Lahey Health

Presentation II:

Specialty Medications – *A Changing Game*

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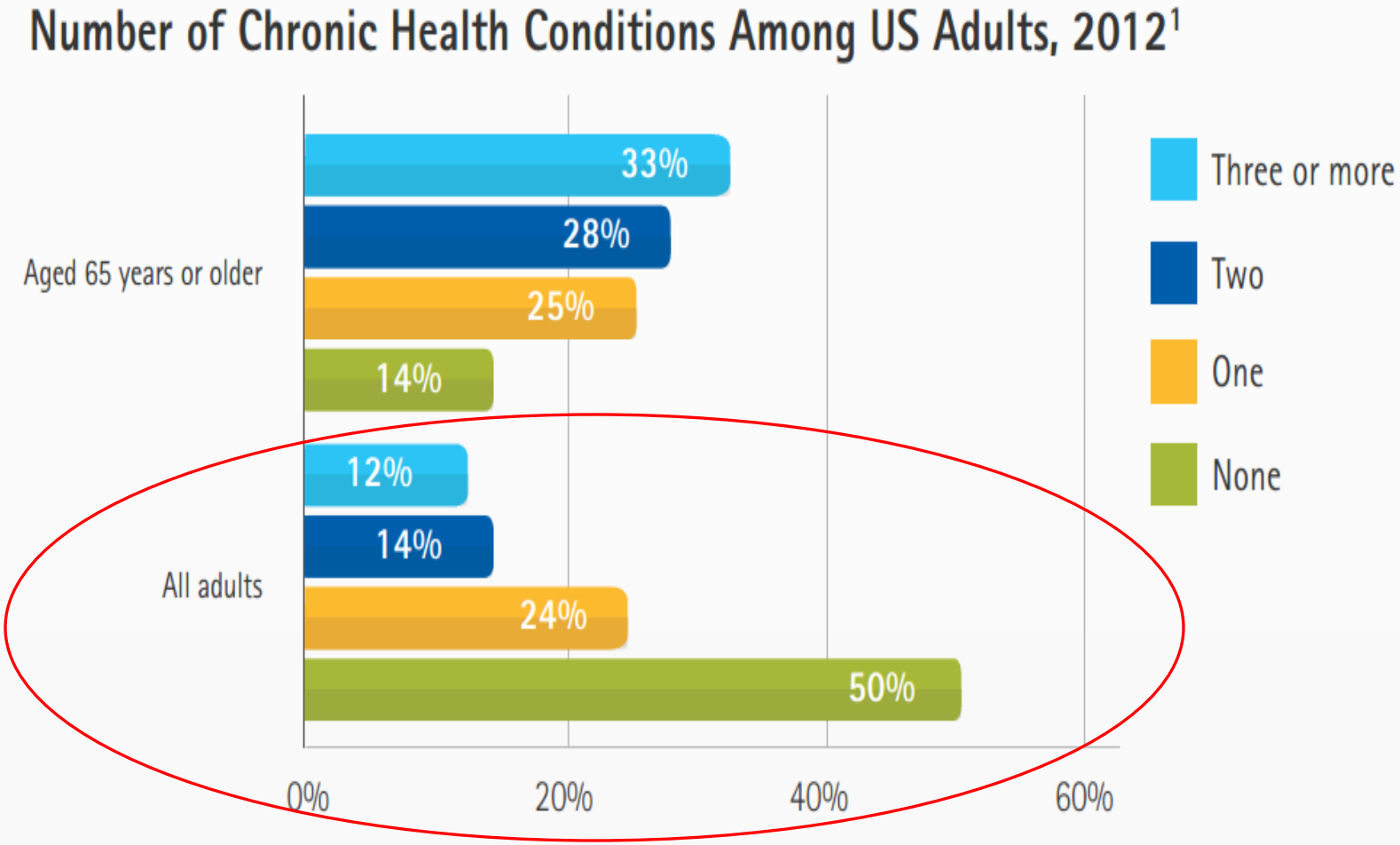
October 1, 2015 12:30pm
October 14, 2015 7:00am
October 27, 2015 5:30pm

Key Points:

1. Discuss Specialty Medications
    - Biologics / Biopharmaceuticals
    - New Biosimilar Market

2. Current State of Pharmacy
    - LCPN / NEPHO Costs

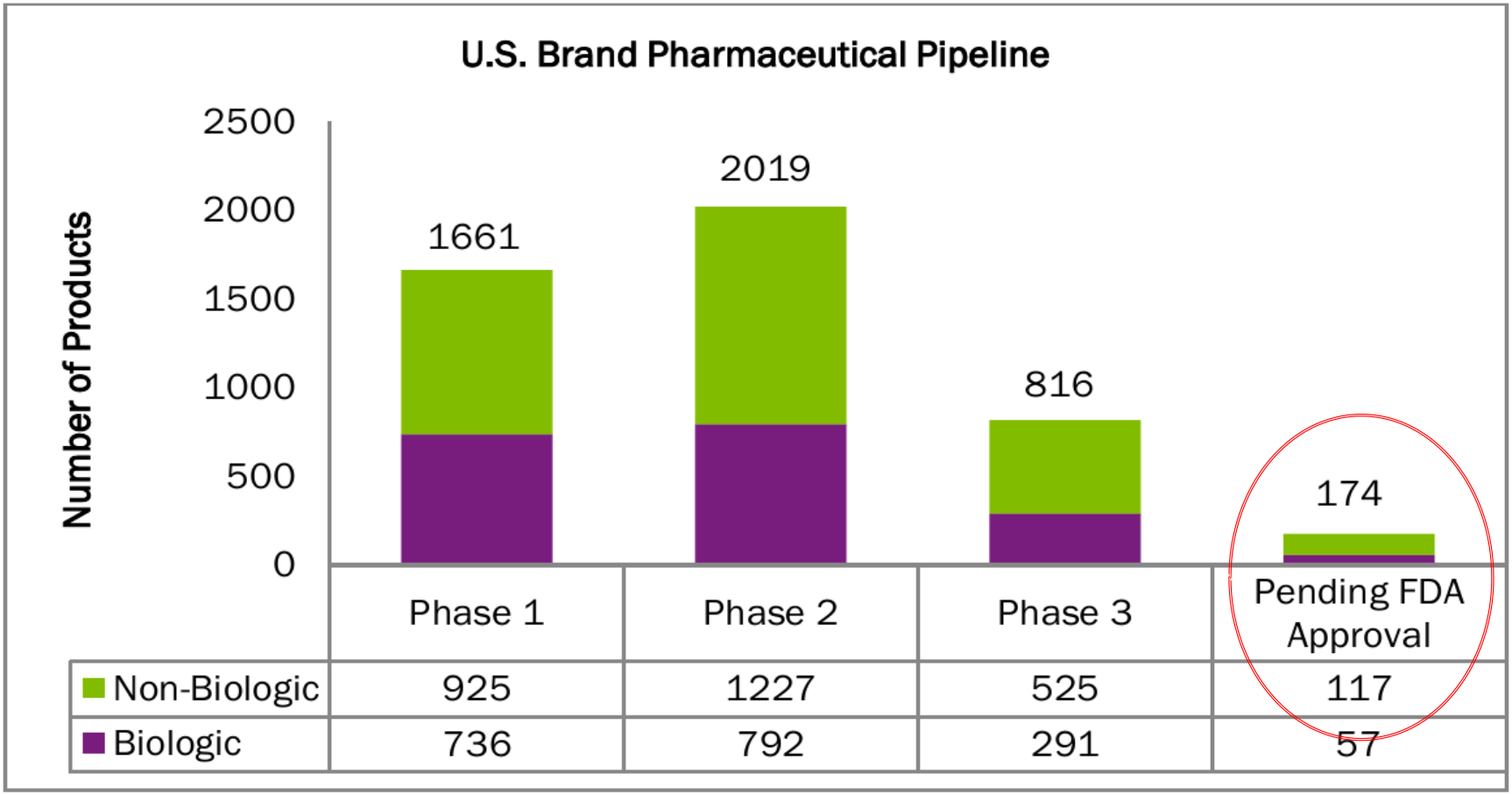
3. Strategies for Cost Control
    - Health Plan / Patient / Provider perspectives
    - LCPN / NEPHO perspective



