Novel Partnership Strategies for Using Outcomes Data to Develop Clinical Utility Evidence

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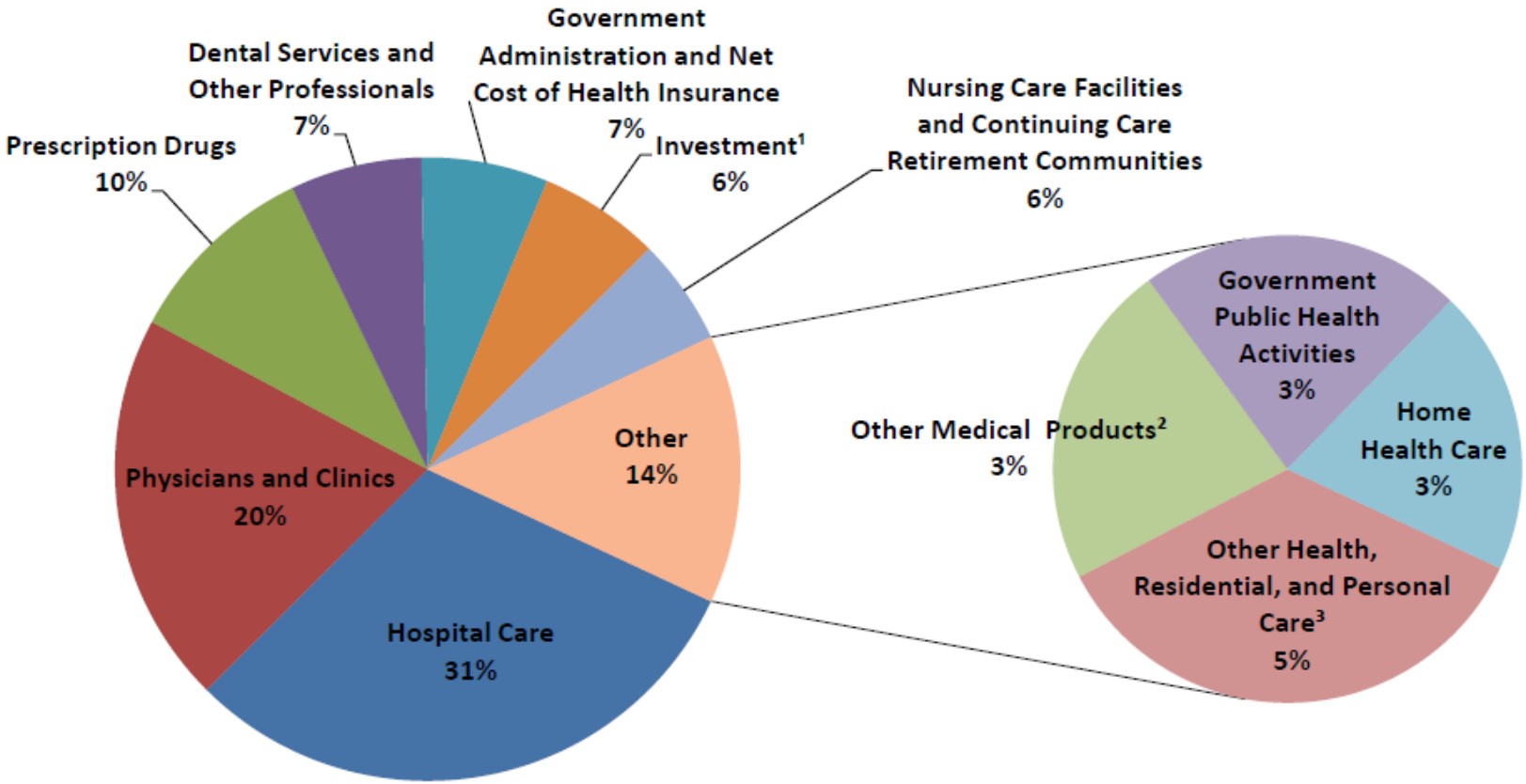
May 24, 2012

Medco Research Institute - Mission

Advance smarter medicine through R&D that illustrates how the integration of new science and technology into advanced pharmacy improves patients' outcomes and reduces health care cost

"What will we do differently because of the result of this research?"

