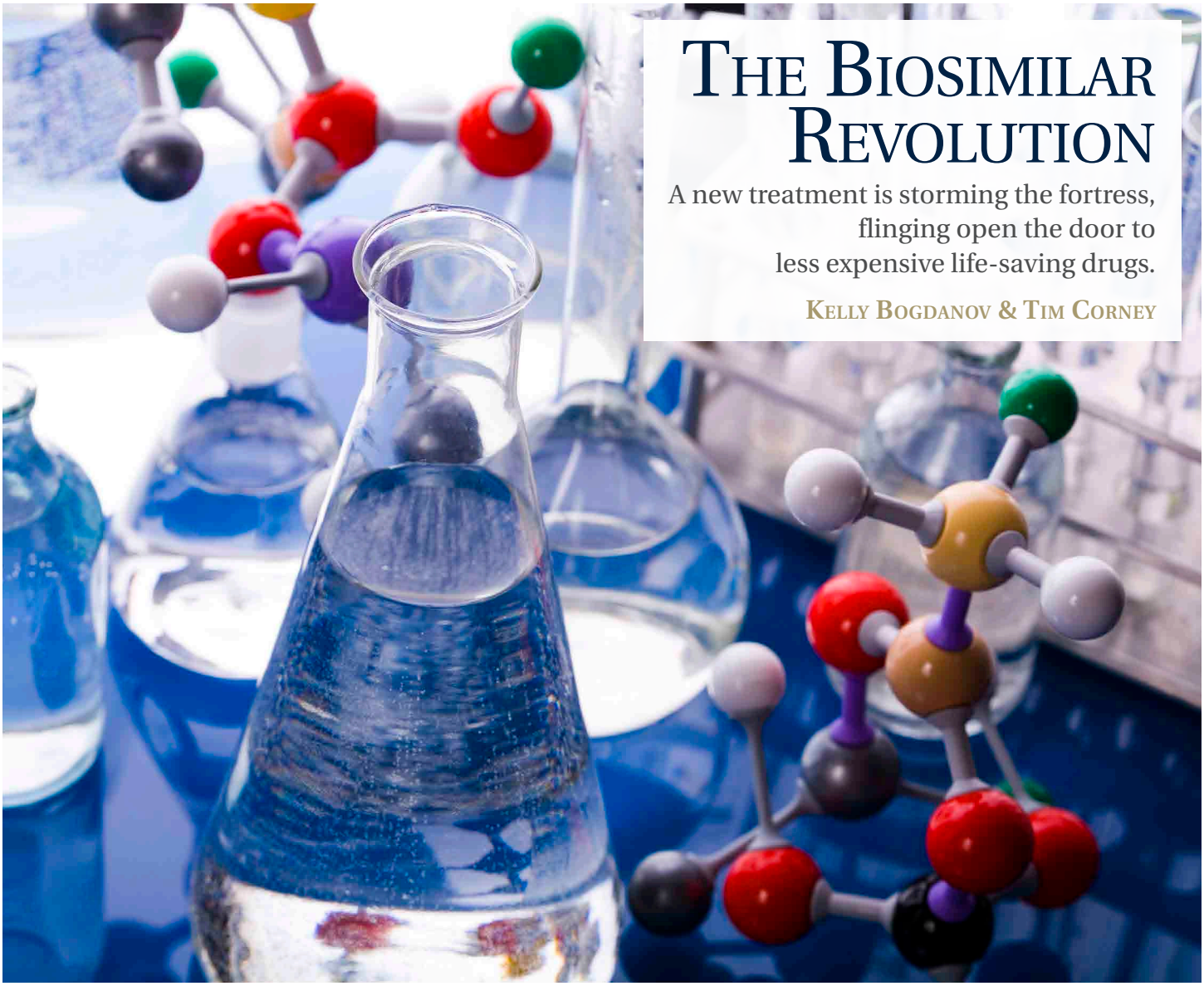
APRIL 2015

RBC WEALTH MANAGEMENT

GLOBAL INSIGHT

SPECIAL REPORT



The Biosimilar Revolution

A new treatment is storming the fortress, flinging open the door to less expensive life-saving drugs.

Kelly Bogdanov & Tim Corney

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Special Report

The Biosimilar Revolution

The competitive landscape in the biotech and pharma industries is being reshaped. In March, the U.S. approved its first biosimilar, an exciting treatment that should cut costs for patients and providers. Investors need to be aware of how the burgeoning biosimilar market will likely determine the winners and losers in the years ahead.

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For years, many investors believed the complex treatment therapies that had traditionally been developed by biotechnology companies were protected within a fortress-like environment, relatively immune from stiff competition and patent cliff risk.

Central to this belief was the view that drugs produced from living cell tissue could not be duplicated due to the natural differences between cells. Additionally, the regulatory landscape in many countries prohibited "generic" competition, and there were significant technological barriers to entry.

Such assumptions are no longer valid.

We believe the biotech and pharmaceutical industries are entering a new phase of heightened competition as biosimilar drugs are about to hit the U.S. market.