Source: US Centers for Disease Control and Prevention.[1]

Healthy Drug Pipeline

- As of August 31, 2015, there are approximately 4,670 products either pending FDA approval or in phase 1, 2, or 3 of clinical development within the United States.



Biologic = blood products, allergenics, recombinant peptides or proteins, monoclonal antibodies, vaccines, and cell or gene therapies (includes both specialty and non-specialty potentially designated products)

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Traditional vs. Specialty Medications

Traditional Medications

brand /generic

- Treatment acute/ chronic conditions
  - Hyperlipidemia
  - Hypertension
  - Diabetes, etc.
- Cost usually < $600 per month (per CMS)
- Retail pharmacy network

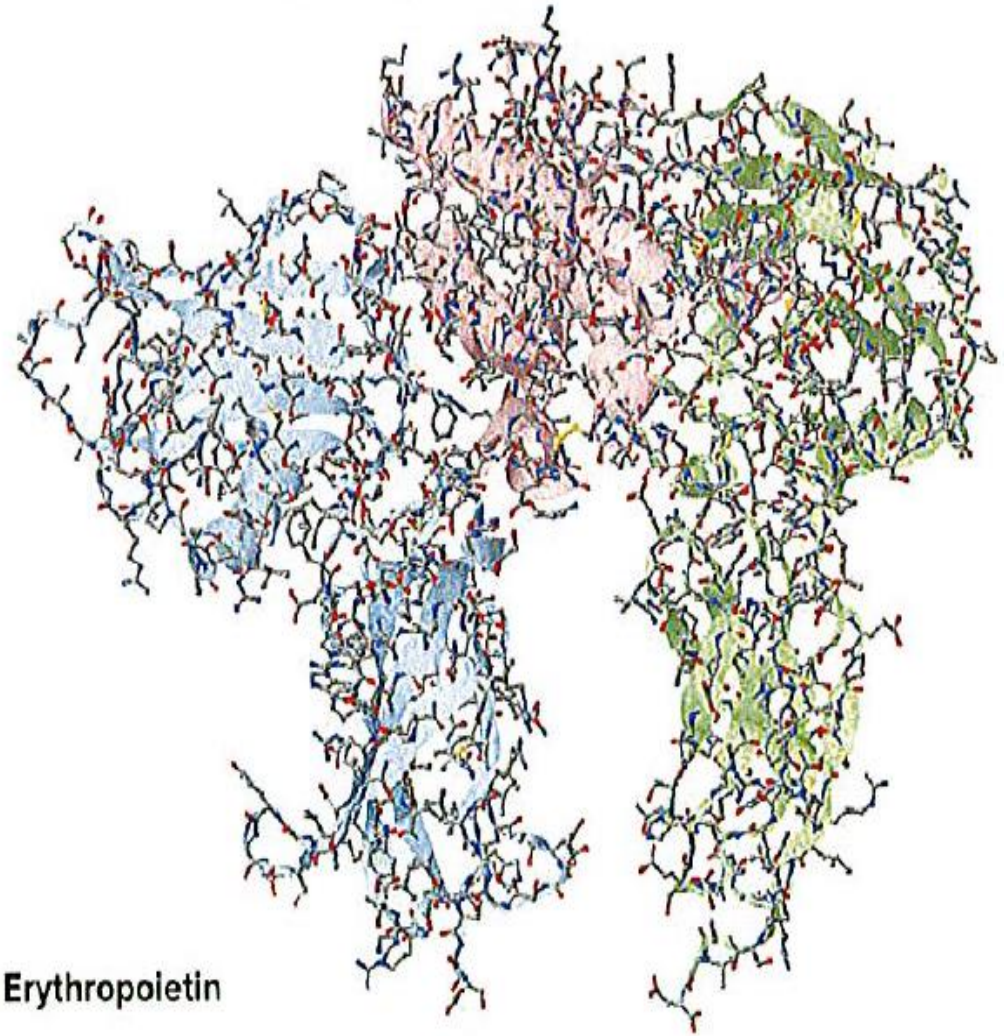
Specialty Medications

known as biologics or biopharmacueticals

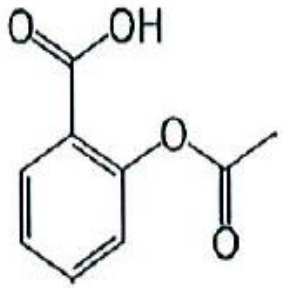
- Treat rare, complex and/or life-threatening conditions
- High annual cost >$600 per month
- Special requirements - storage, handling, dispensing and/or administration
- Require:
  - Patient education
  - Ongoing monitoring
  - Clinical management
- Restricted or limited distribution

The average specialty drug costs $1,776 compared to $54 for a traditional drug

Figure 1 The Differing Complexity of Biologics and Chemical Drugs[29]



