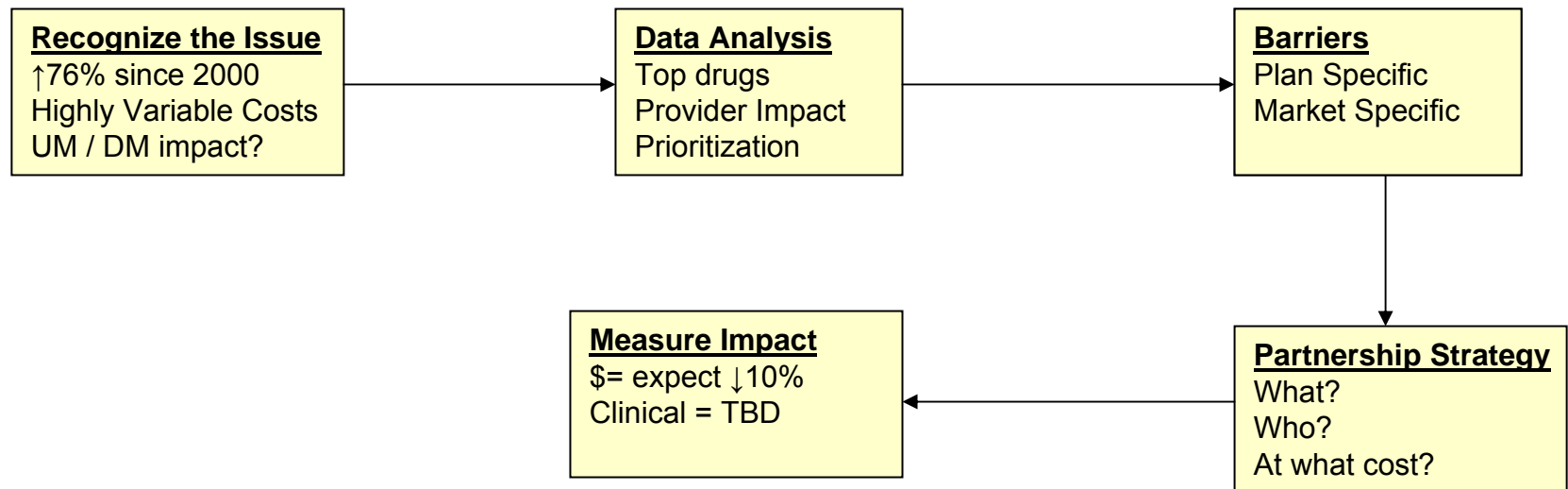
- Express-Scripts
  - Specialty program now includes 76 drugs (250 NDCs)
  - Estimate savings at:
    - 10-20% on medical side
    - 10% on pharmacy side
  - Savings achieved via:
    - Enhanced formulary management
    - Discounted ingredient costs
    - Reduced administrative costs (for claims payment)



# Management Strategies / Outcomes

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## BCBS TN Process



Source: BCBS TN presentation at the IIR Specialty Drug Conference, 2003



# Management Strategies / Outcomes

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## BCBS Tennessee: Keys to Successful Strategy Shift

- Assign a dedicated project manager
- Collect accurate data
- Convert data into information (Prioritization)
- Present options & gain mgt “buy-in”
- Conduct an impact analysis (internal & external)
- Select a specialty pharmacy partner
- Measure outcomes

Source: BCBS TN presentation at the IIR Specialty Drug Conference, 2003



# Management Strategies / Outcomes

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- Regence Blue Shield Specialty Pharmacy Goals
  - Move products from retail and mail order pharmacy to specialty channel
  - Increase utilization of specialty vendor as SOLE supplier of office injectables to Regence providers
  - Decrease provider reimbursement to specialty pharmacy pricing levels
  - Transition prior authorization processes to designated specialty vendor
  - Develop and implement a single reimbursement coverage strategy (Rx vs. Medical)
- Outcomes...TBD

Source: Regence Blue Shield presentation at the IIR Specialty Drug Conference, 2003



