

McKesson Specialty PHARMACY ONCOLOGY Distribution and Reimbursement Strategies for Today and Tomorrow

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May 23, 2007

Oncology Today and Tomorrow

- Oncology Therapy Growth
- Payor Oncology Perceptions
- The Oncology Challenge for Payors and Providers
- Current Payor Oncology Strategies
- Specialty Oncology Management Options
 - Oral Oncology
 - Office Administered Agents (Injectables, Infusables)
 - Hybrid
- Oncology Therapy Management of Tomorrow
- Discussion

Cancer is Complex

- Care and Therapy Vary by Drug, Diagnosis, Stage and Type
- It Does Not Fit Into One Model
 - 30 Day Supplies Can Be Wasteful Due to Therapy Tolerance Issues
- New Drugs and Expanded Indications Make Control Challenging
 - Medical Policy, Formulary and J-code Delays
 - Prior Authorization Challenges
 - Off-label Use Management vs. Appropriate utilization
 - Utilization Management
 - Waste Management
 - Prescribing Trends and Cost Visibility

Oncology Today and Tomorrow

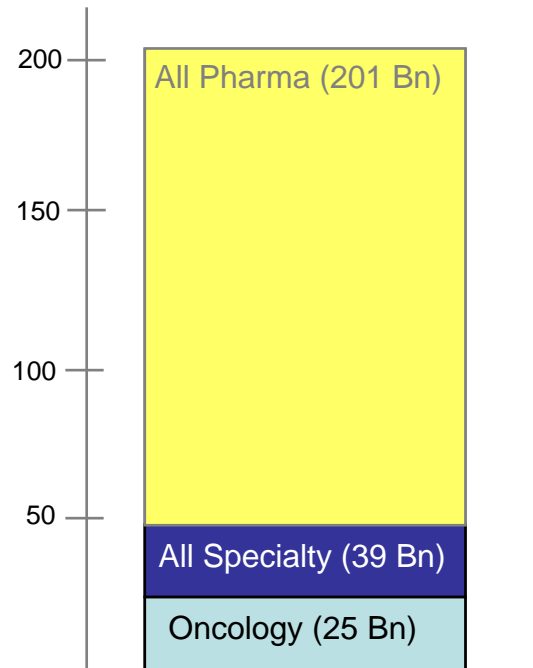
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Biotech Pipeline Evolution

- 80's
- Few Drugs, Indications (HIV, TX..), Members, Specialty Pharmacies
 - High Government Payer Offset
 - Oncology care being delivered in hospital setting
 - Primarily Pharmacy Benefit
 - High Cost / Low Volume = Minimal Plan Impact
- 90's
 - Orphan Drug Act Pipeline Growth + Biotech Investment
 - New Drugs With New Indications (HCV, MS, RA, Psoriasis, RSV, GHD..), More Members and Increased Specialty Players
 - Primarily Pharmacy Benefit - Some Medical Benefit Creep
 - Moderate Cost / Moderate Volume = Moderate Plan Impact

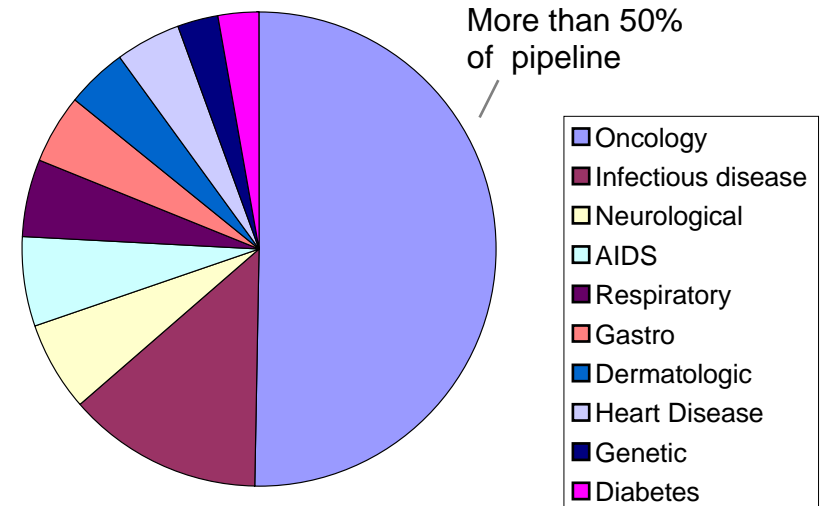
Today: Oncology Is a Large and Growing Piece of the Pharmaceutical Market That Represents More Than Half of Total Pharmaceutical Spend

Breakdown of Pharmaceutical Market



- Oncology and Adjunctive Oncology Products Represent More Than 10% of the Total Pharmaceutical Market and More Than Half of the Specialty Market