Biosimilar treatments are essentially replicas, or copycats, of biologic drugs—the most complex, exotic, and expensive specialty drugs on the market.

Biosimilars, which should be significantly lower in cost, will make it possible for more people to access life-saving or life-improving treatments. This should also benefit health care payers, especially governments, which increasingly shoulder a meaningful portion of the cost burden. And they will likely create major revenue opportunities for select companies.

It follows that biosimilars pose serious competitive challenges and earnings risks for companies with biologics on the market that are nearing patent expiration.

What Is a Biosimilar?

Understanding biosimilars starts with a basic understanding of biologic therapies and how this new emerging area of pharmaceuticals differs from traditional drug development.

Biologics are comprised of complex living organisms, in contrast to traditional drugs such as Lipitor or Celebrex, which are made up of chemical compounds.

The organic materials of a biologic can consist of a wide variety of organisms, including cells from humans or animals, or microorganisms (bacteria). Biologics are typically much more complex in nature relative to chemical compound drugs. Biologic products include vaccines, gene therapies, tissues, therapeutic proteins, and allergenics, to name a few. They usually treat life-threatening or life-altering conditions.

A biosimilar is a therapy that is highly similar to an approved biologic product, and has no clinically meaningful differences in effectiveness, potency, purity, or safety compared to the reference product.

Not Your Father's Generic Drugs

Often biosimilars are defined as "generic versions" of biologic therapies. Such a definition is not only overly simplistic, but also is quite far from the truth. Generic drugs are near-100% copies of conventional pharmaceuticals. They are made from the exact same ingredients, and the variability between a branded and generic drug is virtually zero.

Unlike generics, biosimilars must undergo rigorous testing at all stages of development.

In contrast, biologics deal with large, very complex proteins. They are based on living cells that tend to have natural variability, so biosimilars contain different molecules than those in the original biologic. It is technically impossible to have a true "generic" of a biologic.

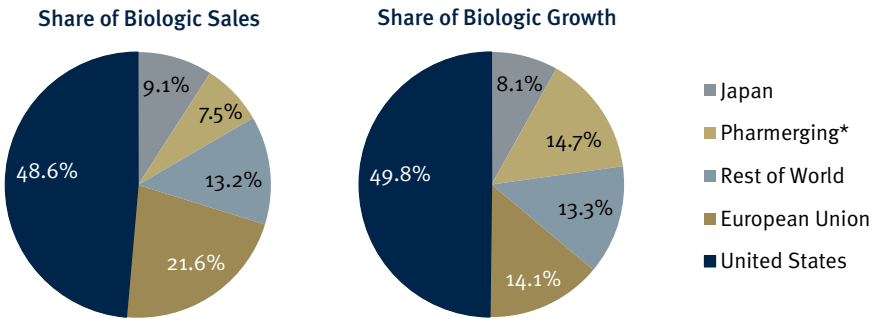
Unlike generics, biosimilars must undergo rigorous testing at all stages of development. The focus of a biosimilar clinical trial, however, is not to establish whether patient benefit exists as that already would have been established by the original biologic's manufacturer. Rather, the trial focuses on demonstrating whether a biosimilar exhibits similar structure, route of administration, and dosage, as well as the same mechanism of action as the biologic. While manufacturers may be allowed to alter the drug delivery system, such changes must maintain the drug's effectiveness.

U.S. Approval Opens the Floodgates

Biosimilars are now available in all major developed nations and many developing countries. The EU was at the forefront, approving its first biosimilar in 2006, and has endorsed 20 others since then. Japan followed with its first approval in 2009, and Canada and Australia in 2010.

But the U.S. Food and Drug Administration's (FDA) green light of the country's first biosimilar treatment in March 2015 was a watershed moment. It dramatically expanded the global biosimilar market and changed the scope of opportunities and challenges facing drug companies.

Share of Biologic Sales and Growth by Country/Region



* "Pharmerging" represents seven emerging markets with strong pharmaceutical sales growth: Brazil, China, India, Mexico, Russia, South Korea, and Turkey.
Source - IMS Health, MIDAS, MAT December 2012

The U.S. currently accounts for nearly half of all biologics consumed worldwide. Futhermore, biologics have the potential to reach 50% of total U.S. drug expenditures by 2018, according to a University of Minnesota study.

In addition to greatly expanding the market, the introduction of biosimilars in the U.S. should incentivize biologic companies to put more resources toward developing drugs in categories that require the greatest innovation and expense, which would make them more difficult to replicate with a biosimilar. We believe this could spur a new wave of innovation in novel drug categories that have unmet medical needs.

Market Opportunity Is Sizeable

In 2014, over $150B was spent on biologics globally ... estimated sales could top $270B by 2020.

This emerging class of treatments poses a serious threat to the profitability of biotech and pharma companies that have approved biologics nearing patent expiration and significant opportunities for biosimilar manufacturers.

To understand the scope of the biosimilar market, it is important to get a sense of the size of the current biologic market. In 2014, over $150B was spent on biologics globally. Our research sources estimate that sales of biologic drugs could top over $270B by 2020.