The Nation's Health Dollar ($2.5 Trillion), Calendar Year 2009: Where It Went



[1] Includes Research (2%) and Structures and Equipment (4%).

[2] Includes Durable (1%) and Non-durable (2%) goods.

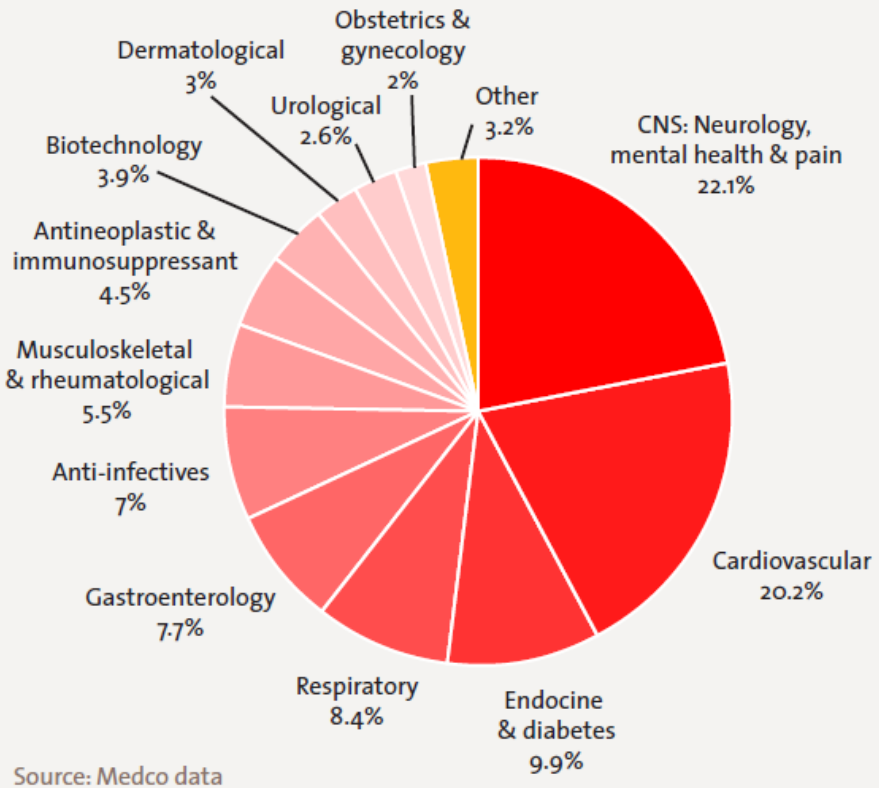
[3] Includes expenditures for residential care facilities, ambulance providers, medical care delivered in non-traditional settings (such as community centers, senior citizens centers, schools, and military field stations), and expenditures for Home and Community Waiver programs under Medicaid.

Note: Sum of pieces may not equal 100% due to rounding.

SOURCE: Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group.