Pipeline Products By Therapeutic Category



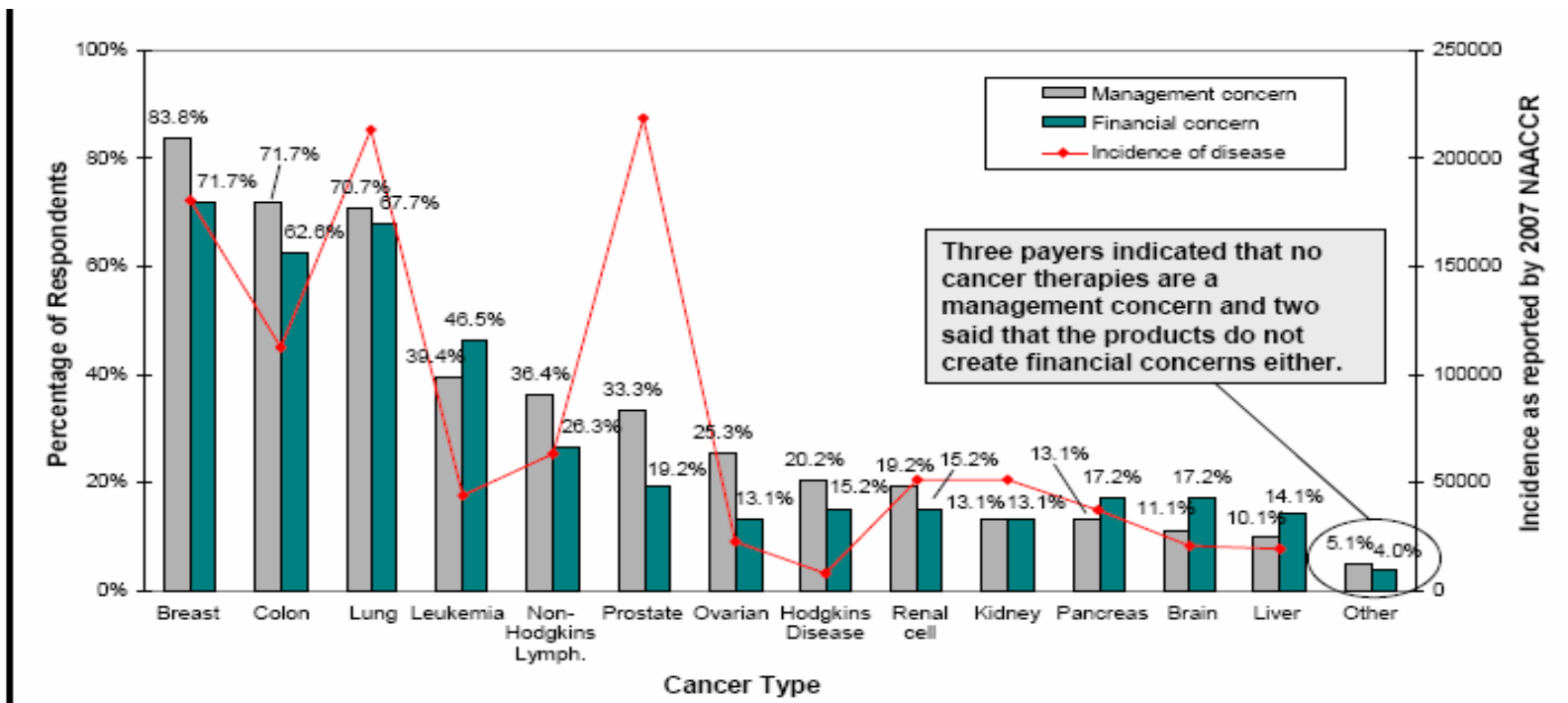
- 400+ Cancer Drugs Are in the Pipeline That Will Hit Medical and Pharmacy Benefit
- Expanded Indications, New Agents, New Forms, Combination Therapies, Vaccines
- Over 30% of Oncology Pipeline Products are Orals
- Significant Clinical and Financial Burden Concerns

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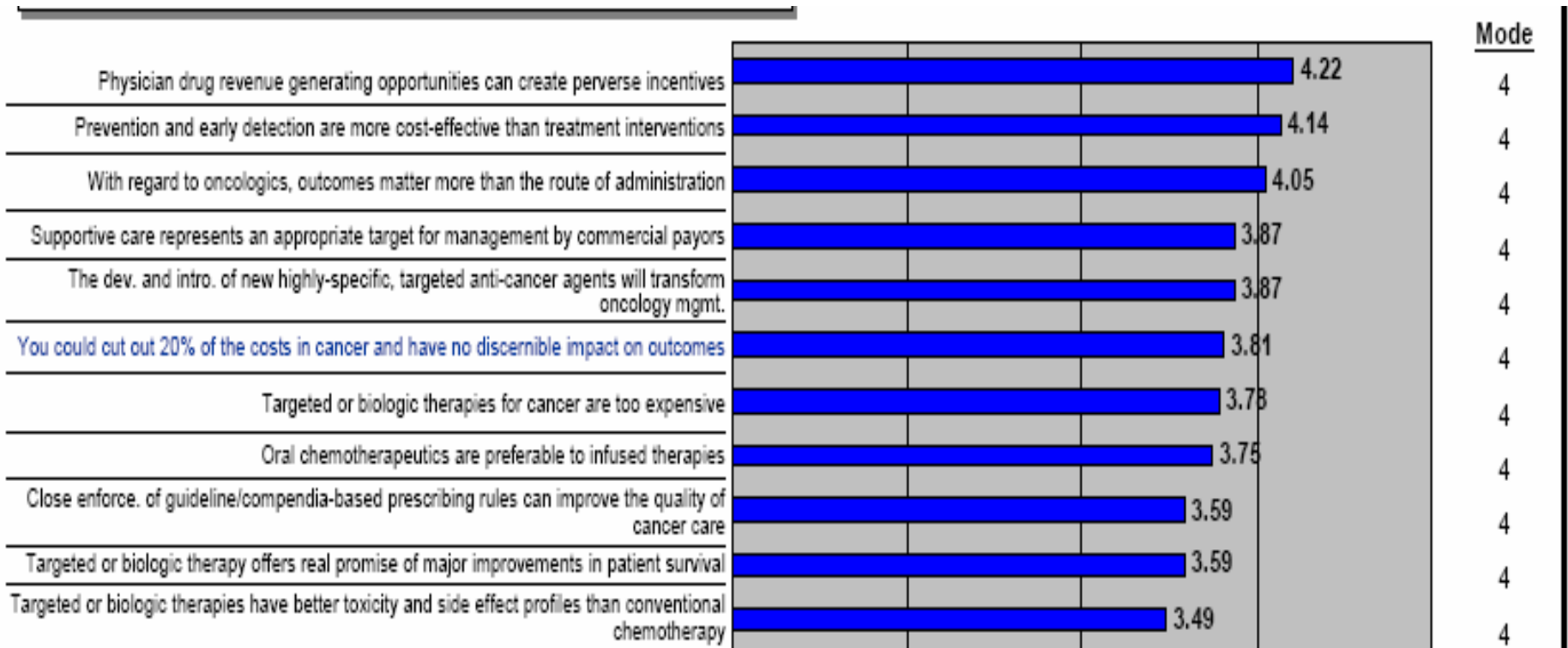
The Oncology Challenge - Financial & Management Concerns

