San Francisco Health Service System

Pharmacy Trends

Board Forum:
November 10, 2016

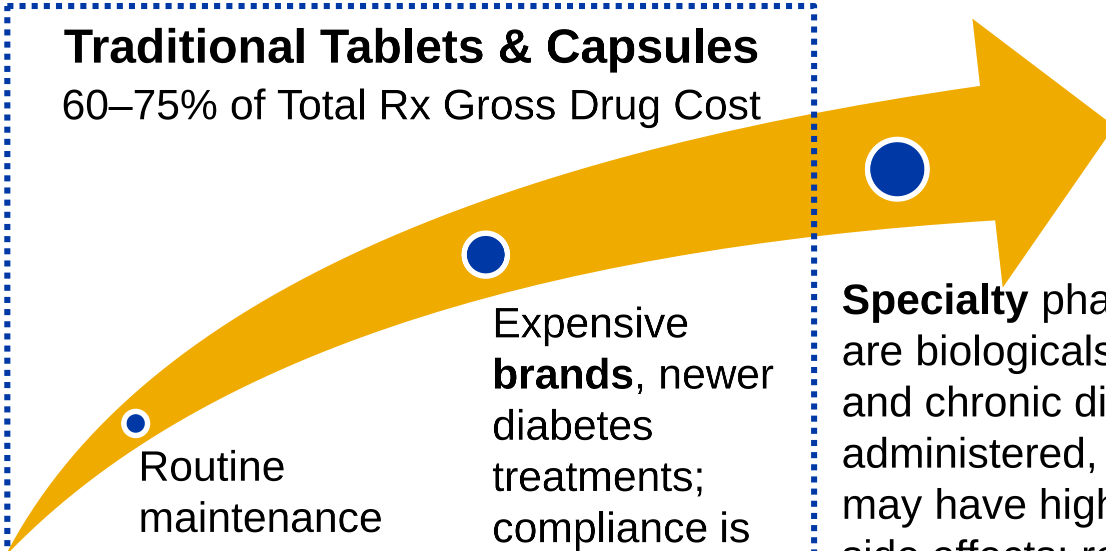
Prepared by:
Aon | Aon Hewitt | Health & Benefits

Empower Results®

Aon's Pharmacy Point of View

We Believe

Getting patients to the
RIGHT drug at the RIGHT channel for the RIGHT price
is the best strategy for managing pharmacy cost and trend



Lower cost and complexity

Traditional Tablets & Capsules
60–75% of Total Rx Gross Drug Cost

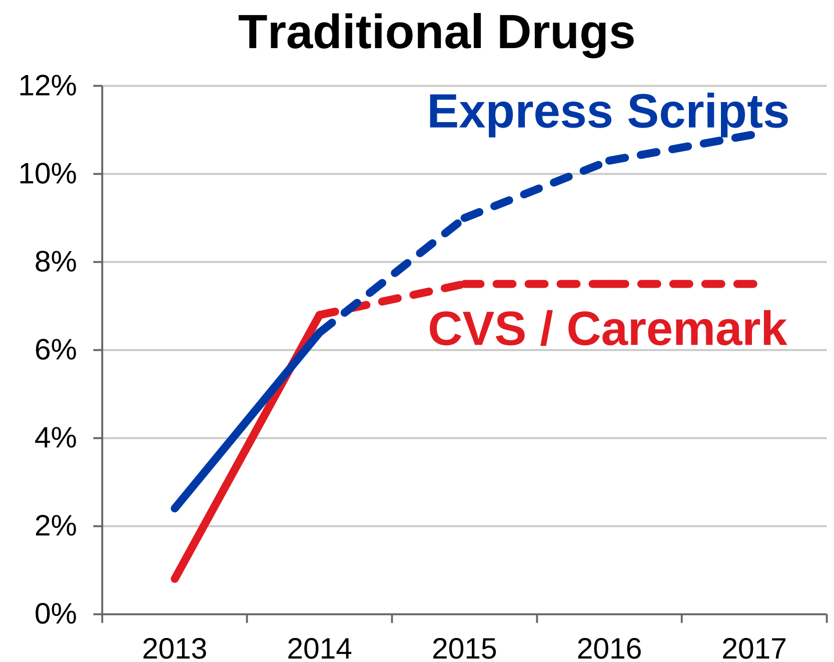
Routine maintenance medications, short-term **generic** antibiotics, and pain killers