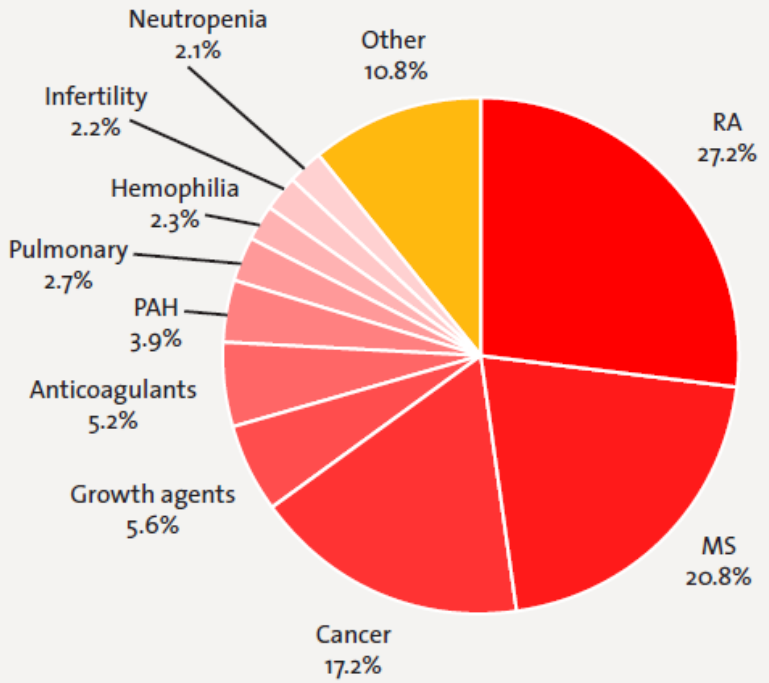
2010 PBM Client Drug Spend

THERAPEUTIC CHAPTERS BY PERCENT CONTRIBUTION TO NET PLAN COSTS



Source: Medco data

SPECIALTY CATEGORIES BY PERCENT CONTRIBUTION TO NET SPECIALTY COSTS



Source: Medco data

FACT

More than 77% of cancer spend occurs in the medical benefit

YEAR IN REVIEW

- Trend growth for cancer medications slowed to 15.7% compared to 23.7% growth in 2010. The 12.7% increase in PMPY cost was the major trend component.
- Revlimid® (lenalidomide) gained first-line use for patients with multiple myeloma.
- In 2011, nine new cancer medications were approved, including three – Yervoy™ (ipilimumab), Sylatron™ (peginterferon alfa-2b) and Zelboraf® (vemurafenib) – to treat melanoma, a rare, but deadly, skin cancer.
- Zelboraf and another new drug, Xalkori® (crizotinib), which treats non-small-cell lung cancer, have corresponding pharmacogenetic tests that identify appropriate patients.
- Jakafi™ (ruxolitinib) is the first medication approved to treat myelofibrosis, a rare form of blood cancer. An oral medication, it is the first in a new class, Janus-Associated kinase inhibitors.
- Two oral cancer drugs, Afinitor® (everolimus) and Sutent® (sunitinib), received additional indications to treat pancreatic cancer.
- Although the Food and Drug Administration (FDA) revoked approval of Avastin® (bevacizumab) for breast cancer, it remains on the market for certain colon, lung, kidney and brain cancers.