- Top Concerns by Cancer Type do not Correlate to Incidence but Cost and Care (UM, PA, Tolerance)



Quantitative research conducted with payors and oncology providers -
 Winter 2007 Managed Care Oncology Index, Fall, 2006 Managed Care Injectables Index - Zitter Group

The Oncology Challenge - Key Issues Identified by Payors



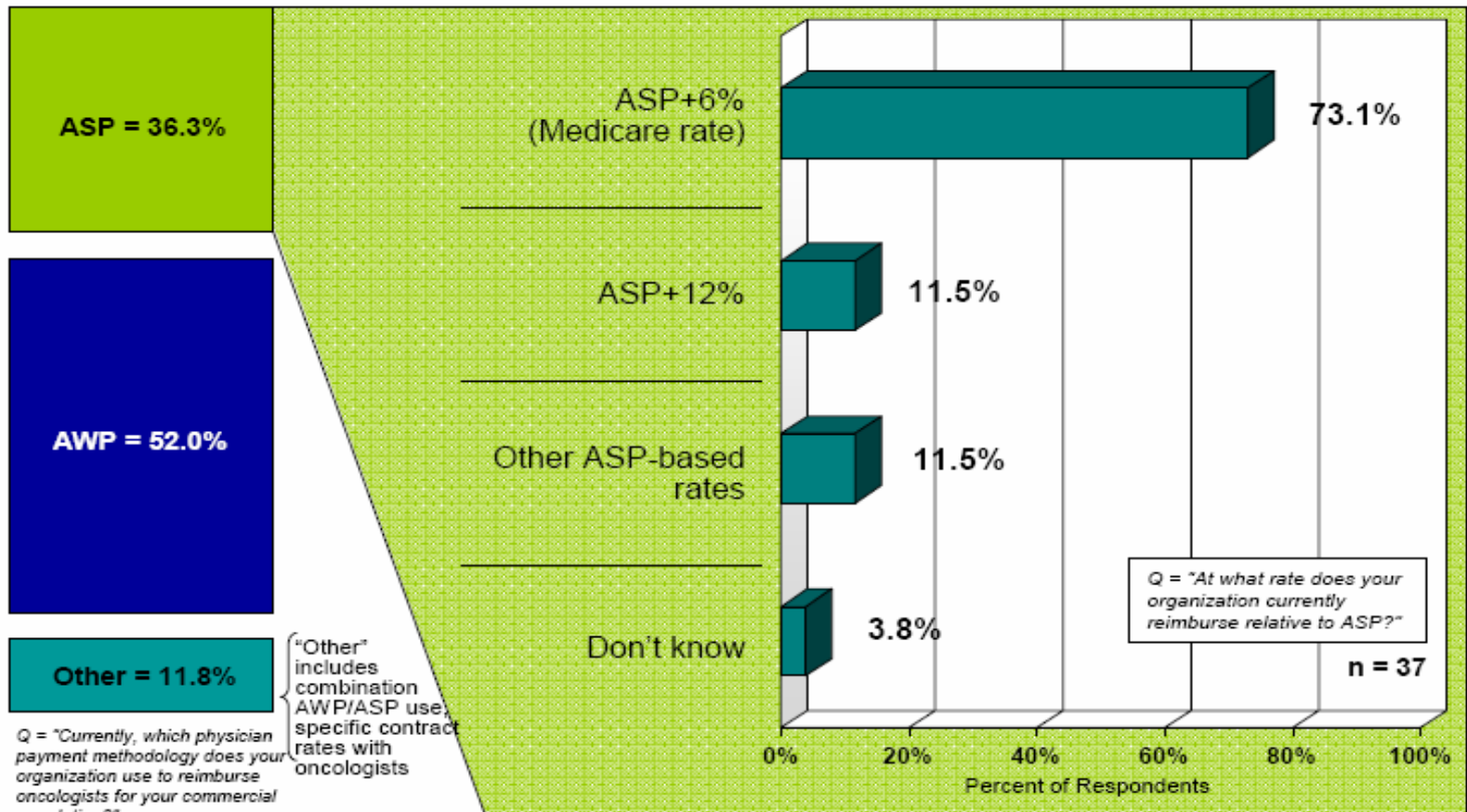
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The Oncology Challenge for Payors - MMA ASP

ASP Focused on Direct Cost Savings.

However, % Based Reimbursement Works Against Low Cost Therapy Preference

CURRENT ONCOLOGIST REIMBURSEMENT POLICY



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The Oncology Challenge - Reimbursement

Reimbursement

- J-codes Are Aggregated Across Multiple NDC's Blurring
 - Drug Cost Management
 - Physician Prescribing Trends
 - Utilization Management
- Miscellaneous J-codes Are Assigned to Newly FDA Approved Drugs
 - Impact Drug/condition Visibility and Management
- Drug Waste Due to Patient Tolerance and Therapy Changes
 - OOP Impact to Patients

Benefit Structure

- Orals Typically Under Retail Contracts Against Pharmacy Benefit
- Infusables and Injectables Are Office or Hospital-based Against Medical Benefit
- Difficult to Negotiate Volume Discounts
- Difficult to Develop and Manage Consistent UM Policies

The Oncology Challenge for Payors - Cost vs. Care

The Cost of New Therapies Are Significant and Long Term Survival Data is Limited. There are not Consistent Clinical Guidelines to help the payor.