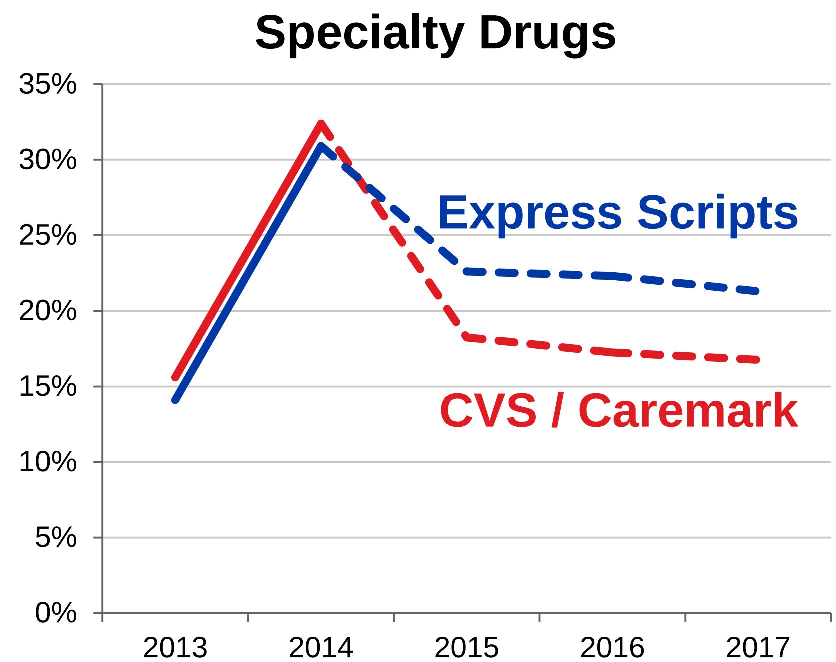
Expensive **brands**, newer diabetes treatments; compliance is important

Higher cost and complexity

Specialty pharmacy medications are biologicals that treat complex and chronic disease, may be self administered, infused or oral, may have high drop off rates and side effects; requires appropriate utilization review and continual oversight; compliance is critical.

2015–2017 Forecast





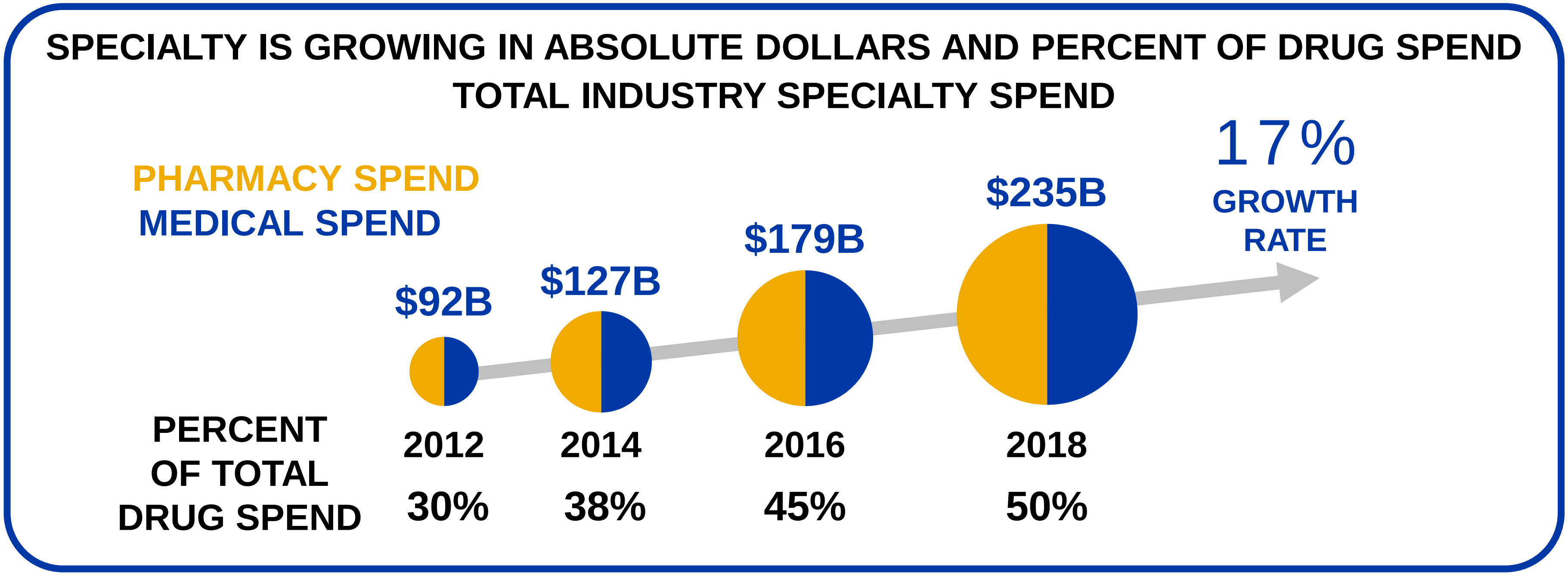
	2013	2014	2015	2016	2017
CVS / Caremark	0.8%	6.8%	4.5 – 10.5%	4.5 – 10.5%	4.5 – 10.5%
Express Scripts	2.4%	6.4%	9.0%	10.3%	10.9%

	2013	2014	2015	2016	2017
CVS / Caremark	15.6%	32.4%	15 – 21.5%	14 – 20.5%	14 – 19.5%
Express Scripts	14.1%	30.9%	22.6%	22.3%	21.3%

Source: *2015 Trend report CVS Caremark and Express Scripts.; For 2015, 2016 and 2017, midpoint was used where a range was provided*

Specialty Drugs: Why Do We Care?