Erythropoietin

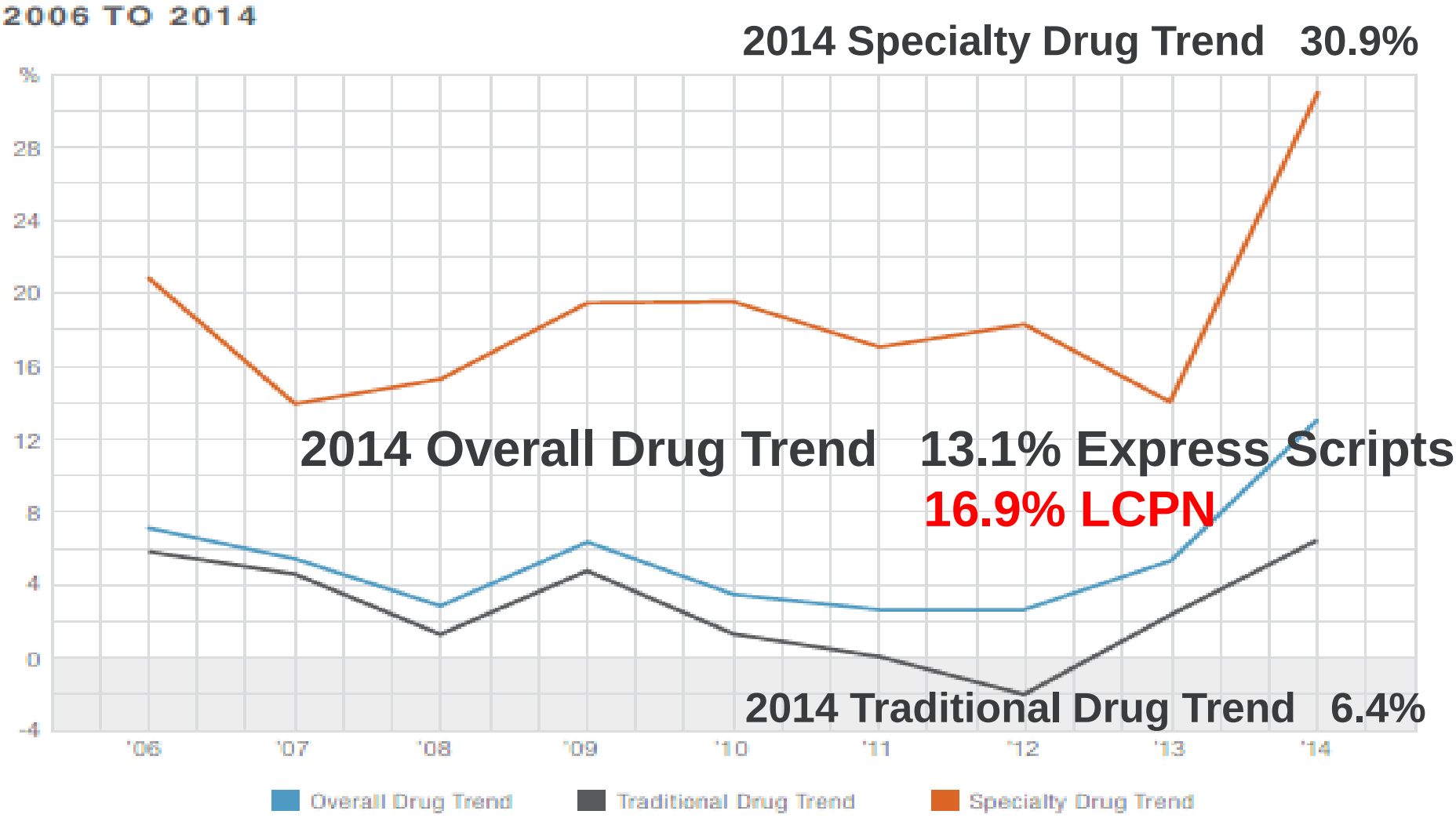


Aspirin

This illustration depicts the markedly greater structural complexity of the biologic agent, erythropoietin, compared with aspirin, a conventional, small-molecule chemical drug.

TRADITIONAL, SPECIALTY AND OVERALL TREND

2006 TO 2014



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Traditional Medication Cost Increases

- Unprecedented brand / generic cost increases since 2012
- Manufacturer consolidation, drug shortages, profit-taking
- Insulin manufacturers have taken quarterly increases in 2014

Colchicine (Colcrys)

Digoxin is now ~ >$1 per tablet

Doxycycline ~ $3 - $4 per tablet

Pyrimethamine (Daraprim) ~ $750 / tablet (Turing Pharma)

Quinine (Qualaquin)

Cycloserine (Seromycin) $17/capsule to $360 then back to $35 / capsule

Other Drug Increases – Valeant Pharmaceuticals

Drug	2013	2015	Treatment	Trend
Glumetza 1000 mg tablets (#90)	$896	$10,000	Diabetes	**1016%**
Sypine 250 mg capsules (#100)	$1,385	$21,267	Wilson Disease	**1436%**
Cuprimine 250 mg capsules (#100)	$888	$26,189	Wilson Disease	**2849%**
Isuprel 0.2ml ampules (#25)	$4,489	$36,811	Slow or irregular heart rate	**720%**

Note: The rights to Syprine, Cuprimine and Demser were acquired by Valeant in 2010. Source: AB Bernstein OCT. 4, 2015 By The New York Times

COMPONENTS OF TREND FOR THE TOP 10 TRADITIONAL THERAPY CLASSES

RANKED BY 2014 PMPY SPEND

			TREND		
RANK	THERAPY CLASS	PMPY SPEND	UTILIZATION	UNIT COST	TOTAL
1	Diabetes	$97.68	1.7%	16.3%	18.0%
2	High Blood Cholesterol	$48.73	-2.9%	-3.9%	-6.8%
3	Compounded Drugs	$46.04	0.2%	128.2%	128.4%
4	Pain/Inflammation	$45.98	0.3%	15.7%	16.0%
5	High Blood Pressure/Heart Disease	$36.06	-0.4%	-12.2%	-12.6%
6	Heartburn/Ulcer Disease	$33.40	-1.4%	-9.2%	-10.6%
7	Asthma	$29.59	-3.2%	-11.6%	-14.9%
8	Attention Disorders	$27.97	3.4%	2.9%	6.3%
9	Depression	$25.98	2.1%	-20.5%	-18.4%
10	Mental/Neurological Disorders	$24.85	-0.5%	9.6%	9.1%
	TOTAL TRADITIONAL	$668.75	-0.1%	6.5%	6.4%

2014 Trend would have been 2.3% if Compounded Drugs were excluded

EMD Serono Specialty Digest, 11th Edition Managed Care Strategies for Specialty Pharmaceuticals

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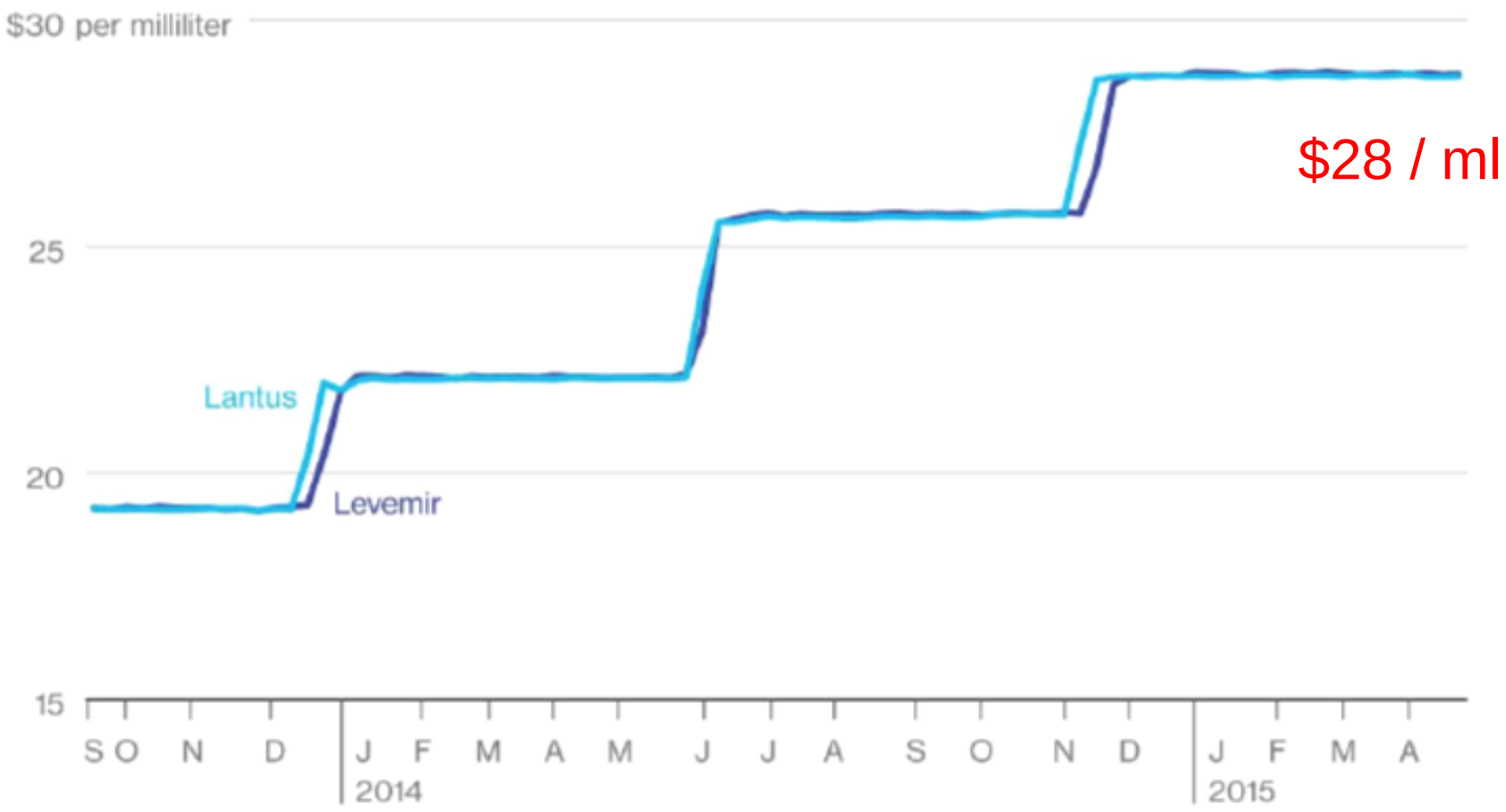
Shadow Pricing