Example: Metastatic Colorectal Cancer Therapies Can Range from \$65 to >\$30,000

Source: Zitter Group

Table. Estimated Drug Costs for Eight Weeks of Treatment for Metastatic Colorectal Cancer.

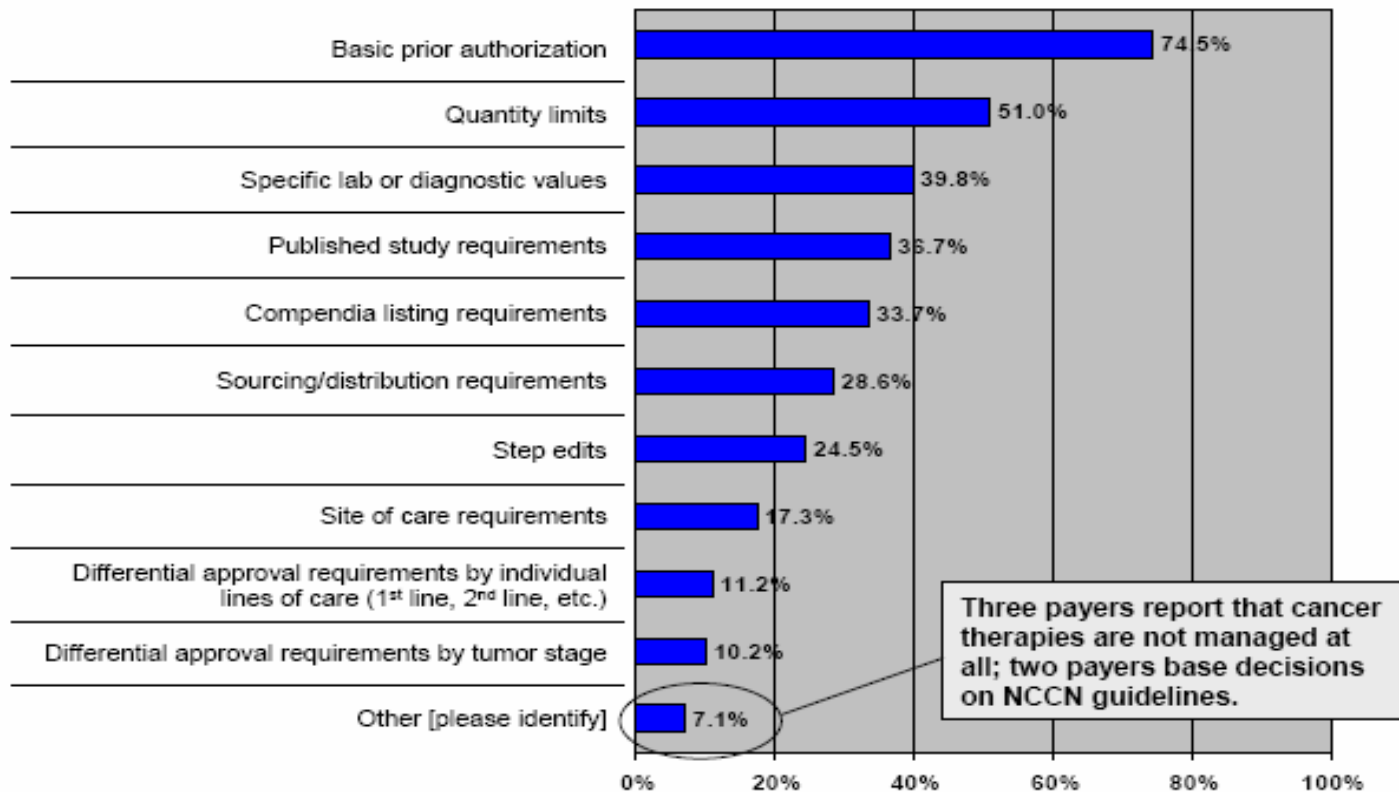
Regimen	Drugs and Schedule of Administration	Drug Costs* \$
Regimens containing fluorouracil		
Mayo Clinic	Monthly bolus of fluorouracil plus leucovorin	63
Roswell Park	Weekly bolus of fluorouracil plus leucovorin	304
LV5FU2	Biweekly fluorouracil plus leucovorin in a 48-hr infusion	263
Regimens containing irinotecan or oxaliplatin		
Irinotecan alone	Weekly bolus	9,497
IFL	Weekly bolus of fluorouracil plus irinotecan	9,539
FOLFIRI	LV5FU2 with biweekly irinotecan	9,381
FOLFOX	LV5FU2 with biweekly oxaliplatin	11,889
Regimens containing bevacizumab or cetuximab		
FOLFIRI with bevacizumab	FOLFIRI with fortnightly bevacizumab	21,399
FOLFOX with bevacizumab	FOLFOX with biweekly bevacizumab	21,033
Irinotecan with cetuximab	Weekly irinotecan plus cetuximab	30,790
FOLFIRI with cetuximab	FOLFIRI and weekly cetuximab	30,675

* Costs represent 95 percent of the average wholesale price in May 2004.

