Customer Perspective on Biosimilars and Interchangeable Biologics: Naming and State Legislative Issues

February 4, 2014

Biologics Offer Major Advances in Treatment But Present Significant Individual and Collective Costs

Top 10 Medicare Part B Drugs in 2010[1]		
Brand	Generic	Payments
Epogen®	Epoetin alfa	$1,596,124,727
Rituxan®	Rituximab	1,026,800,032
Lucentis®	Ranibizumab	938,982,813
Avastin®	Bevacizumab	886,978,637
Neulasta® /Neupogen®	Pegfilgrastim and Filgrastim	826,064,372
Aranesp® and Epogen®/Procrit®	Darbepoetin alfa and Epoetin alfa	735,746,040
Remicade®	Infliximab	691,839,042
Alimta®	Pemetrexed	313,758,293
Taxotere®	Docetaxel	302,430,188
Herceptin®	Trastuzumab	295,221,227

- Spending on biologic drugs is growing nearly twice as quickly as spending on small-molecule drugs; overall US biologic drug sales reached $48 billion in 2009.[2]
- Biologics are generally more costly than small-molecule drugs on a per-treatment basis, with costs up to $200,000 per year, often for the duration of a patient's life.

Slide source: Avalere Health

1. 2009 and 2010 five percent Carrier and Outpatient Standard Analytic Files (SAF).
2. Aggarwal, Saurabh. "What's fueling the biotech engine—2009–2010." *Nature Biotechnology.* 2010 Nov;28(11):1165-71.
3. Pollack, Andrew. "Costly Drugs Known as Biologics Prompt Exclusivity Debate." *New York Times.* July 21, 2009

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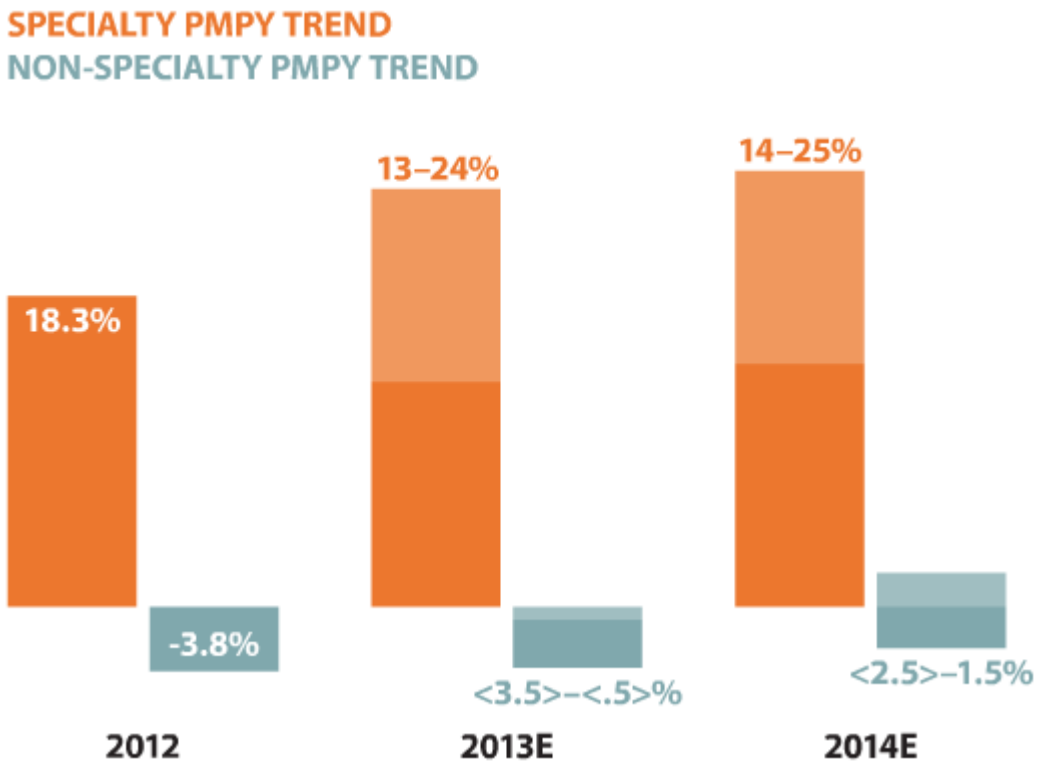
The Challenge: Double-Digit Specialty Trend is Driving Pharmacy Trend[1]



Consider:

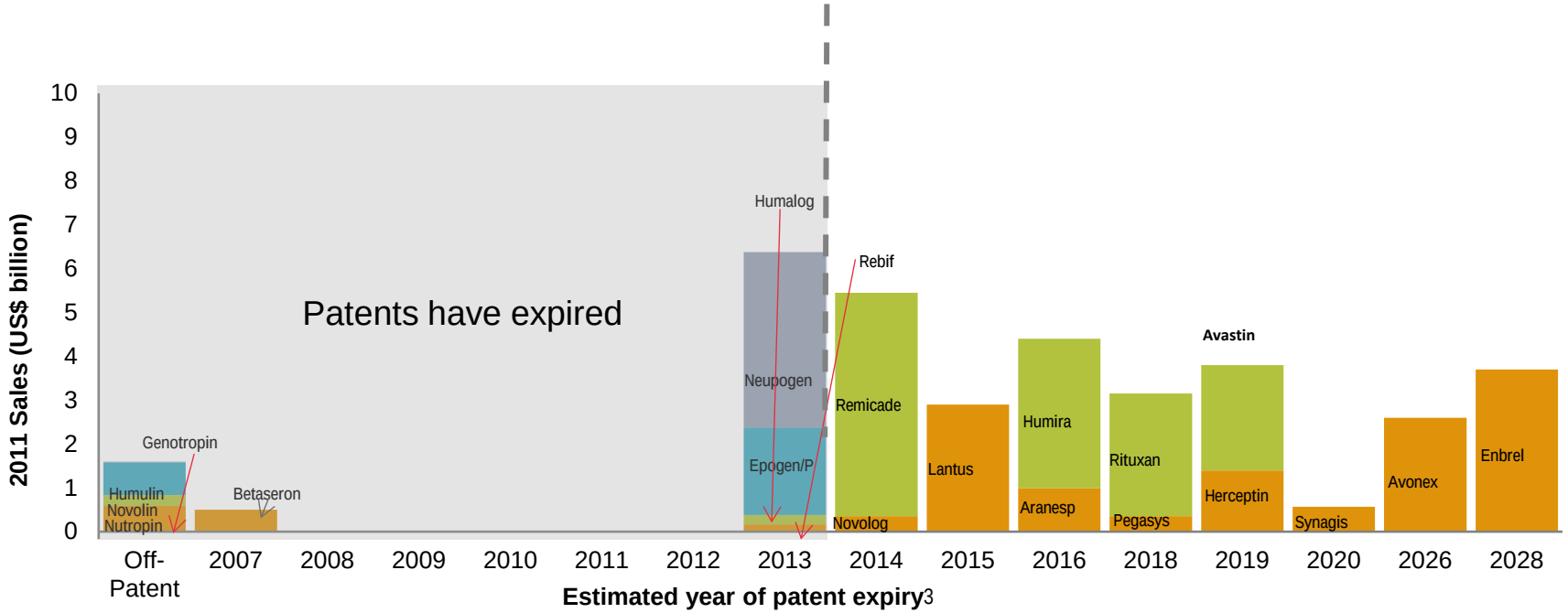
- Last year, specialty accounted for **more than one quarter** of total prescription spend.
- With 16 new products, specialty drugs dominated 2012 launches and spending on new brands—**$3.9 billion of $7 billion total**.
- In 2013, the FDA began granting Breakthrough Therapy Designations, which could further fast-track new medicines, accelerating approval **from eight to 10 years down to just two**.
- New breakthrough products expected over the next few years include drugs for heptatis C, multiple sclerosis, cystic fibrosis, and a number of cancers—some of these medicines are likely to set **new standards for treatment**.[2]

With a flood of new generics, spending on traditional drugs actually declined in 2012, and that decline is expected to continue for the next two years. On the other hand, specialty trend has tracked in the double digits for years and is expected to continue to rise.

1. CVS Caremark Analytics, 2013; CVS Caremark non-specialty drug trend, 2012, Caremark BOB trend cohort, Enterprise Analytics, 2013.
2. Source: Declining Medical Use and Costs: For Better or Worse? A Preview of the Use of Medicines in the U.S., IMS Health Informatics, 2013.

Slide source: CVS Caremark Insights 2013, available at http://viewer.zmags.com/publication/6283db2d#/6283db2d/2

Biologic Patent Expirations Create New Possibilities for Competition from Biosimilars and Interchangeable Biologics



- A number of top-selling biologic brands are to lose product patent protection over the next five years.
- The Congressional Budget Office (CBO) estimated that the biosimilars pathway would reduce direct spending by the federal government by $5.9 billion over the 2009-2018 period.[1]

Slide Source: Avalere Health

Adapted from: Lanthier, M., et al. "Economic issues with follow-on protein products." Nature Reviews Drug Discovery 7, (September 2008) 733-737

1. Congressional Budget Office. "Biologics Price Competition and Innovation Act of 2007." June 25, 2008.
2. IHS. "Generics and Biosimilars Market Access in Europe." October 25, 2011.
3. 2011 sales data sourced from company annual reports

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Timely Biosimilar Policy Development Critical to Marketplace Success

CVS Caremark supports efforts to remove barriers and facilitate the approval of biosimilars in order to increase access to life-saving medications by making them more affordable.