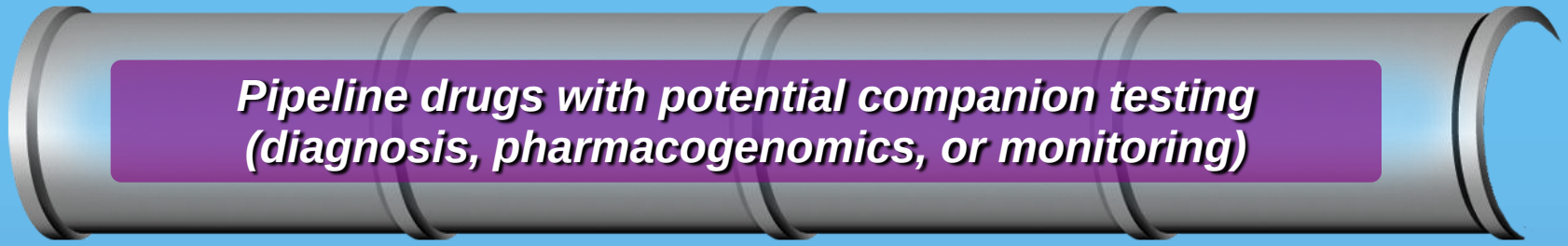
A CLOSER LOOK

- In late 1992, the FDA began an accelerated process for certain drugs to treat serious conditions. By mid-2010, 35 new cancer drugs had received accelerated approvals; 26 of them were converted to regular approvals after their clinical benefits were proven.[24]
- Inasmuch as more than half of the cancer drugs approved in 2011 are administered orally, the pharmacy benefit, which covers most oral drugs, will be most directly affected by their use.
- As drugs that target very specific cancer types are approved, pharmacogenomics is assuming a greater role in cancer treatment. Express Scripts offers solutions that help plan sponsors incorporate evidence-based pharmacogenomic testing to identify patients most appropriate for targeted treatments.
- Utilization programs for cancer patients also must consider pain medications, drugs to treat blood cell deficiencies and other supportive therapies that many cancer patients need.

WHAT'S AHEAD

- Inlyta® (axitinib), an oral, targeted therapy, was approved in January 2012 for advanced kidney cancer. Also in January, Erivedge™ (vismodegib) was approved to treat certain patients with basal cell carcinoma.
- Tivozanib, another oral, targeted therapy, may be approved in 2012 for advanced kidney cancer.
- Additional oral cancer drugs that may be approved within the next 12 months are cabozantinib (for thyroid cancer), regorafenib (for colorectal cancer) and ridaforolimus (for bone and soft-tissue sarcomas).

Pipeline drugs with potential companion testing (diagnosis, pharmacogenomics, or monitoring)



2012

Ivacaftor (Kalydeco)
CFTR G551D
Ridaforolimus
HER2 / EGFR **Pertuzumab**
HER2
Tafamidis
V30M TTR mutation
Bosutinib
BCR-ABL **Mipomersen**
APO B-100
Omacetaxine
BCR-ABL

2013

Trastuzumab-emtansine
HER2
Afatinib*
EGFR mutations
Ponatinib*
BCR-ABL T315I

2014

Iniparib
BRCA
Dacomitinib*
KRAS
CO-101
hENT1
Elacytarabine*
hENT1
Darapladib
Lp-PLA2
Midostaurin*
FLT3 receptor
Dalcetrapib
CETP mutations
Migalastat
Alpha-Gal A mutations

2015 & beyond

Bapineuzumab
ApoE4
Pacritinib
JAK2 V617F
AEZS-108*
LHRH receptor+
Solanezumab
Amyloid beta variations
Neratinib
HER2
Rindopepimut
EGFRvIII

Updated 02.27.12

Sources: FDC Reports. NDA Pipeline. www.ndapipeline.com; FDC Reports. "The Pink Sheet." www.thepinksheet.com; R&D Insight. http://bi.adisinsight.com. DataMonitor. Pipeline Insight. www.datamonitor.com. Pharmacogenomics Reporter www.genomeweb.com

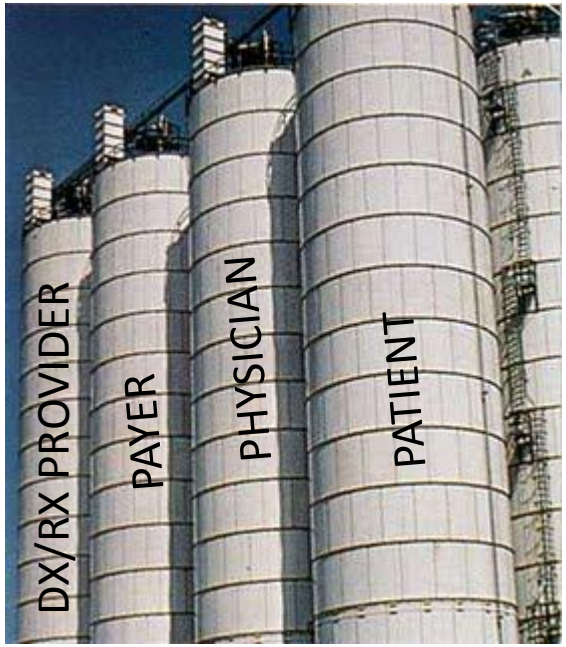
The stars are not aligned....