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The Oncology Challenge - Payor Financial and Management Strategies



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The development of any solution in oncology must take into account the unique characteristics of the disease state

Key considerations in oncology management

- Oncologists must hold inventory in-office
 - 80%+ of patients experience a change in regimen at some point in cancer therapy; change usually occurs day of administration
 - Reliance on traditional specialty pharmacy (30 day + refill call) may result in drug waste based on cancer types and therapy protocol

- Unpredictability in use of treatment regimens
 - Treatment is often not clear-cut and depends on physician preference
 - Collaboration with physicians on optimal protocols likely to result in best patient outcomes

- High-profile disease state
 - Very sensitive and powerful patient / provider population

Payor Oncology Distribution Strategies

Orals - Pharmacy Benefit - SP
Price discount/UM

Office Administered Products - Medical Benefit
Control costs in the buy and bill model

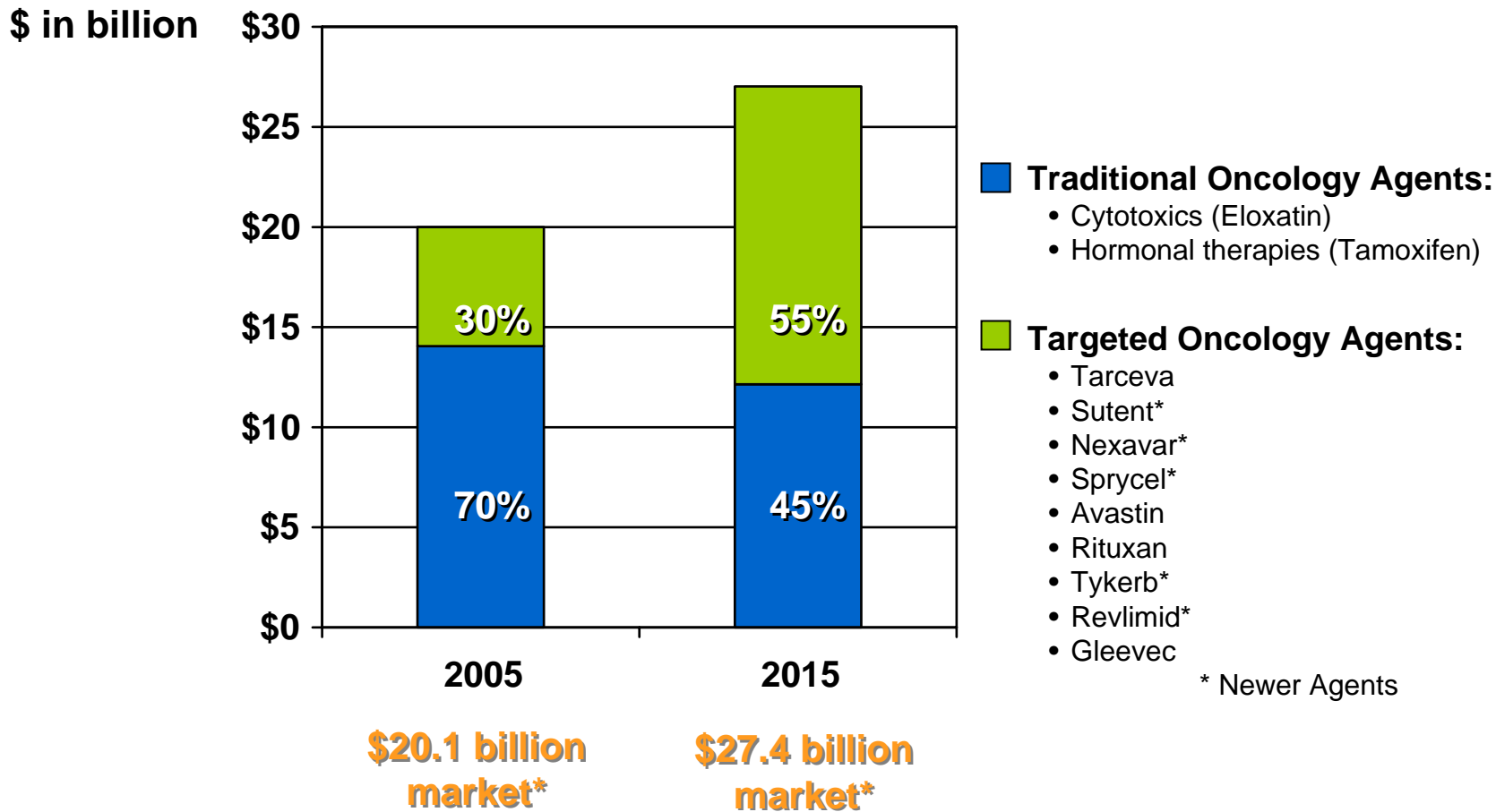
**Office Administered Products - Medical Benefit
Hybrid - Choice Model**
Reduce Rx reimbursement
MD buy and bill, SP distribution or consignment
Alternate infusion site network
Increase administration reimbursement

Oral Oncology Market Trends

- **Oral cancer drugs are becoming significant spend drivers**
 - Four new products approved in the last year, more than 100 are in the pipeline
 - Expanded indications for current products are likely.
 - Off-label usage is prevalent (even considering compendial approval)
 - Newer regimens can cost \$5,000 to \$10,000 for a month of treatment.
 - Many products are incremental to current regimens and will generate new utilization.
- **Treatment cycles are longer**
 - Many of the newer, more targeted products are better tolerated and can therefore be used as maintenance treatment.
 - Products such as REVLIMID® and SPRYCEL® are often administered for years until there is disease progression.
 - Treatment costs will continue to expand as these drugs are used on a longer-term basis, and in combination with other products.
- **Careful monitoring and management of the oral oncolytic category is critical:**
 - *....to limit off-label use vs appropriate utilization*
 - *....to monitor patient compliance*
 - *....to drive cost containment and consistent discounts*

Oncology Market: Oral Oncology Management

Targeted vs. Traditional agents growth



Source: Datamonitor Report: Top 20 Cancer Therapeutics – New Treatment Paradigms Transforming Market Outlook. July 2006

* Sales generated across seven markets: US, UK, France, Germany, Italy, Spain and Japan