- Specialty drugs are used only by 1 – 2% of the population in the U.S., but they now account for about 30% of drug costs.
- In the next 3 – 5 years, specialty drugs spend is expected to exceed 50% of total prescription drug costs.



Source: *http://georgevanantwerp.com/tag/drug-trend/*

Examples of Specialty Drugs

Condition	Oral Specialty Drugs	Self Injectable Medications	Office Administered Medications
Multiple Sclerosis	Gilenya: $60K	Copaxone: $55K	Tysabri: $28K
Rheumatoid Arthritis / Ulcerative Colitis / Psoriasis	Xeljanz: $24K	Enbrel: $23K	Remicade: $19K
Pulmonary Hypertension	Letairis: $106K	N/A	Flolan: $00K

Note: *Costs shown are annual*

Value of Specialty Drugs

Example 1: Leukemia—Gleevec (imatinib)

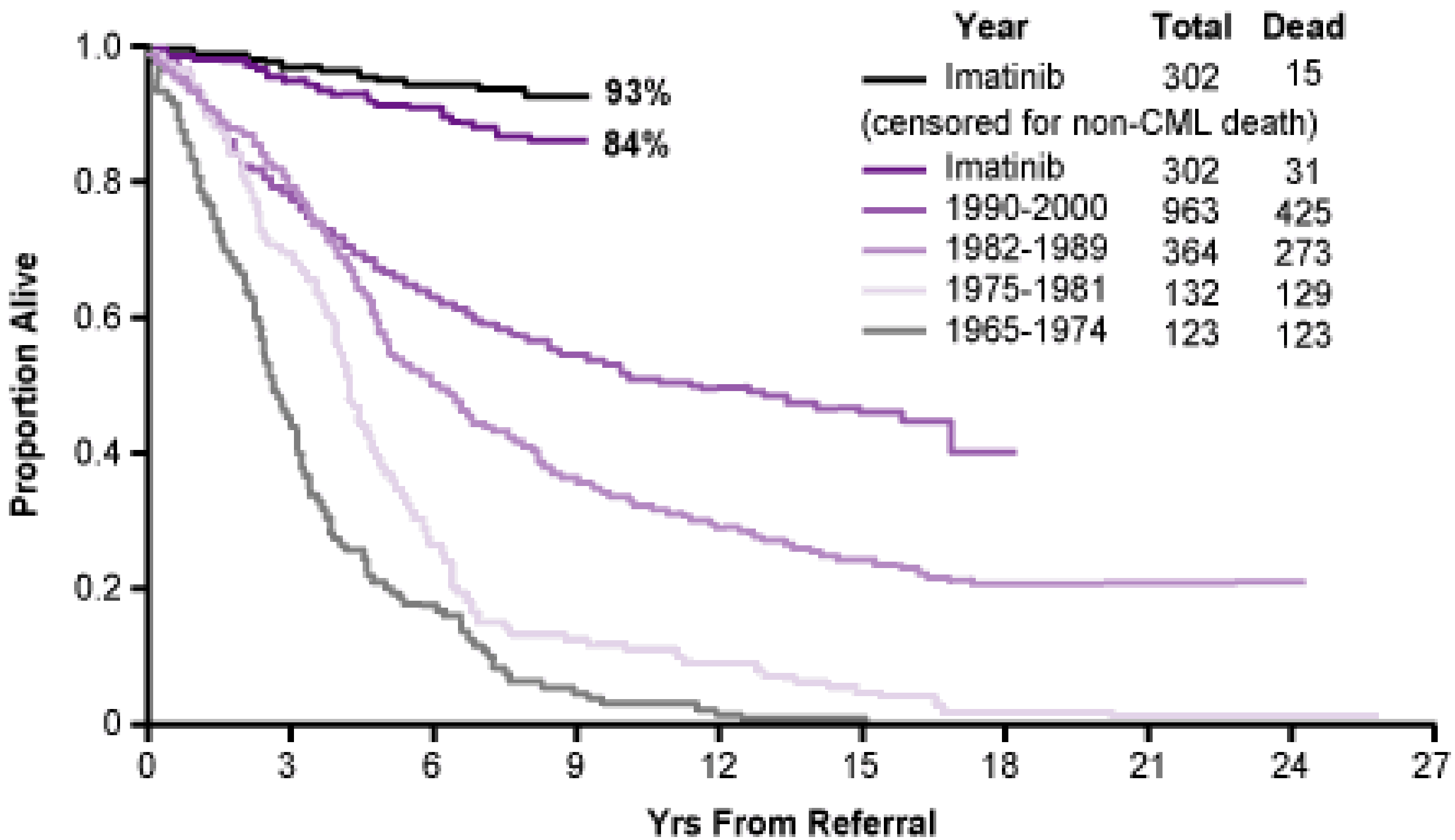


Figure courtesy of Elias Jabbour, MD.