Prices for some competing drugs go up in lockstep, rising the same amount at about the same time.



Source: Bloomberg Intelligence analysis of Symphony Health Solutions data

Hot Drugs, Big One-Year Price Jumps

Prices for many brand-name pharmaceuticals are soaring. Of 15 that saw 20%-plus price increases since last year, three are for diabetes.

Drug Dosage | Quantity	Drugmaker	Condition	Quarterly Price	Price growth Q1 2014–Q1 2015
Welchol 625MG | 1 pill or capsule	Daiichi Sankyo	High cholesterol		40.3%
EpiPen 0.3MG injection | 1 EpiPen	Mylan	Allergic reactions		32.0%
Lantus Vial injection | 1 milliliter	Sanofi	Diabetes		29.9%
Levemir Vial injection | 1 milliliter	Novo Nordisk	Diabetes		29.9%
Aggrenox 25-200MG | 1 pill or capsule	Boehringer Ingelheim	Stroke prevention		26.4%
Strattera 25MG | 1 pill or capsule	Eli Lilly	ADHD		25.4%
Lovaza 1GM | 1 pill or capsule	GlaxoSmithKline	High triglycerides		25.1%
Lamictal 100MG | 1 pill or capsule	GlaxoSmithKline	Epilepsy		24.2%
Nasonex 500MCG/AC | 1 gram	Merck & Co.	Allergies		24.1%
Forteo SOL 600/2.4ML | 1 milliliter	Eli Lilly	Osteoporosis		24.0%
Benicar 40MG | 1 pill or capsule	Daiichi Sankyo	High blood pressure		23.8%
Celebrex 200MG | 1 pill or capsule	Pfizer	Arthritis pain		22.5%
Viagra 25MG | 1 pill or capsule	Pfizer	Erectile dysfunction		21.9%
Renvela PAK 0.8GM | 1 package	Sanofi	Kidney disease		20.9%
Novolog Vial injection | 1 milliliter	Novo Nordisk	Diabetes		20.9%

Source: Analysis by DRX based on average wholesale prices
Note: See bottom of story for company comments

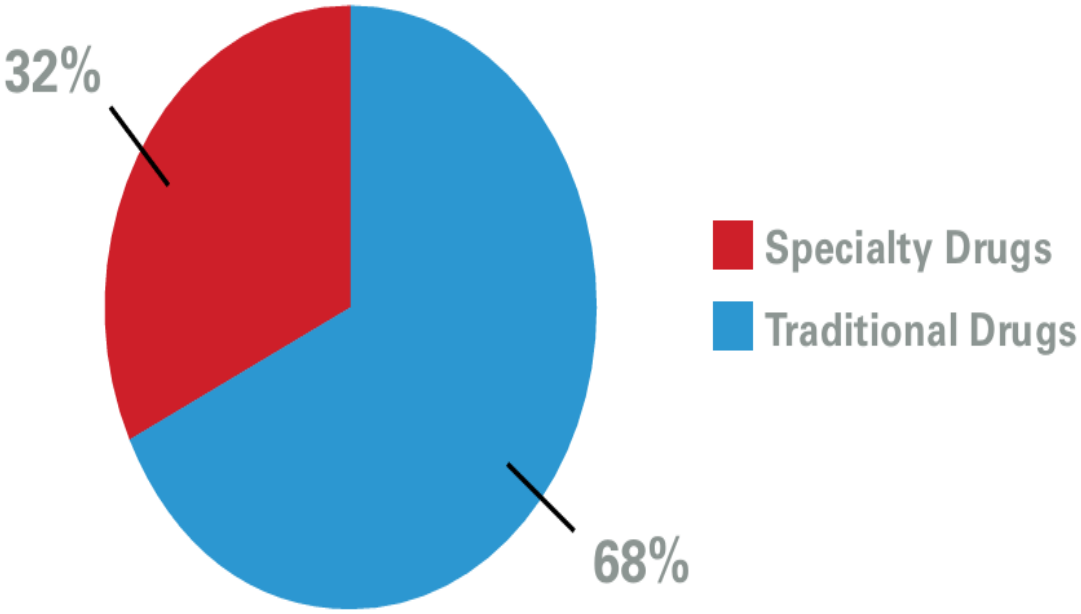
Specialty Medications

Common Specialty Therapeutic Areas

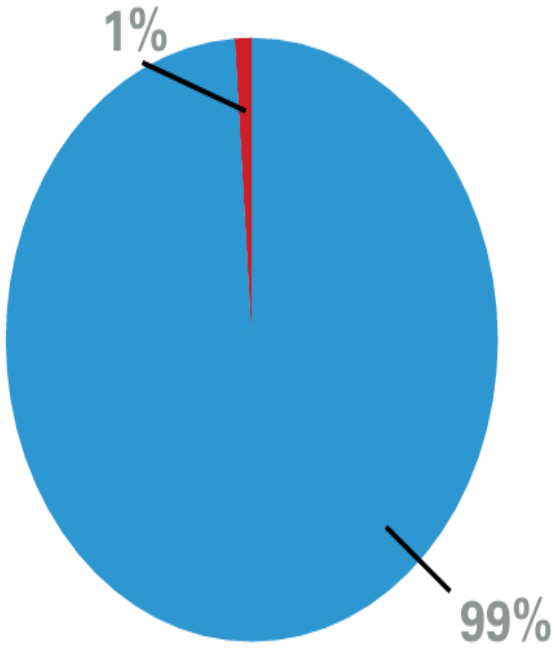
- Allergic Asthma
- Anemia/Neutropenia
- Crohn's Disease
- Cystic Fibrosis
- Enzyme Replacement Therapy
- Growth Hormone
- Hepatitis C
- Hemophilia
- Hereditary Angioedema
- Infertility
- Multiple Sclerosis
- Oncology
- Osteoporosis
- PKU
- Psoriasis
- Psoriatic Arthritis
- Pulmonary Hypertension
- Rheumatoid Arthritis

In 1990, 10 specialty drugs were on the market.
In 2012, over 900 specialty drugs were in development.