Targets for Oral Oncology Management

NEWLY APPROVED PRODUCTS	RECOMMENDED DOSE	PACKAGING	AWP
NEXAVAR® (sorafenib)	400mg twice daily	200 mg, 120 tabs/bottle	\$5,416.25
SUTENT® (sunitinib)	50mg orally once daily	12.5mg, 30 caps/bottle	\$2,003.94
		25mg, 30 caps/bottle	\$4,007.81
		50mg, 30 caps/bottle	\$8,015.63
REVLIMID® (lenalidomide)	5mg orally once daily	5 mg, 30 caps/bottle	\$7,740.00
	10mg orally once daily	10 mg, 30 caps/bottle	\$8,100.00
	15mg orally once daily	15 mg, 21 caps/bottle	\$7,350.00
	25mg orally once daily	25 mg, 25 caps/bottle	\$9,218.75
SPRYCEL® (dasatinib)	20mg	60 tabs/bottle	\$2,208.75
	50mg	60 tabs/bottle	\$4,417.50
	70mg	60 tabs/bottle	\$4,871.25
OTHER ORAL ONCOLOGY PRODUCTS	RECOMMENDED DOSE	PACKAGING	AWP
TARGRETIN® (bexarotene)	300 mg/m ² /day	75mg	\$2,714.00
XELODA® (capecitabine)	1,250 mg/m ² twice daily	150mg / 500mg	\$286.19 / \$1,907.71
IRESSA® (gefitinib)	250 mg daily	250mg	\$2,127.35
GLEEVEC® (imatinib mesylate)	40 mg daily	100mg / 400mg	\$2,751.98 / \$3,302.38
THALOMID® (thalidomide)	100 to 300 mg daily	50mg, 28 / 100mg, 28 / 200mg, 28	\$2,132.58 / \$3,750.30 / \$4,269.84
TEMODAR® (temozolomide)	75 mg/m ² daily	20mg, 20 / 100mg 20 / 250mg, 20	\$725.20 / \$3,626.10 / \$9,065.25
TARCEVA® (erlotinib)	NSCLC 150 mg daily Pancreatic 100 mg daily	25mg / 100mg / 150mg	\$1,078.13 / \$2,961.25 / \$3,349.38

Benefits of a Managed Oral Oncology Program

Cost



- Cost Containment**
- Competitive Pricing
 - Growing Category With Very High Cost
 - Leverages Better Pricing Than Retail
 - Minimizes Waste
 - Controls Off-label Use

Clinical



- Clinical Support**
- PA/UM Support
 - Comprehensive Patient Assessment Prior to Dispensing
 - Side Effects Management and Counseling
 - Accurate Management of Weight-based Dosing
 - Compliance Monitoring
 - Pipeline and Payor Updates
 - Rx and Disease Specific Care and Distribution

Convenience



- Member Convenience**
- All Drugs
 - Speeds Access
 - High Patient Care
 - Frequent Calls
 - Compliance Monitoring
 - Educational and QOL Materials Delivered to Door
 - Anywhere/overnight Delivery
 - Psychosocial Support

Data



- Data and Analytics**
- In-depth Analysis of Category Spending
 - Tracking of Utilization Trends
 - Support for Cost vs. Care Decisions
 - Pipeline Monitoring and Individual Plan Impact Analysis

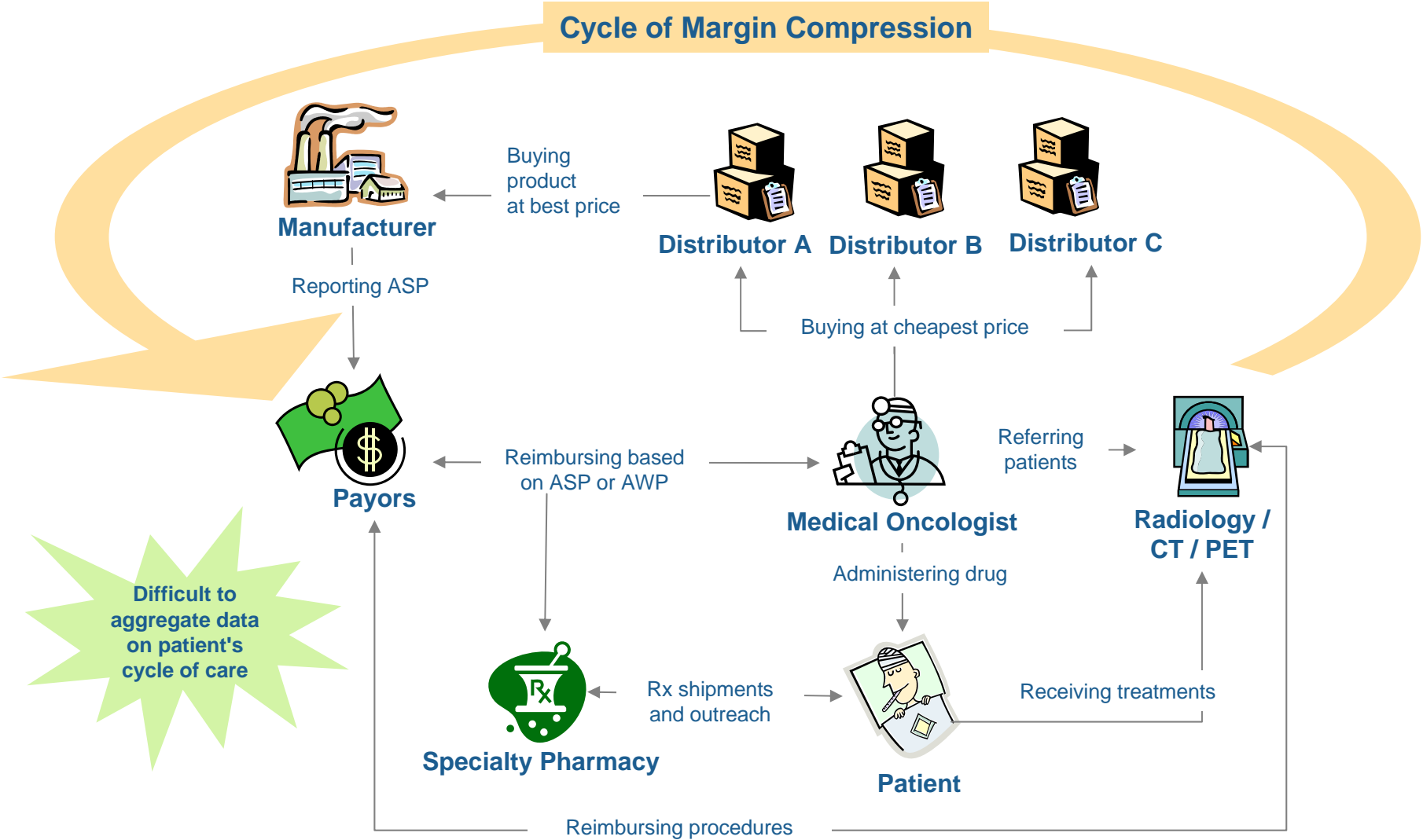
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The Current Model for Distribution of Oncology Pharmaceuticals Is Unsustainable for All Players