Source: *http://www.clinicaloptions.com*

Value of Specialty Drugs

Example 2: Hepatitis C

Agents	Timeline of Approval	Cure Rate 12 Weeks Post-Treatment (SVR12)	Duration of Treatment	Total Cost of Therapy
PEG-Interferon + Ribavirin	1998	44%	24 – 48 weeks	$20– 40K
Victrelis (boceprevir)	2011	68%	8 – 24 weeks	$26 – 49K
Incivek (telaprevir)	2011	75%	12 – 24 weeks	$50K
Sovaldi (sofosbuvir)	2013	95 – 99%	12 weeks	$84K
Harvoni (sofosbuvir + ledipasvir)	2014	95 – 98%	8 – 24 weeks	$95K
Viekira Pak (ombitasvir + paritaprevir + ritonavir + dasabuvir)	2014	95 – 99%	12 – 24weeks	$84K

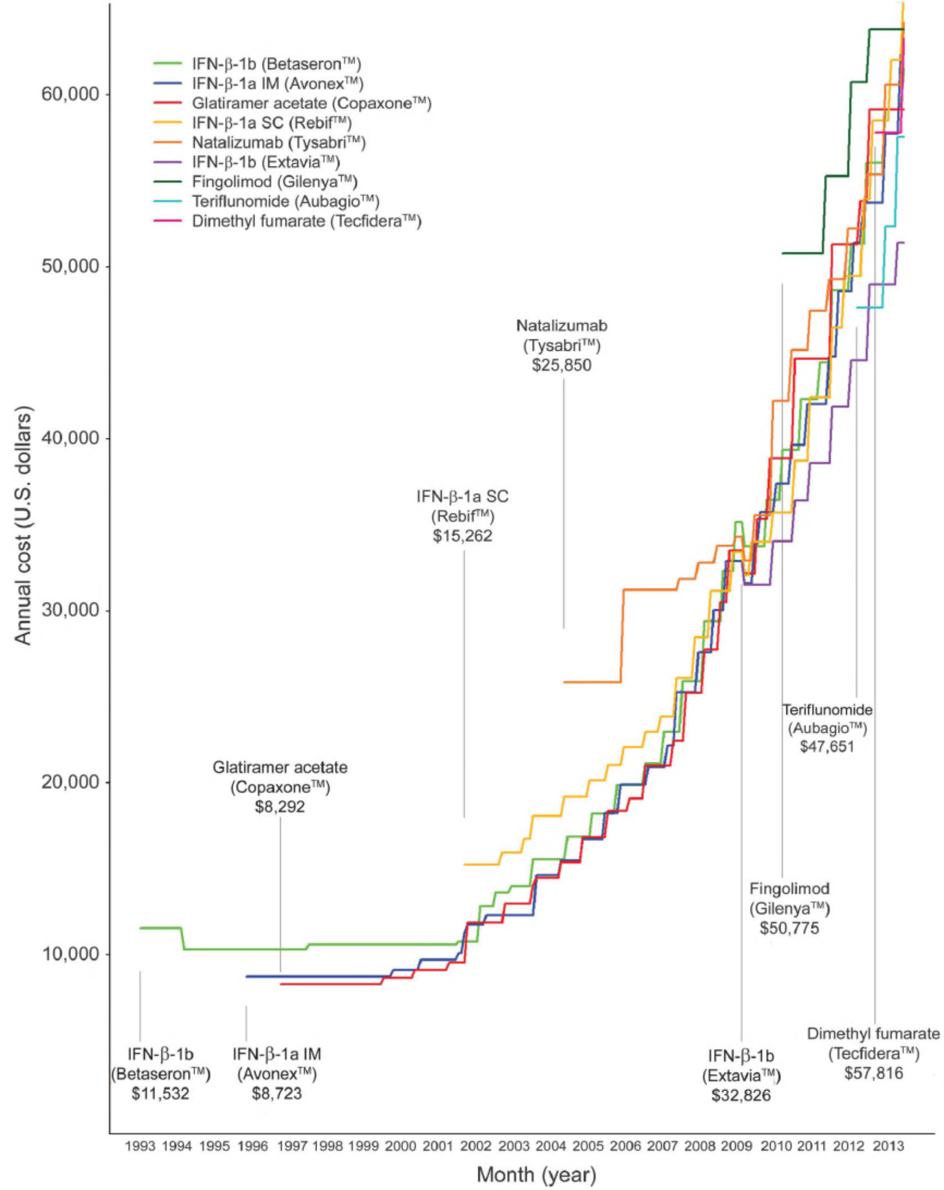
Drivers of Specialty Drug Costs

1. Price inflation
2. New drugs
3. New indications
4. Lack of generic / biosimilar alternatives
5. Direct to Consumer Marketing

1 Specialty Drug Price Inflation

Example: Multiple Sclerosis

- Cost of Multiple Sclerosis drugs has increased over 20 years from less than $10,000 per year to over $60,000 per year.
  - Manufacturers are exhibiting shadow pricing (i.e., match each other’s list prices).