- It is important to ensure that biosimilars, like all new therapies, are determined to be safe and effective by the Food and Drug Administration (FDA), however the implementation is taking too long and should be shortened.
- The FDA should determine on a case-by-case basis the need for additional clinical studies prior to approval, as well as any post-marketing studies.
- CVS Caremark opposes activities by individual states to establish standards in conflict with FDA decisions on biosimilar and interchangeable biologics.

BPCIA = Biologic s Price Competition and Innovations Act

Naming Issue Threatens to Thwart Promise of Biosimilars

- BPCIA did not include specific statutory language regarding the naming of approved biosimilar products, instead leaving it up to the FDA.
  - Some stakeholders want to see biosimilars given nonproprietary names that have a unique suffix or prefix for each product approved in order to provide an additional product-specific field for easier adverse event tracking and other post-market safety purposes. Such proposals confuse the role of the nonproprietary name, which describes the active ingredient, with the brand name which describes the product.
- There is important precedent to products having the same name:
  - Products with the same active ingredient have always shared the same International Nonproprietary Name (INN) issued by the World Health Organization (WHO).
  - In the US, we have multiple biologic products on the market today with the same nonproprietary names even though made by different sponsors and never compared.
  - The same INN also applies to generic and to brand drugs, to biologics that have gone through multiple manufacturing changes during their life time, including in the US.
  - Biosimilars approved in Europe and elsewhere have the same INN as their reference with no evidence of safety problems even though extensively used.

BPCIA = Biologic s Price Competition and Innovations Act

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CVS Caremark Believes Providing Biosimilars with Unique Names will Create Barriers to Substitution

- Biosimilars will have brand names, and so be like other biologics on the US market today.
  - All leading sponsors of biosimilars have brand names for their products.
  - All product labels have information that makes products distinguishable.
- If the nonproprietary naming issue is resolved to require different/distinct prefix or suffix, states will likely not allow the substitution of a brand product with a biosimilar that explicitly cites it as its reference product
  - Even if FDA has designated a biosimilar as interchangeable with its reference, the different nonproprietary name will be used to suggest that the active ingredient in the two medicines are different.
  - Different INN names will make for a less competitive biologic marketplace.
  - Unique INNs have the potential to create unnecessary confusion among healthcare providers and patients by perpetrating the notion that an interchangeable biosimilar is “different.”

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CVS Caremark is Very Focused on Biosimilar Legislative Activity at the State Level

- CVS Caremark opposes activities by individual states to establish standards in conflict with FDA decisions on biosimilar medications.
  - In 2013, CVS Caremark opposed all proposed biosimilar legislation in the states, and opposes the new legislative language introduced at this point in the 2014 sessions.
  - Only FDA sees data on drug applications, and only FDA can enforce accurate labels.
- Such 2014 proposals include:
  - If a biological product is dispensed, the pharmacist or designee shall, within 10 days following the dispensing, record the name and manufacturer of the product dispensed in an interoperable health records system shared with the prescribing practitioner, to the extent such a system is available, or,
  - In the case that an interoperable electronic health system in not in place, communicate to the prescribing practitioner the name and manufacturer of the biological product dispensed to the patient for all biological products.
- The second provision would provide no added benefit to the patient and create unnecessary communications between pharmacies and prescriber offices.

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Current Pharmacy Best Practices to Continue Once Biosimilars Are Available in the US

- Pharmacies today track which product is dispensed to which patient, and all applicable product and manufacturer information on the prescription label is appropriately recorded in the patient record. This will continue to be the case if and when biosimilars and interchangeable biologics become available on the US market.
- In the event of a recall of a biosimilar or interchanegable biologic, pharmacies have the necessary information, can and will track the products, and will reach out to patients, just as they do for brand biologics today.
- Specialty pharmacy disease support resources will be made available to patients prescribed biosimilars to support their care as required. These will include:
  - Refill reminders; delivery coordination; insurance verification; clinical interventions; patient education; adherence counseling; psychosocial assessment; patient assistance programs.