Dilemma – Office administered products

Payors

- High cost and reimbursement
- Difficult utilization management
- Approved/Appropriate clinical utilization

Physician Practices

- Inventory carrying cost
- Billing and reimbursement processing
- Account receivables management
- Specialized staff resource costs

Current Options

- Buy and Bill
- Consignment Inventory at Offices
- Product Replacement Options
 - None Get to True Utilization Data and Drug-specific NDC Level for Formulary and Cost-management Opportunities for the Payer.
 - Limited Cost Savings Without Reimbursement Strategy AND Utilization Management

This model creates gaps in oncology management that translate into opportunities to improve the disease state's management

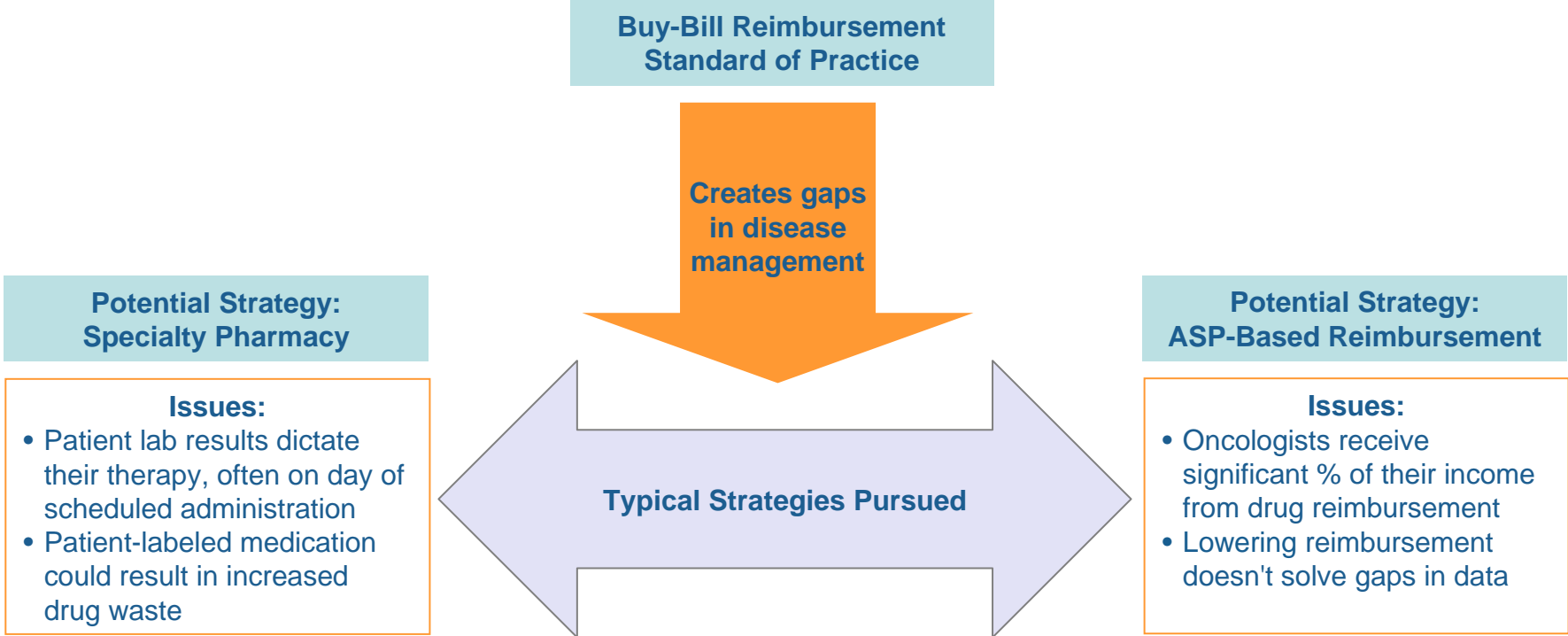
Gaps in oncology management

- Lack of NDC-level Claims Data
- Inconsistent Billing Procedures Across Providers
- Post-administration Billing
- Pharmacy Benefit Data Separate From Medical Benefit Data
- Strained Relationships With Physicians Due to Their Reliance on Drug Economics
- Patient Support Confined to Physician Office