Annual costs estimated from average wholesale prices (AWP), or wholesale acquisition costs if AWP not reported, and discounted 12%. IFN = interferon.

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New Entries to the Specialty Drug Market

Hepatitis C Treatments

- Treatments available:
  - Gilead:
    - Sovaldi® and Harvoni®
  - Abbvie:
    - Viekira Pak® and Technivie®
  - BMS:
    - Daklinza®
  - Merck:
    - Zepatier®
- Major pharmaceutical breakthroughs with huge price tags
- Treatment costs range from $50K to $170K per patient

PCSK9 Inhibitors for Treatment of Hypertension

- Praluent—approved July 2015
- Repatha—approved April 2016
- Cholesterol lowering injectable treatments
- Used for patients resistant to statin therapy or who have heterozygous familial cholesterolemia
- Cost $14,000 per year

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New Entries to the Specialty Drug Market

Cystic Fibrosis

- Affects 30,000 patients in U.S.
- Kalydeco currently available for $300K per year, and approved for one mutation
impacting 2,000 patients
- Orkambi was approved July 2, 2015 for more mutations and impacts ~14,000 additional patients
- Annual cost = ~$300K

PD-1* Inhibitors for Cancer

- Potentially useful in the treatment of several types of cancer including melanoma, lung, breast, kidney, and bladder cancers
- Keytruda, approved in September of 2014 for the treatment of advanced or un-resected melanoma, is estimated to cost $150K a year
- Opdivo, approved in December of 2014, is also used to treat melanoma and is estimated to cost $143K a year

**Programmed T-Cell Death*

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New Entries to the Specialty Drug Market

Heart Failure

- Affects 5.7 million Americans ≥ 20 years of age
- 870,000 new cases per year
- Entresto—approved July 2015
- First in-class combination of Angiotensin Receptor and Neprilysin inhibitor (ARNi)
- Demonstrates mortality benefit
- Cost per day = $15
- Sales Forecast for 2020: >$5 billion worldwide

Hypoactive Sexual Desire Disorder

- Estimated that about 35–40% of women are affected by decreased sexual desire
- Expected approval of new drug, Addyi, in April 2016
- Nonhormonal treatment option
- Risk Evaluation and Mitigation Strategies (REMS) program recommended due to concerning drug interactions and side effects

3 New Specialty Drug Indications Drive Substantial Cost Increases

Indications for Humira

Rheumatoid arthritis, 2002

AWP = $653
Annual Sales = $4.3M

Psoriatic arthritis, 2005

AWP = $720
Annual Sales = $0.9B

Ankylosing spondylitis, 2006

AWP = $755
Annual Sales = $1.2B

Crohn’s disease, 2007

AWP = $792
Annual Sales = $1.6B

Plaque psoriasis & J.RA, 2008

AWP = $871
Annual Sales = $2.2B

Ulcerative colitis, 2012

AWP = $1,229
Annual Sales = $4.6B

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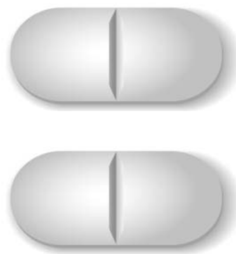
Biosimilars Create Opportunity for Cost Savings

- **Definition:** A biological product that has **demonstrated significant similarity** to an FDA-approved product and **does not possess any meaningful differences in safety and efficacy** than the reference product.
- Potential launch of biosimilars in the U.S. market will be a win-win for patients, payors, and the companies across the Rx Channel that distribute / dispense specialty drugs.
- Savings can be on medical or pharmacy side depending on distribution channel:
  - Savings with traditional drugs is 75%–85%
  - Savings with biosimilar is 10%–25%

Similar but



not the same

Biosimilar medicines may not be exact duplicates

4 Biosimilar Launches Are Making Headlines

REUTERS

HEALTH NEWS | Thu Sep 3, 2015 | 8:13am EDT

Novartis launches first U.S. 'biosimilar' drug at 15 percent discount

*Novartis kicked off a new era in U.S. medicine on September 3, 2015, with the launch of **Zarxio**, the first "biosimilar" at a discount of 15 percent to the original drug, Neupogen.*

HEALTH NEWS | Wed Apr 6, 2016 | 12:19am EDT

FDA approves biosimilar to J&J's Remicade for multiple diseases

*The U.S. Food and Drug Administration (FDA) on Tuesday approved Inflectra, a cheaper version of Johnson & Johnson's drug **Remicade**, to treat Crohn's disease, ulcerative colitis, rheumatoid arthritis, psoriasis and arthritis of the spine.*