Prescription Drug Spending in 2014



Prescriptions Written in 2014



Source: The Express Scripts 2014 Drug Trend Report. March 2015. Available at: http://lab.express-scripts.com/drug-trend-report/

2014 Approximate MONTHLY Cost for Specialty Meds

Medication	Sample indication for medication use	Monthly cost for sample indication
Provenge (sipuleucel-T)	Metastatic prostate cancer	$105,800
Sovaldi (sofosbuvir)	Hepatitis C	$29,900
Olysio (simeprevir)	Hepatitis C	$23,600
Rituxan (rituximab)	Non-Hodgkin's lymphoma	$21,900
Gleevec (imatinib)	Chronic myeloid leukemia	$11,900
Avastin (bevacizumab)	Metastatic colorectal cancer	$11,600
Revlimid (lenalidomide)	Multiple myeloma	$9,300
Neulasta (pegfilgrastim)	Neutropenia	$5,700

Source: Adapted from Specialty Medications: Traditional And Novel Tools Can Address Rising Spending On These Costly Drugs, Exhibit 1. Health Affairs, 33, no. 10 (2014).

TREND FORECAST FOR KEY SPECIALTY THERAPY CLASSES

2015 - 2017

	TREND FORECAST*		
THERAPY CLASS	**2015**	**2016**	**2017**
Inflammatory Conditions	21.6%	21.6%	21.1%
Multiple Sclerosis	11.3%	6.5%	3.0%
Oncology	21.6%	20.4%	19.8%
Hepatitis C	66.5%	55.4%	44.3%
HIV	17.3%	16.6%	16.2%
Miscellaneous Specialty Conditions	31.1%	29.7%	28.2%
Growth Deficiency	12.5%	10.4%	10.5%
Hemophilia	3.9%	3.3%	3.4%
Pulmonary Arterial Hypertension	12.5%	12.0%	12.1%
Transplant	-5.8%	-1.3%	0.0%
Hereditary Angioedema	22.5%	24.2%	20.7%
Other Specialty Classes	6.7%	6.7%	6.4%
TOTAL SPECIALTY	**22.6%**	**22.3%**	**21.3%**

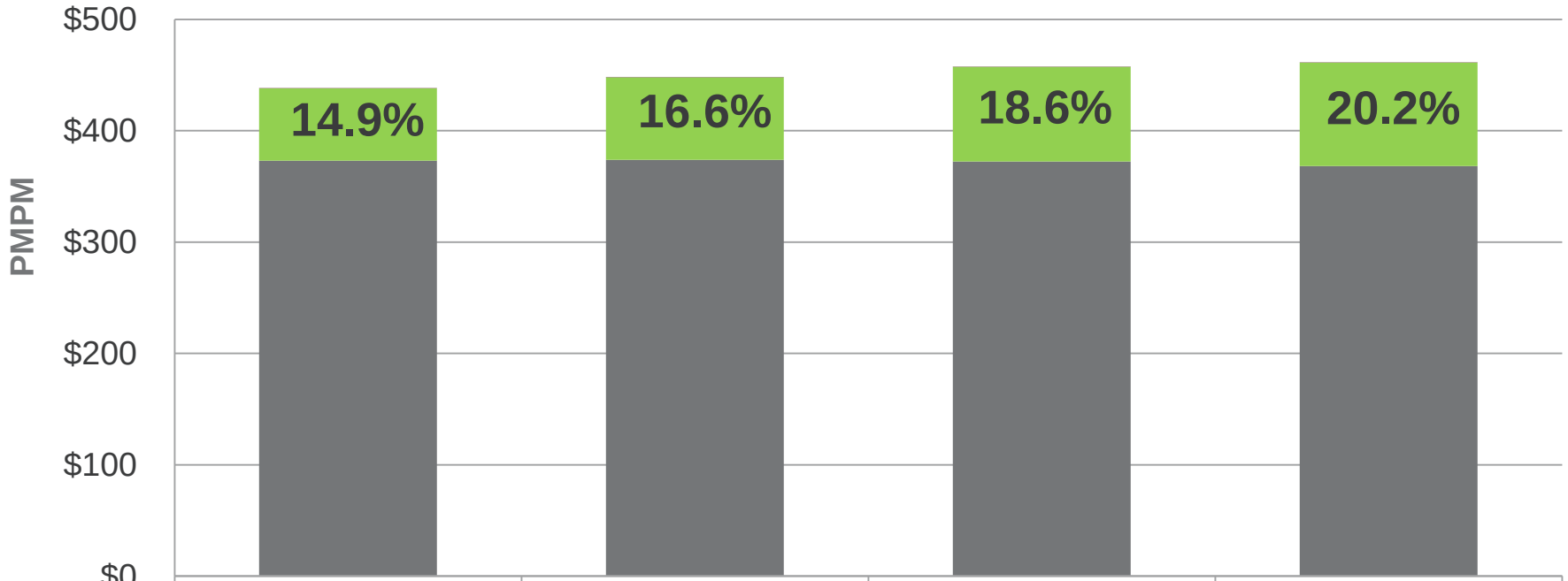
*Trend is forecast only for specialty medications billed through the pharmacy benefit.

EMD Serono Specialty Digest, 11th Edition Managed Care Strategies for Specialty Pharmaceuticals

LCPN Pharmacy Expenses

(NEPHO, LACU, WIN)

% of Total Medical Expenses (TME)*



	2012	2013	2014	Q1 2015
% Pharmacy of TME	14.90%	16.60%	18.60%	20.20%
PHARMACY	$65.12	$74.16	$85.29	$93.06
MEDICAL	$373.06	$373.93	$372.27	$368.27