# Management Strategies / Outcomes

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## Key Issues to Address:

- Coverage decisions
- Reimbursement approach & levels
- Utilization management
- Financial & clinical outcomes modeling



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# A View Towards The Future



# A View Towards the Future

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- More competition
  - From specialty pharmacy providers
  - From biotech firms
- Better data analytics to support:
  - Outcomes research (clinical & economic)
  - Evidence based coverage criteria
- Customized care
  - Focused on individual patients



# A View Towards the Future

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- The actuarial challenge
  - Forecasting timing of new medication entrants
  - Forecasting importance of new medication on treatment patterns
  - Forecasting potential medical offset provided by new medications
  - Forecasting how introduction of new medications may increase demand for physician services



# A View Towards the Future

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- Financing the Specialty Pharmacy Benefit: The Patient Role
  - Copays are inadequate
  - Co-insurance without caps could be financially devastating
  - Issue will become even worse with migration to consumer directed care
  - Combination of tools:
    - Deductibles
    - Annual out of pocket max
    - Co-insurance
    - Lifetime max



# A View Towards the Future

## Last Hope for Lymphoma, \$28,000 a Dose

By LUCETTE LAGNADO

**'GOOD TO the last drop,'** says Marie, a patient with advanced lymphoma, as a Lucite-coated hypodermic syringe pumps a \$28,000 dose of Zevalin into her system.

Less than 10 minutes later, the 79-year-old Medicare beneficiary is done, the ninth patient at Massey Cancer Center in Richmond, Va., to get the drug, which is considered so safe she doesn't have to linger for observation.

Zevalin, made by Idec Pharmaceuticals Corp., is one of a new class of biotech cancer treatments that use monoclonal antibodies, armed with radioactive isotopes, to deliver potentially lethal doses of radiation to tumor cells. Generally taken after other treatments fail, it comes in a single dose, which is a great relief to patients who have already endured many months of chemotherapy. It significantly reduces some of the unpleasant side-effects associated with traditional chemotherapy, such as nausea and hair loss. And it also keeps patients out of the hospital, says Harold Chung, a Massey oncologist who also is Marie's doctor.

But despite its \$28,000 price tag, Zevalin doesn't necessarily work. And that is raising difficult questions about whether it and other very expensive therapies are worth the price. The costs are especially tough on cancer centers caring for the underinsured, where doctors worry about how to give top-of-the-line drugs to rich and poor patients alike without going bankrupt.

Thomas Scully, who presides over the nation's Medicare system, says he was as-



**Melvin Fratkin** of Virginia Commonwealth University holds a syringe that is used to deliver Zevalin.

high-priced cancer treatments but eventually gave the go-ahead.

Chief medical officer Sean Tunis says it's common practice for Medicare to offer reimbursement for most drugs approved by the Food and Drug Administration. But continuing that approach means Medicare costs could skyrocket in coming years. Dr. Tunis adds that the FDA is now approving some treatments, Zevalin included, under its "accelerated" approval process, which means more studies are needed to make sure the drugs are safe and effective. In short, prices are going up, even though it's not clear how much benefit the drugs provide.

"It's not that I'm a cheapskate, but what  
*Please Turn to Page B2, Column 6*

### Costly Care

Cancer treatments are creating burdens for patients and the healthcare system. A sampling:

DRUG	TREATMENT	COST
<b>Zevalin</b>	Lymphoma	<b>\$28,000 per injection</b>
<b>Fludara (Fludarabine)</b>	Leukemia	<b>\$400-\$750 per day per infusion</b>
<b>Rituxan</b>	Lymphoma	<b>Typical infusion costs \$3,530</b>
<b>Taxol</b>	Breast cancer	<b>\$1,757 per infusion</b>

Sources: Dalton Oncology Clinic Pharmacy; Massey Cancer Center, Richmond, Va.; IDEC Pharmaceuticals

WSJ June 18, 2003



# A View Towards The Future

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## *Steep Price of Roche AIDS Drug May Put It Out of Patients' Reach*

By VANESSA FUHRMANS

A new AIDS drug that promises to help patients who have failed to respond to other medications is likely to carry a price tag more than double the most expensive treatments on the market, setting the stage for a wrenching debate over who will get it and who will pay for it.