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Biosimilar Launches Are Making Headlines

Biosimilar Pipeline

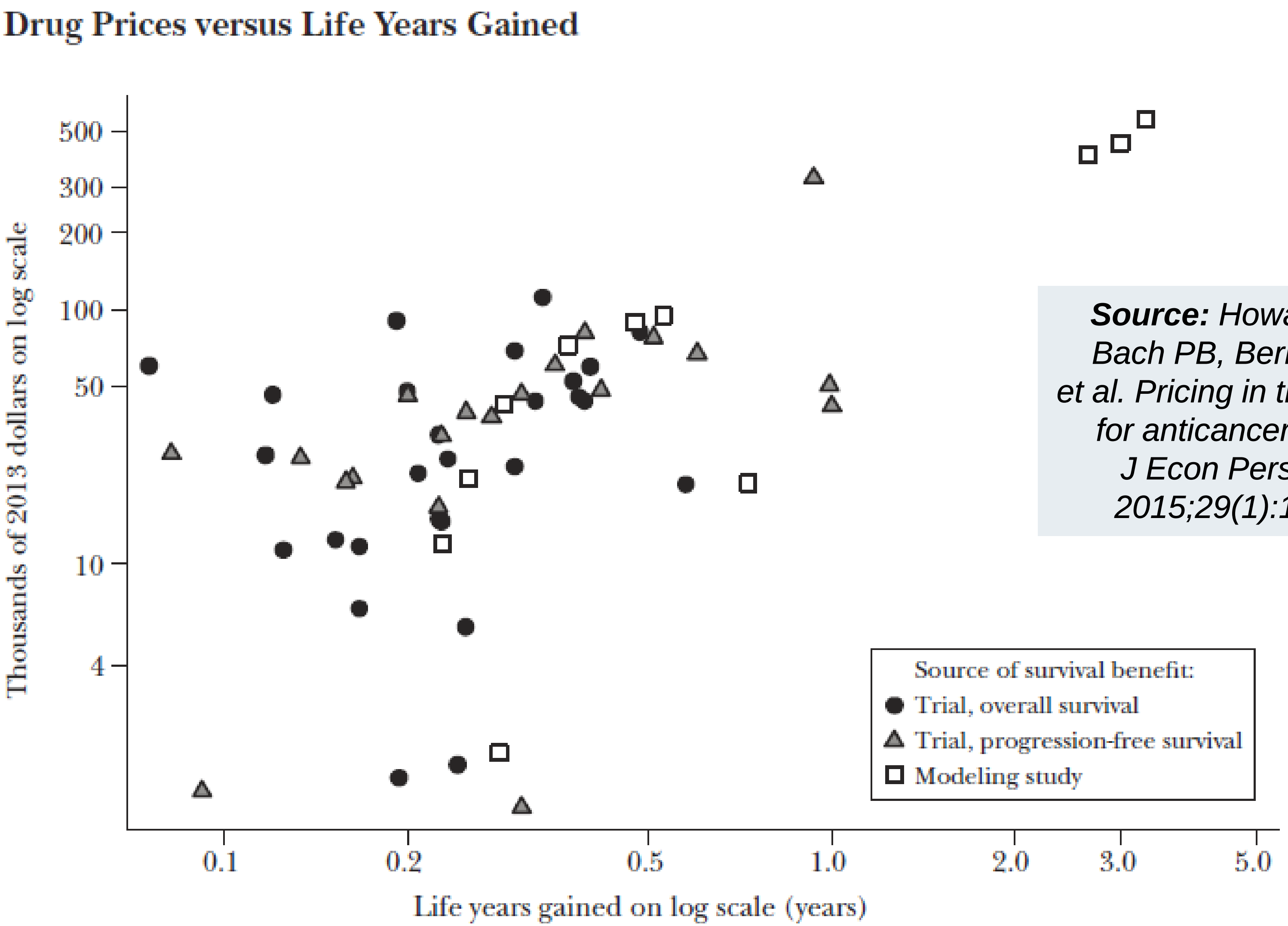
Biosimilar		Brand Product	Therapeutic Class	Expected Approval Date	Expected Launch Date
Grastofil	(filgrastim)	Neuopgen	Blood modifier (increases WBC)	Q2 2016	Q4 2016
Retacrit	(epoetin alfa)	Epogen and Procrit	Anemia	Q4 2016	Q2 2017
Inflectra	(infliximab)	Remicade	Inflammatory conditions	April 2016	October 2016
	(pegfilgrastim)	Neulasta	Blood modifier (increases WBC)	Q2 2016	Q4 2016
	(etanercept)	Enbrel	Inflammatory conditions	June 2, 2016	December 2, 2016
	(adalimumab)	Humira	Inflammatory conditions	September 25, 2016	March 25, 2017