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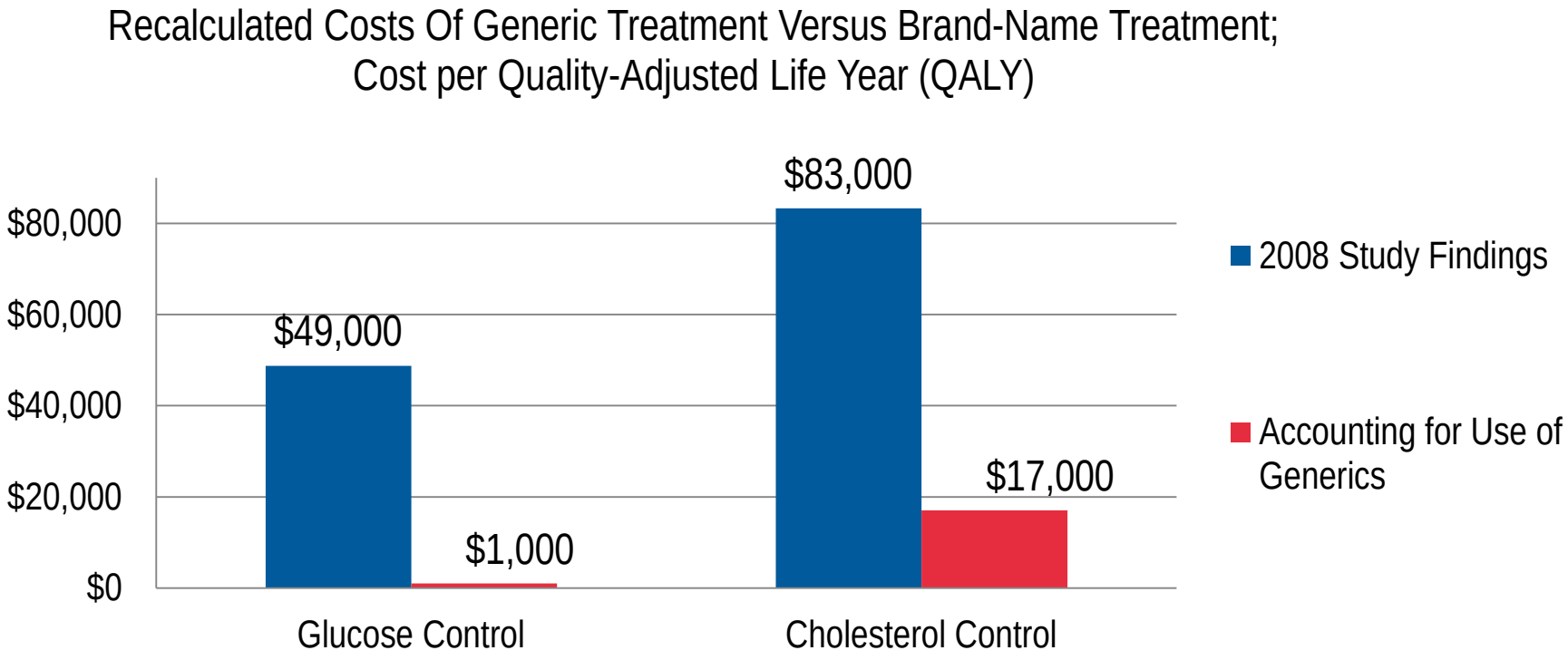
Pharmacy Has Successful History of Appropriately Managing Generic Medications; Bodes Well for Future with Biosimilars



CVS Caremark believes that biosimilars and interchangeable biologics will provide specialty pharmacies with critical tools to help manage the cost of specialty products over time.

Source: Shrank, W.H., Choudry, N.K., Liberman, J.N., and Brennan, T.A. (2011) "The use of generic drugs in prevention of chronic disease is far more cost-effective than thought, and may save money." *Health Affairs*. Accessed January 28, 2014, at http://content.healthaffairs.org/content/30/7/1351.full

CVS Caremark Supports Biosimilars and Interchangeable Biologics Being Made Available to US Patients

- This will put US patients on par with patients in Europe and elsewhere where biosimilars are already available on the market.
- Such products will allow an increase in access and affordability to critical lifesaving medicines, and stimulate innovation just as was the case for generic drugs post 1984.
- Only FDA sees the data in applications, and so only the FDA can ensure accurate designations of biologics as originator, biosimilar and interchangeable biologics.
- CVS Caremark encourages states to recognize an FDA designation that a biologic is interchangeable in the same manner as states do today when FDA designates a drug as therapeutically equivalent. This will enable pharmacies to efficiently deploy all of their careful systems available today to this future generation of medicines.

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