**TME (Pharmacy + Medical Expenses) BCBS, HPHC, Tufts Commercial Plans*

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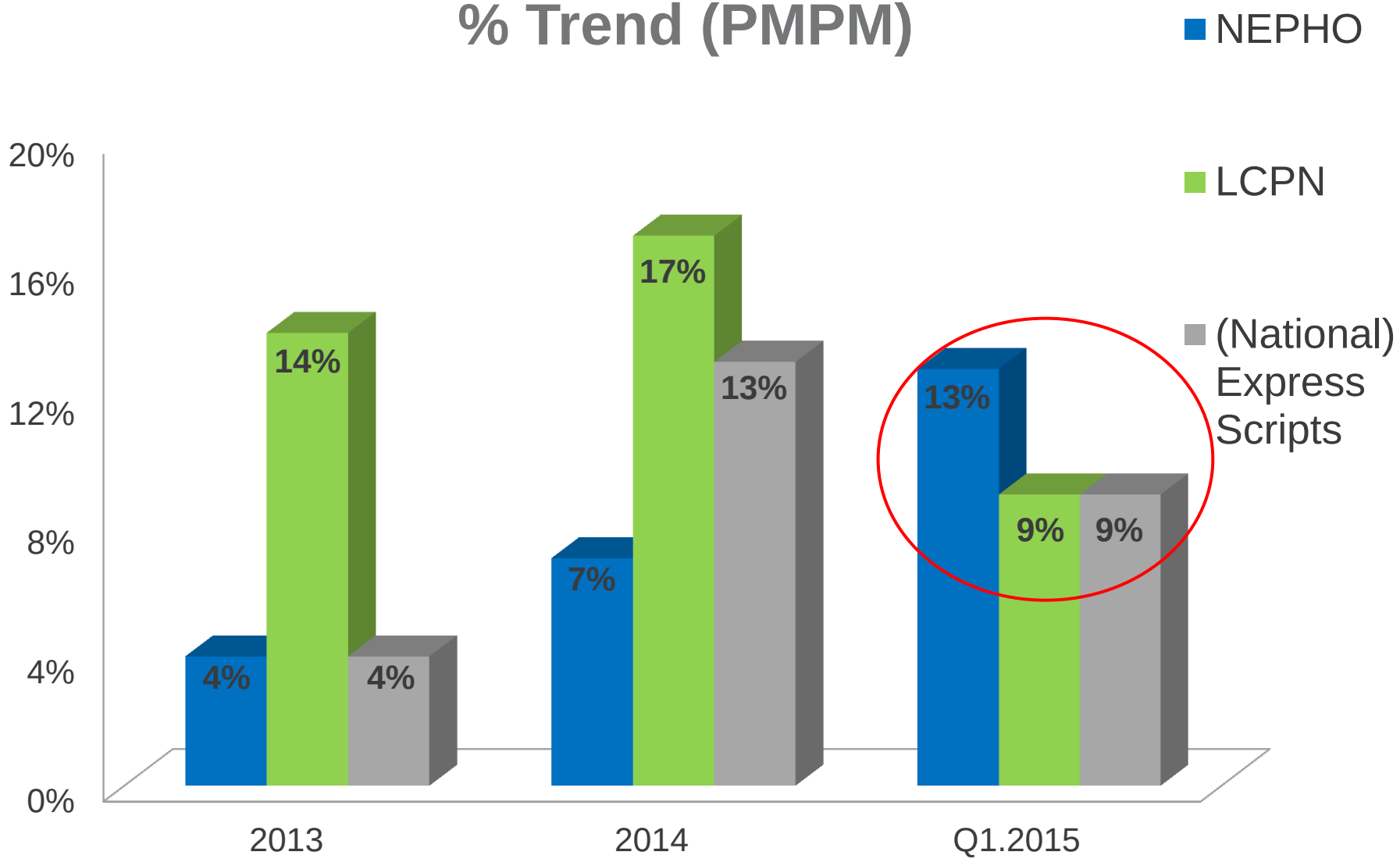
NEPHO / LCPN / National % Trend (PMPM)



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Non-Adherence

Cause for concern: BOTH Traditional and Specialty Meds

30% – 40% of US adults are non-adherent to chronic meds

Traditional Meds - Express Scripts 2014 Report

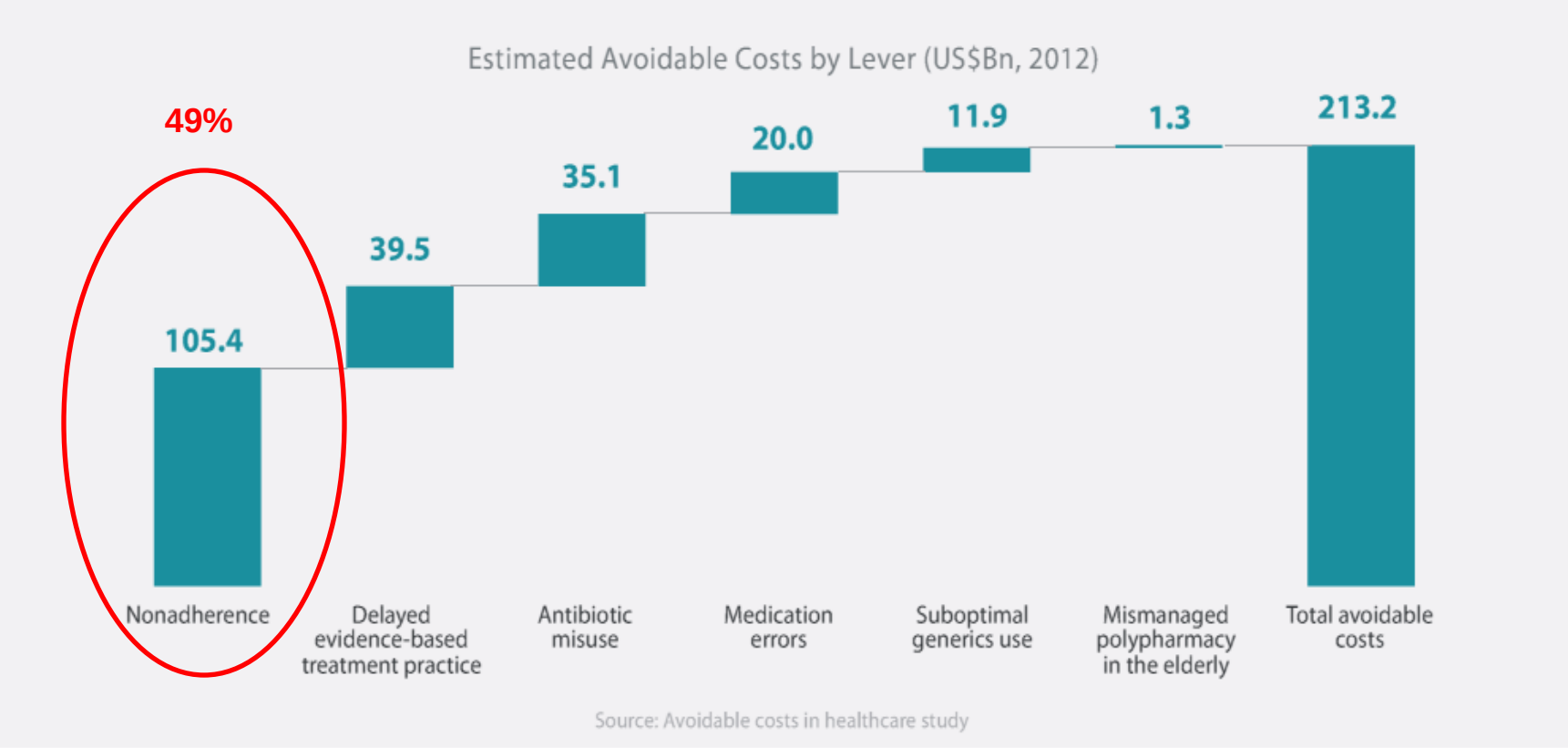
- 39% of pts on diabetes meds non-adherent
- 79 % of pts started on pregabalin (Lyrica) for neuropathic pain discontinued within 1 year (SE: dizziness, peripheral edema, etc.)
- 55% of adults and 78% of pediatric pts non-adherent to asthma medication