Cancer Life Expectancy Impact and Cost

Agents Used	Indication	Impact [1]	Cost
Cyramza (ramucirumab)	Gastric Cancer Metastatic NSCLC (Non-Small Cell Lung Cancer)	Gained 1.4 months	$ 71,286
Opdivo (nivolumab)	Metastatic Melanoma Metastatic Sq. NSCLC	Gained 3.2 months	$111,190
Farydak (panobinostat)	Multiple Myeloma	Gained 3.91 months	$143,237
Ibrance (palbociclib)	ER+, HER2– Breast Cancer	Gained 10 months	$255,819
Lenvima (lenvatinib)	Thyroid Cancer	Gained 14.7 months	$408,456

[1] Progression Free Survival

Price Per Life-Year Gained Varies Significantly for Drugs

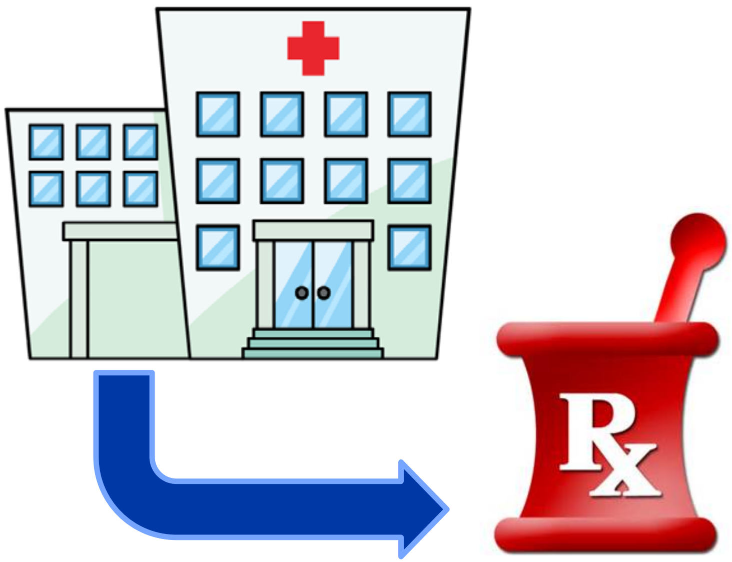


Source: *Howard DH, Bach PB, Berndt ER, et al. Pricing in the market for anticancer drugs; J Econ Perspect. 2015;29(1):139-62*

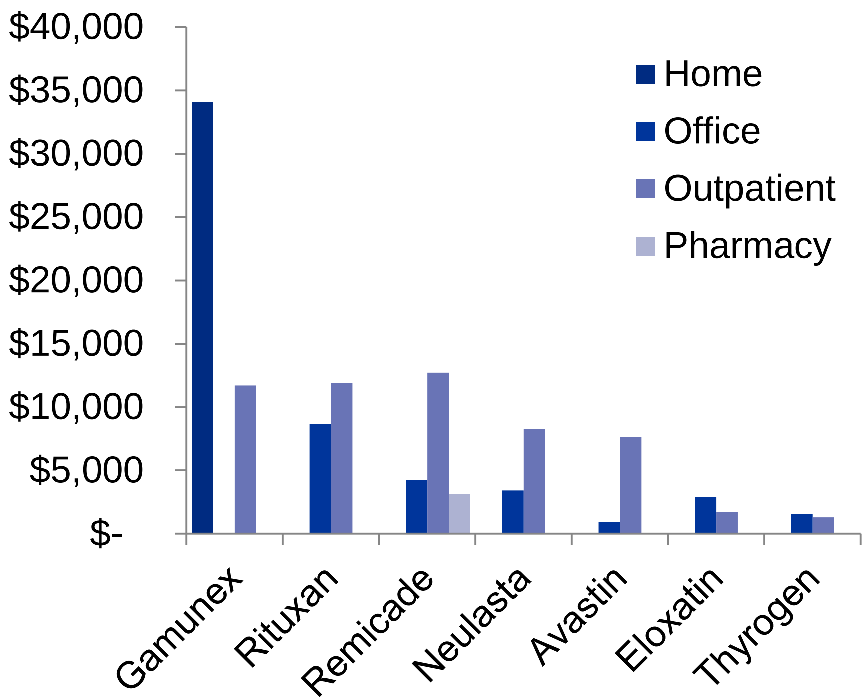
Specialty Site of Care Management

76% of employers…

….participate in or are considering carving out specialty drugs from the medical benefit [1]



…participate in or are considering site of care management [2]



Sources:

[1] Aon Health Survey, 2016

[2] Aon Hewitt site of care client analysis, 2013

Site of Care Management—Administration Costs

Administration costs vary significantly by site of care

	Drug Administration Cost, Outpatient Hospital	Drug Administration Cost, Physician Office
Drug	**Average Cost**	**Average Cost**
All	$605	$114
Specific Drugs		
Neulasta	$120	$50
Remicade	$487	$220
Avastin	$714	$122
Herceptin	$632	$269
Rituxan	$1,075	$389