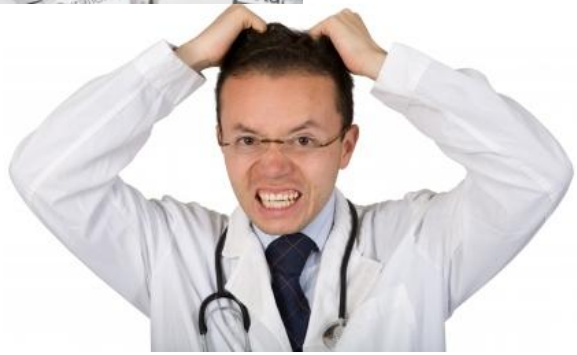
Client[1,2]	Patient[1,2]	Provider
• Lower cost • Safer, more effective treatment • Consistent management across benefits	• Improved health outcomes • Fewer health and safety issues • Lower cost	• Allows buy and bill to remain • Up-front PA reduces administrative burden • Improved clinical information

Lack of compliance with protocols, overutilization, utilization outside formulary guidelines, and other manageable nonconformities related to medical-billed specialty spend cost clients **~$8 billion** per year.[1]

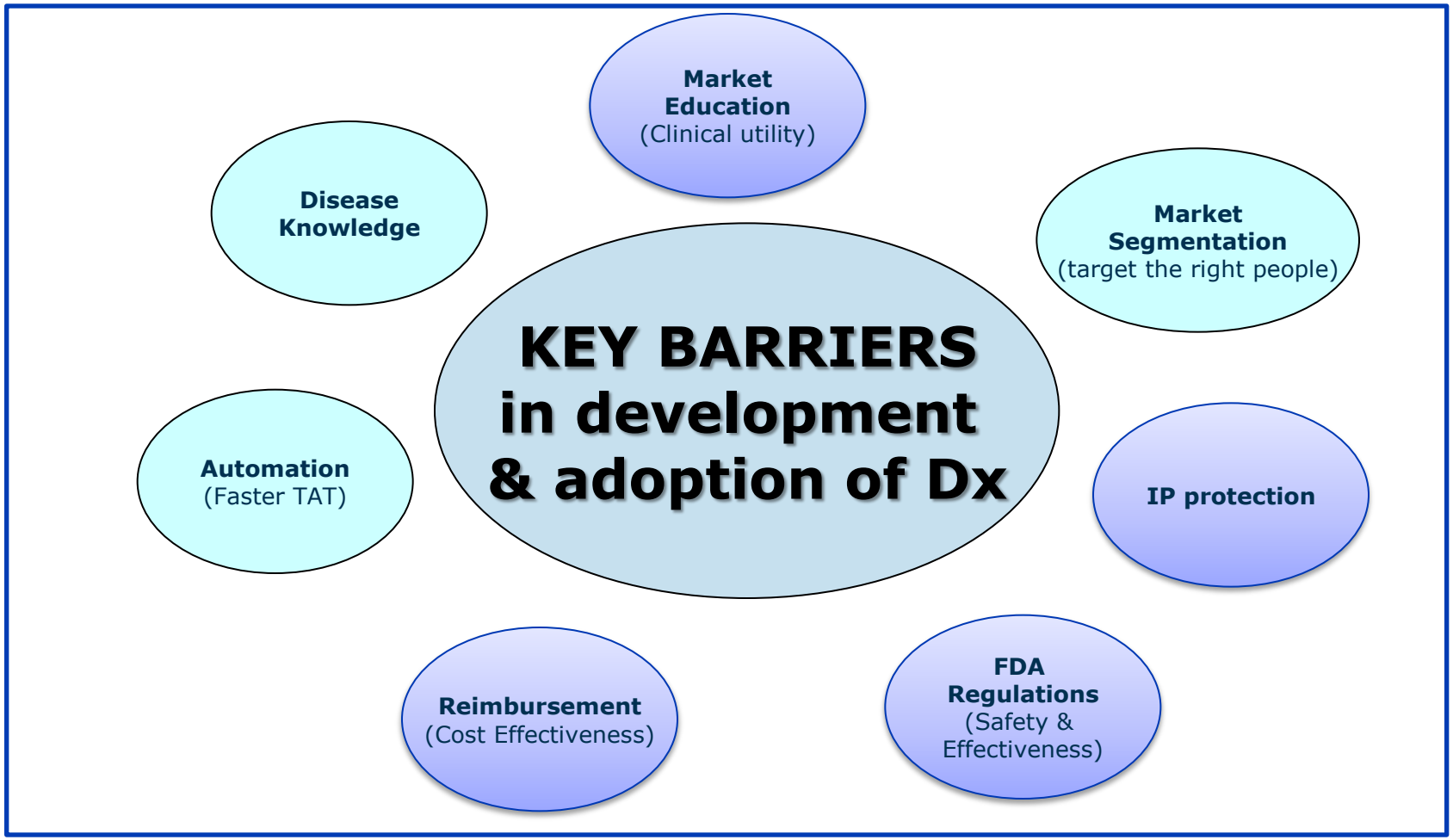
1 Estimated 13% coverage management, claims management and site of care savings across estimated $60B medical-billed specialty market. Medco 2011 data and IMS 2011 data on market size.
2 Potential value based on use of Drug Utilization Reviews for medical side Prior Authorizations.