Specialty Meds

- Consider cost of non-adherence @ $1000 / tablet

Other Pharmacy Cost Drivers: Non-Adherence

Exhibit 1: Avoidable U.S. healthcare costs add up to $213 billion

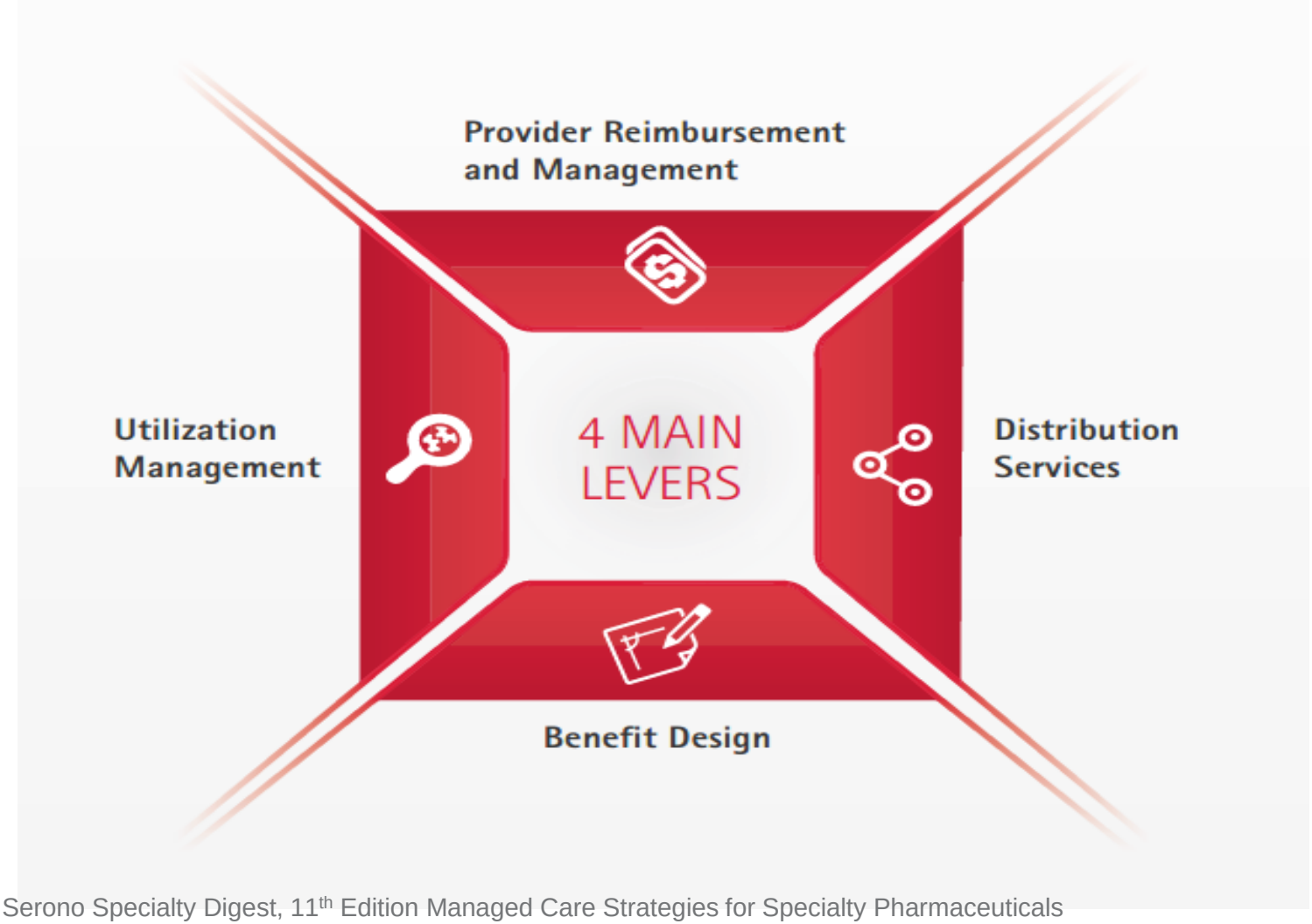


Avoidable Costs in US Healthcare: The $200 Billion Opportunity from Using Medicines More Responsibly IMS Institute for Healthcare Informatics June 2013

Strategies / Trends to Control Costs

- Health Plan Cost Control Strategies
- Therapy Class Management - Clinical Guidelines
- Biosimilar Medication Market
- Future Strategies for Management

Specialty Medication Cost Control Strategies



EMD Serono Specialty Digest, 11th Edition Managed Care Strategies for Specialty Pharmaceuticals

Benefit Design - Cost Control Lever

Patient cost share strategies

- High-deductible (HDHP) plans

  Medicare Part – D - $350 (prescription only)

  Commercial – Average $2,500

Incentive tiers / Formulary management

- Preferred and non-preferred
- Multi-tier cost share (e.g. Tier 1 – Tier 5 for some)

  % cost of medication vs. fixed Tier cost
- Separate cost share structures for Specialty Meds

Distribution Services - Cost Control Lever

- Specialty Pharmacy Providers (SPPs) – required for some meds
  - Acredo
  - Caremark
- Utilization and therapy management
  - Prior Authorization, J-code / NDC crosswalks
  - Appropriate doses
  - Manage adverse events / drug waste, abuse and misuse
  - Track medication discontinuation rates and reasons
  - Adherence management
- Seek financial assistance for patients

Utilization Management - Cost Control Lever

- Preferred products and rebates by PBM (CVS Caremark, Express Scripts)

  Within each Therapeutic Class

- Partial fill – reduces waste

  Patients stop due to side effects, hospital admissions etc.

  Typically 2 week supply (oral meds)

- Required medication adherence programs – pharmacist managed

- Outcomes-based contracts between Pharma / Payers

  Proven benefit of medications before health plan covers med

Provider Reimbursement & Management - Cost Control Lever

- Specialty drug reimbursement rates - limited by payers
  - Average Wholesale Price (AWP) – minus discount (0% - 26%)
  - Average Sales Price (ASP) - plus discount (6% - 20%)
    - Specialty pharmacies, Home Infusion Providers
    - Physician in-office providers
- Site of service strategy requirement - Botox, IVIG, RA, Crohns, Remicade), MS etc.
  - Physician Office
  - Hospital Outpatient Facilities
  - Ambulatory Infusion Centers
  - Patient's home – Infusion vendors
- Episode of care (EOC) Reimbursement vs. Traditional fee-for-service
  - Bundled payments for entire EOC
    - (e.g. BPCI Bundled Payment Care Improvement - ACO)
- Medical Claims Coding and Billing Changes
  - Movement to NDC drug code pre-payment approval - J-Codes not specific

Therapy Class / Medication Management

Focus - 4 Specialty Therapy Classes: 60% - 70% of expenses

- Oncology
- Multiple Sclerosis
- Immune Modulators
- Hepatitis C

Therapeutic Class Management Strategies

- Specialty Medications:

  Less expensive alternatives are not available

  Therapeutically beneficial – Hep C > 90% cure rates

- Focus on adherence to evidence-based guidelines / clinical pathways
- Companion diagnostics - treatment based on patients genetic composition
- Risk sharing based on improved patient adherence/ outcomes (i.e. SVR for Hep C pts)
- Increase use of palliative care where appropriate
- P & T Cost & Benefits Calculator Tools