Source: *http://www.artemetrx.com/2014/10/site-of-care-management-opportunities/*

The Changing Market

Generics

- 86% of all drugs dispensed are generics.
- Generics account for 22% of gross cost.
- 80% of all generic prescriptions cost less than $20.
- 75% of all generics have price inflation of less than 2%.
- Though gross margin on generic drugs at mail order remains high, mail order utilization has been flat or declining mainly due to the availability of mail at retail network arrangements.
- As the number of traditional blockbuster brands losing patents shrink, the opportunity for increased savings for moving patients from brands to generics is reduced.
- The introduction of copay cards and patient assistance programs has improved the staying power of brands.

The Changing Market

Rebates

- Over the past three years, rebates as a percentage of gross cost have increased from mid single digits (6 – 8%) to high teens (17 – 19%).
- In 2015, 21% of all rebates came from specialty medications (up from 13.7% in 2014).
- Inflation protection rebates as a percent of total rebates have almost doubled from 2014 to 2015 (4.4% – 7.4%).
- Rebates may continue to grow as a percentage of gross cost as manufacturers look to drive increased market share via preferred product status or exclusivity, although low net pricing (low list pricing inclusive of discounts and rebates) appears to be on the horizon.
- Pharmacy Benefit Managers (PBMs) will continue to profit from services and programs offered to plan sponsors designed to capture additional rebate dollars.

The Changing Market

Specialty

- 1-2% of all drugs dispensed are specialty medications.
- Specialty medications account for 31% of gross cost.
- Industry projections put this number near 50% by 2020 if not sooner.
- Specialty pharmacy will continue to be a profit driver for Pharmacy Benefit Managers via exclusive network arrangements.

SFHSS Pharmacy Experience: 2012 – 2015

	Blue Shield of California (Flex Funded)				Kaiser Permanente			
Year	**Rx Claims PMPM**	**Change**	**% Specialty Drugs**	**% of Total Medical Spend**	**Rx Claims PMPM**	**Change**	**% Specialty Drugs**	**% of Total Medical Spend**
2012	$80.10	—	—	10.5%	$44.06	—	—	10.5%
2013	$78.91	-1.5%	—	14.3%	$44.88	1.8%	—	10.6%
2014	$94.17	19.3%	—	15.7%	$49.77	10.9%	—	11.0%
2015	$108.15	14.8%	28.5%	17.8%	$63.02	26.6%	31.1%	13.8%

- Pharmacy costs have increased in the past 4 years from a low of 10.5% of costs:
  - Kaiser grew by 31.1%
  - BSC grew by 69.5%
- Specialty drugs have driven this increase in costs.

Traditional Drug Toolkit

Where Are You on This Continuum?

Traditional

- Generic incentives (Dispense As Written)
- Basic drug utilization review and utilization management
- Core fraud, waste, and abuse programs
- Tactics to drive use of 90-day fills (at better pricing)
- Communication strategies

Evolving

- Narrow or tiered networks
- Formulary exclusions / restrictions
- Enhanced step therapy protocols
- Compound Management
- Value based design
- Decision-support tools
- Smarter communication strategies
- Group coalition purchasing

Transformational

- Expansion of genetic testing
- Enhanced counseling / gaps in care programs
- Enhanced value based design
- Integrate measurement and strategy
- Medical
  - Absence
  - Wellness
- Effective engagement

The Specialty Pharmacy Toolkit Is Shifting

Where Are You on This Continuum?

Traditional | **Evolving** | **Transformational**

Traditional

- Prior authorization
- Specialty pharmacy networks
- Prospective patient follow-ups
- Competitive pricing
- Rx formulary management
- Average Selling Price pricing on medical
- Adherence management
- Day supply limits

The Specialty Pharmacy Toolkit Is Shifting

Where Are You on This Continuum?

Traditional	Evolving	Transformational

- Enhanced prior authorization
- Step therapy / drug exclusions
- Disease management for specialty
- Medical rebates
- Medical vs. pharmacy coverage
- Medical vs. pharmacy benefit design
- Patient Assistance Programs
- Specialty copays
- Coalition Purchasing

The Specialty Pharmacy Toolkit Is Shifting

Where Are You on This Continuum?

Traditional | **Evolving** | **Transformational**

- Medical formulary management
- 340B drug pricing programs
- Focusing on Quality Adjusted Life Years (QALYs) for pricing
- Legislative push on limiting drug costs
- Outcomes focused rebate contracting
- Managing site of care for specialty
- Biosimilars
- Genetic testing

Conclusion

- Drug trends are back in the double digits for the near future.
- Specialty drugs are key drivers of trends.
- Many specialty drugs provide improved care.
- Employers have several solutions for managing specialty drugs as well as traditional drugs.