Roche Holding AG said it will price the drug, called Fuzeon, in Europe at €18,980 (\$20,424) for a year's supply. Though Fuzeon isn't expected to receive marketing approval in the U.S. and Europe for several weeks, the Swiss drug maker took the unusual step of disclosing the European price now to provide advance notice to health-care officials in Europe and AIDS-treatment programs

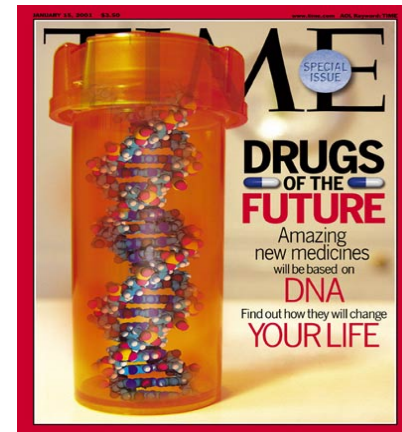
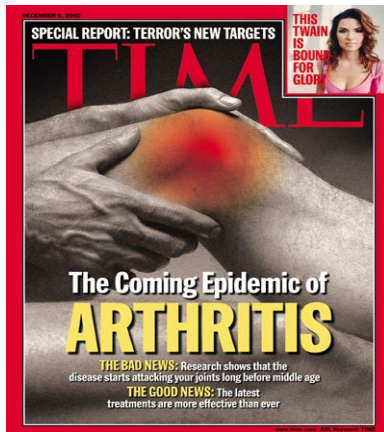
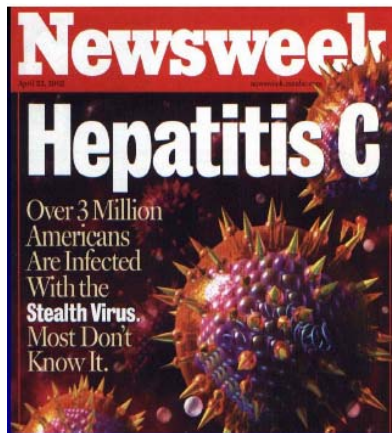
Montgomery, chief of the California Department of Health Services' Office of AIDS. He estimates some 30% of the program's 25,000 patients show signs of resistance to at least one or two existing AIDS drugs and might benefit from Fuzeon. "But we just don't know if we'll have the money to pay for it."

Doctors and patient groups consider Fuzeon the biggest advance in AIDS treatment since the advent of so-called protease inhibitors in the mid-1990s because of its ability to beat down the hardest forms of the virus. Unlike existing AIDS drugs, which block replication of the virus after it infects a cell, Fuzeon stops it from entering a cell in the first place.

In each of two large-scale clinical trials, results of which were published last year, one group of patients was given a



# A View Towards The Future



# Helpful Resources

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- Ernst & Young Global Biotechnology Report
- Specialty Pharmacy: Stakeholders, Strategies & Markets, AIS Health 2003
- How health plans should deliver high-cost, low-volume biotech drugs and injectables, AIS audio conference / Webcast May 21, 2003
- Other resources:
  - Investment banker / analyst reports (SG Cowan, Goldman Sachs, etc.)
  - SEC filings for publicly traded specialty pharmacy providers
  - Trade organization websites (Biotechnology Industry Assn, PhRMA)
- Selected Journal Articles:
  - Johnson N. Creating an outcomes focused formulary: resources to assist in determining a drug's value. *Formulary* 2001; 36: 807-810.
  - Sirois P (senior editor). HMOs should prepare now to get a handle on injectables. *Managed Care* April 2002: 42H-42N.
  - Morrow T. MC Strategy: Create competition in expanding biotech field. *Managed Care* September 2003.



# Pharmaceutical Strategies Group

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