Working in silos does not work





Sustaining Dx growth requires overcoming key barriers



Personalized Medicine- The role of Diagnostic

- Personalized medicine is typically considered to be the application of genomic and molecular data to better target healthcare delivery[1].

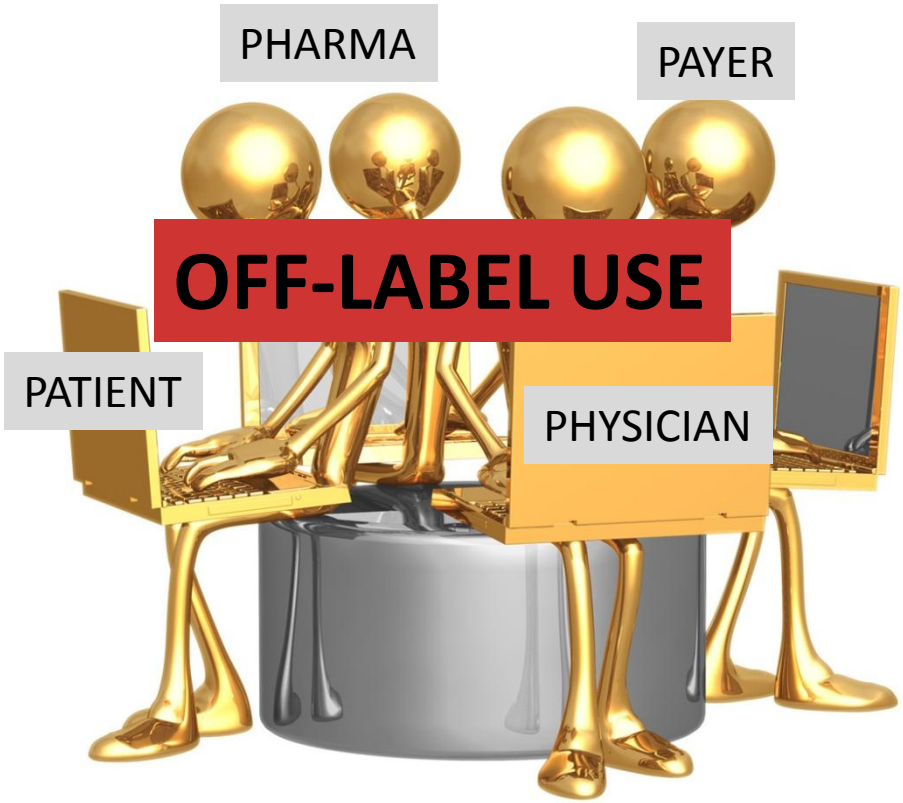
- Diagnostic companies struggle every day with payers' question to determine whether a diagnostic test is clinically and cost-effective[1]:
  - How well does the test perform?
  - Do the test results change subsequent care?
  - Does the change in care lead to better health outcomes?
  - What is the impact on overall cost?