Opportunities for improvement

- Proactive Management of Appropriate Utilization, Optimal Dosing, and Pre-authorizations
- Visibility to Drug Cost on Medical Benefit
- Comprehensive Data on Patient Cycle of Care, Including Pharmacy and Services Claims
- Patient Support Beyond the Physician Office

Due to the unique nature of oncology, the typical strategies employed for management of specialty pharmaceuticals are only marginally effective



Alternative, oncology-specific solutions required

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Building a Spectrum of Oncology Management by Leveraging the Assets of All Models - Hybrid Option

- Minimal Workflow Change for MD and Payor

- Maximum Workflow Change for MD and Payor



Do Nothing

Oral Oncology Program - SP

- Pharmacy Benefit
- Specialty Network or Exclusive
- Cost, Performance and Utilization Metrics

Office Administered Products - Managed Buy & Bill @ Wholesaler/GPO

- Medical Benefit
- Reduced drug reimbursement
- Increased administration fee.
- Payor requires prior auth
- Payor reimburses at set drug and administration rate
- Cost, Performance and Utilization Metrics

Specialty Oncology Program

- Pharmacy and Medical Benefit
- Payor, MD, Pharmacy
- Set drug reimbursement increase MD admin fee
- MD buy & bill of infusables
- MD order thru SP for injectables and orals
- SP contracted as medical provider or migrate new products to pharmacy benefit

Building a Spectrum of Oncology Management by Leveraging the Assets of All Models - Hybrid Option

Billing and reimbursement

- Full billing information to be provided AFTER procedure / drug administration; window of time post-administration must be established
- Claims processor can bill for both product and services / admin fees if desired
- Claims processor can bill for secondary insurance if desired
- Co-pay collection to be facilitated by either up-front credit card information or post-procedural billing via mail (up to certain co-payment threshold)
- Billing information may be provided by phone, fax, web / email form, or print-out / transmission from practice management system (but must contain NDC)

Inventory management

- Distributor maintains inventory records based on product shipped vs.. product used

This model holds benefits for both the oncologist and the payor

Physician Benefits	Payor Benefits
<ul style="list-style-type: none">▪ Optimizes Profitability through outsourcing of back-office functions and lowering financial risks associated with drugs▪ Enables Focus on patient care rather than drug economics▪ Maintains Processes by keeping inventory on-hand in physician office.▪ Provides Visibility into reimbursement up-front to insure proper payments▪ Cooperates With Payors in a way that maintains operational independence	<ul style="list-style-type: none">▪ Provides Greater Insight into oncology spend through aggregated, NDC-level data on drug usage and patient-specific cycle of care▪ Increases Billing Efficiency through the aggregation of claims submittal through a single entity▪ Reduces Provider Costs associated with buying-and-billing that are ultimately passed on to the payor▪ Aligns Interests of payor and physician related to minimizing waste, optimizing patient regimens, and maximizing operational efficiency in the physician office

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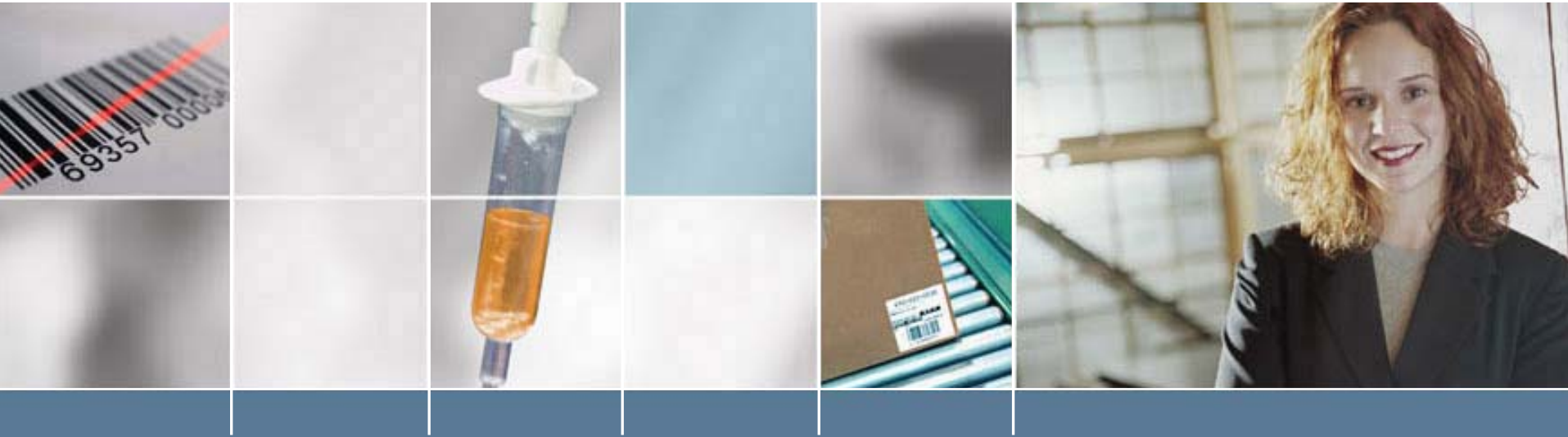
Oncology Therapy Management of Tomorrow

Oncology market will continue to grow as the population ages, therapies comes to market and cancer survivor population increases

- Cancer Prevention Initiatives
 - Genetic Tests and Screens
 - Chemoprevention
 - Vaccines
- Improved Cancer Screenings and Genomic Testing
 - Early Diagnosis
 - Response to Therapy Predictors
 - Targeted Cancer Treatments
- Biotech and Genetic Therapies
 - Stem Cell Treatments
 - Biomarkers
 - Improved Therapy Delivery Applications
- Oncology Clinical Pathways and Better Defined Efficacy Initiatives
 - Pay for Performance
 - Outcomes and Cost Savings by Cancer Type Vs. Benefit Model

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