  Institute for Clinical and Economic Review (ICER) - non-profit

  New England Comparative Effectiveness Public Advisory Council (CEPAC)

  National Comprehensive Cancer Network (NCCN)

Biosimilar Medications - Potential Game Savers

Specialty Meds / Biologics / Biopharmaceuticals

- derived from live, biological sources (blood products, proteins, antibodies, etc.)
- mimic pathways within our bodies

- **Biosimilars** – What are they?
  - COPIES of complex therapeutic proteins (specialty meds / biologics /biopharmaceutical)
  - not developed by the original manufacturer
  - approved through slow and complicated regulatory process

Biosimilars - continued

Specialty Meds	Traditional Meds
Biosimilars (large molecules)	Generics (small molecules)

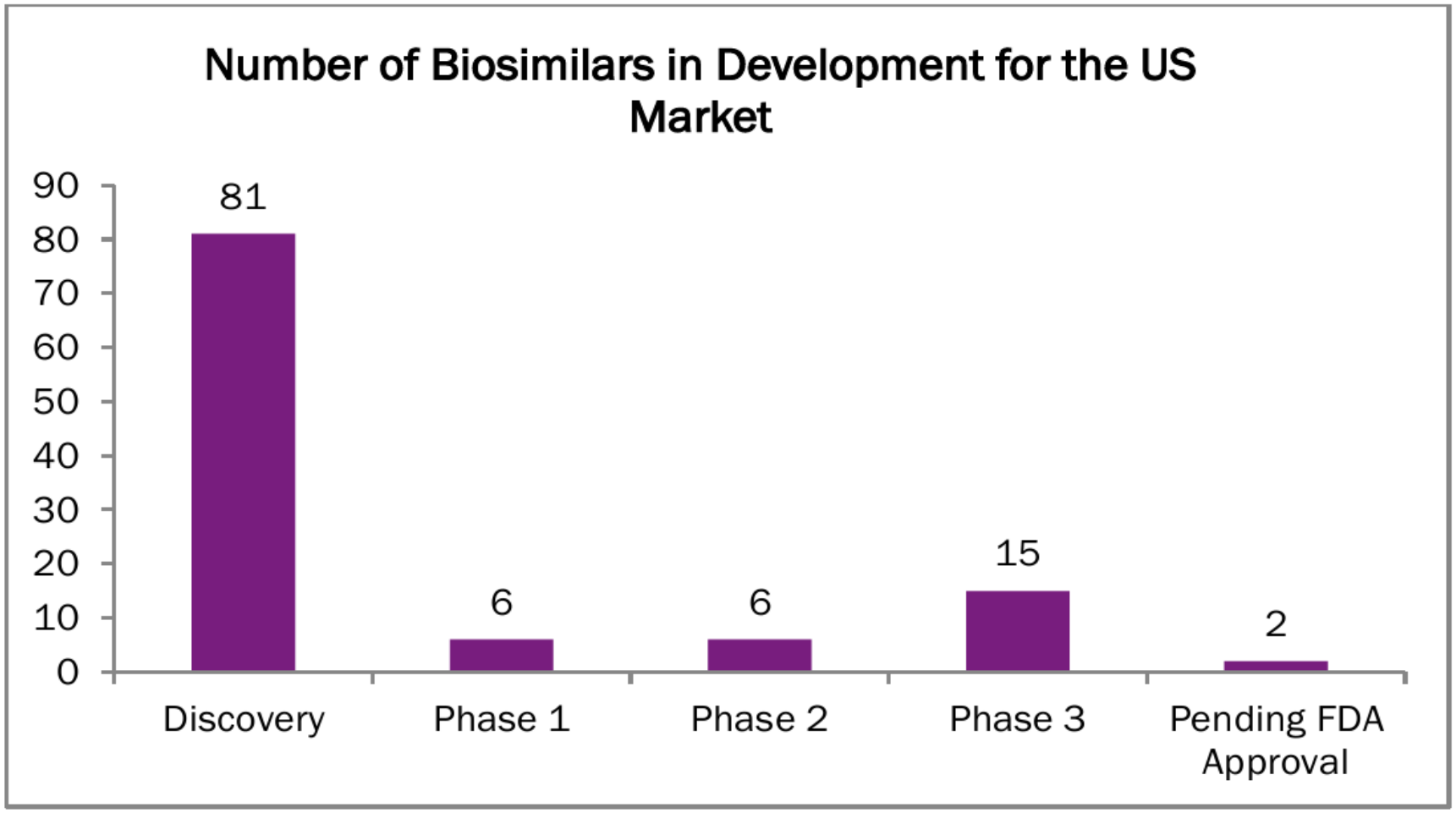
- must contain the identical active ingredient in the reference product
- not a generic equivalent
- cannot be generically substituted by pharmacist
- potency, purity and safety same as the reference product
- may differ from biologic by formulation / delivery system and have some minor differences in clinically inactive components

First Biosimilar - Neupogen (filgrastim) released as brand name **Zarxio**

filgrastim - sndz (Sandoz) – released 15% discount

Biosimilar Market

pipeline snapshot



Biosimilars - Naming Game

- FDA requiring a 4 letter suffix to identify the manufacturer
- Neupogen
  - filgrastim-sndz - Sandoz
  - filgrastim-bflm - Novartis
  - filgrastim-jcwp – Amgen
  - filgrastim-vkzt - Teva
- Coming Soon:
  - Epogen (Amgen) - epoetin alfa-cgkn
  - Remicade (JNJ) infliximab-hjm

Biosimilar Facts:

- Specific guidelines set by the FDA before submitting an application
- Biosimilar pathway 351(k) requires clinical studies
- Traditional generic pathway does not require clinical studies;
  only demonstration of bioequivalence.
- Cost of developing biosimilars is estimated between $75 and $250 million

- **What are the Potential Savings??**
  - Expected to have 15% -30% discount compared to biologic / biopharmaceutical
  - 2020 - Expected sales for biosimilars ~$35 billion globally
    for biologics with patent expiration worth about $81 billion.

Biosimilar Laws

National:

- Slow approval of new biosimilars (FDA approval - numerous federal / state regulatory & legal hurdles)
- Substitution process is confusing

Massachusetts is ready for substitution:

- June 2014, House Bill 3734, “An Act Relative to the Substitution of Interchangeable Biosimilars”
- Substitution of “interchangeable” biological products with requirements:
  - Substitution of biosimilars - FDA determined “interchangeable”
  - Prescribers retain “dispense as written” authority
  - RPh must notify prescribing doctors of biosimilars substitutions
  - RPh must notify patients / retain records of biosimilar substitutions

Future Strategies for Pharmacy Cost Management

- Continued implementation of site of service management
- 340b Shared Savings – shared with payers

  discounted drugs for facilities /programs for some federal programs
- Additional cost share tiers for biosimilars
- Medical policies / guidelines for tumor genome sequencing
- Joint contracting with molecular diagnostics / genetic testing vendors

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Questions / Comments

References:

EMD Serono Specialty Digest, 11th Edition Managed Care Strategies for Specialty Pharmaceuticals

Clinical and Formulary Decisions for Biosimilars, Stephen Lucio et al Hospital Pharm Volume 49: Supplement 1, 2014

Catamaran Rx Outlook Focus: Biosimilars Vol 1 Issue 7, October 2014