The Medco Research Institute has been working with Dx companies to generate real-world evidence for product market success.

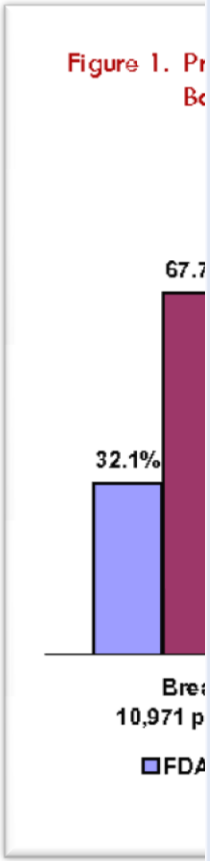
[1] Express Scripts 2012 Drug Trend Report

Integrated Offerings: pre, peri and post-launch

TODAY



Off-label use of oncology drugs in a community oncology EMR databa



How do the compendia compare?

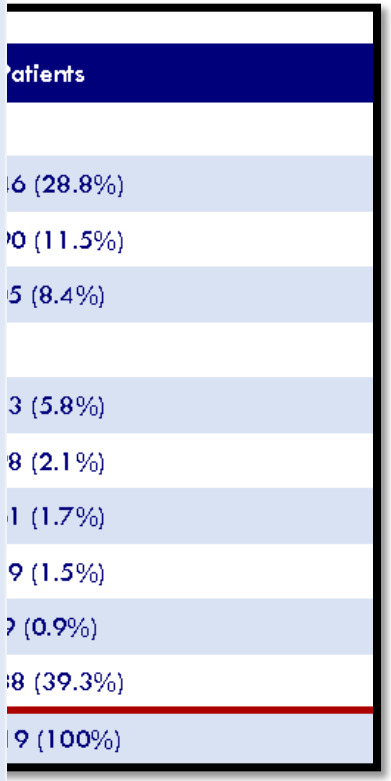
Researchers found little consistency in listings of agent-cancer combinations in the various compendia

● = Yes ● = No

Agent and cancer combination	American Hospital Formulary Service Drug Information	Clinical Pharmacology	Drugdex	National Comprehensive Cancer Network Drugs and Biologics Compendium
Bevacizumab for breast cancer	●	● / ●*	●	●
Bevacizumab for lung cancer	●	●	●	●
Oxaliplatin for breast cancer	●	●	●	●
Oxaliplatin for lung cancer	●	●	●	●
Irinotecan for breast cancer	●	●	●	●
Docetaxel for esophageal cancer	●	●	●	●
Docetaxel for gastric cancer	●	●	●	●
Docetaxel for ovarian cancer	●	●	●	●
Gemcitabine for biliary tract cancer	●	●	●	●
Gemcitabine for bladder cancer	●	●	●	●
Gemcitabine for ovary cancer	●	●	●	●
Rituximab for chronic lymphocytic leukemia	●	●	●	●
Erlotinib for head and neck cancer	●	●	●	●
Erlotinib for pancreatic cancer	●	●	●	●**
Of these, number of indications discussed in each compendia	2	9 (10)*	14	9

* Indicates a change between the 2006 and 2008 reviews.
**A trial is under way.
Source: *Annals of Internal Medicine*, 2009; 150:340

When Should Insurers Cover Off-Label Drug Usage? Managed Care, 2009



* Stephen R, et all: UBC poster at ISPOR 2009

TOMORROW

Thank You