In addition to the sheer size of the market, biologics have emerged as the fastest-growing segment of the pharmaceuticals industry. By the end of 2015, biologics will likely represent 70% of the top-10 drugs by sales, a near doubling in less than 10 years.

During the next five years, patents will expire for nine biologics currently representing over $60B in annual sales (see table). Upon expiration, these drugs no longer will be shielded from competition, and approved biosimilars can be introduced into the market. The amount of money at stake is massive, and the potential "land grab" in a very short period of time provides huge incentives to all players developing biosimilar treatments.

Top Biologic Drugs Nearing or Beyond Patent Expiration

Company	Drug	Primary Use	Sales 2013 (US$B)	Patent Expiration FDA	Patent Expiration EU
AbbVie	Humira	Rheumatoid Arthritis	$10.7	Dec 2016	Apr 2018
Amgen	Enbrel	Rheumatoid Arthritis	$8.5	Aug 2019*	Feb 2015
Sanofi	Lantus	Diabetes	$7.5	Feb 2015	May 2015
Roche	Herceptin	Breast Cancer	$6.7	Jul 2019	Jul 2014**
Roche	Avastin	Various cancers	$6.6	Jul 2019	Jan 2022
Merck/JNJ	Remicade	Crohn's Disease	$6.3	Sep 2018	Feb 2015
Biogen/Roche	Rituxan	Non-Hodgkin's Lymphoma	$6.0	Sep 2018	Nov 2013
Roche/Novartis	Lucentis	Macular Degeneration	$4.1	Jun 2020	Jun 2022
Teva/Sanofi	Copaxone	Multiple Sclerosis	$3.8	May 2014	Jan 2015
Total			$60.2		

* Enbrel has multiple uses with U.S. patents expiring from 2019–2029; 2019 patent is for psoriatic arthritis
** In the U.K.; other major EU markets follow in August 2015
Source - RBC Dominion Securities, RBC Wealth Management, Corporate filings, Generics and Biosimilars Initiative, national research correspondent

Going forward, we expect to see increased competitive pressures on branded biologics as drug companies seek to lay claim on the biosimilar opportunity long-term. For example, Pfizer's recently announced $16B acquisition of Hospira centers on Pfizer increasing its exposure to injectables and biosimilars through Hospira's industry-leading portfolio.

Interchangeability Could Be Underestimated

Biosimilar market opportunities could expand further if regulatory agencies grant "interchangeability."

Biosimilar market opportunities could expand further if regulatory agencies grant "interchangeability."

Currently in the U.S. and many other countries, a physician or other health care provider must prescribe a specific biosimilar in order for it to be dispensed by a pharmacist or medical facility.

If interchangeability were allowed, pharmacists could proactively intervene and dispense interchangeable biosimilars for equivalent biologic prescriptions without consulting the prescribing physician, similar to how they may now substitute a generic in place of a branded drug. In other words, if a doctor prescribes a biologic, the patient could end up with a biosimilar.

Not all biosimilars would qualify as interchangeables, and some drug makers may not seek the classification. Achieving this status would likely require the biosimilar manufacturer to exceed a higher hurdle during regulatory trials, so development costs would be greater and scientific methods to conduct the trials would be more advanced. But, if deemed interchangeable, the manufacturer would likely benefit from much faster, wider adoption rates in the health care industry and reduced marketing costs.

There is a range of views as to *if* or *when* interchangeability could occur worldwide. France approved a process for interchangeability in early 2014. The FDA is establishing a framework and expects to review applications for two interchangeable biosimilars this year, and plans to provide guidance thereafter. From our vantage point, it seems the FDA could be in position to approve interchangeability for select biosimilars within three years.

Governments Stand to Benefit

Beyond the obvious financial benefits biosimilars should provide manufacturers, there are also very large incentives for governments and regulators to push appropriate biosimilars to market.

Currently, $4 out of every $10 the U.S. spends on prescription medication is being allocated to complex biologics, with the cost of just one treatment or dose often ranging from $1,000 to more than $50,000.

A number of analysts estimate biosimilars could shave 20%–30% off the price of competing biologics. However, management at CVS Caremark, one of the largest U.S. drug store chains and pharmacy benefit managers, believes copycat drugs could result in even greater price reductions to the tune of 40%–50% relative to current prices of branded biologics. These reductions would be consistent with what has been observed in Europe, Japan, and Canada.

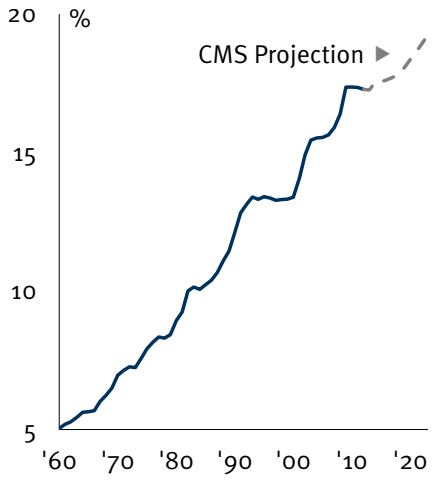
In our view, we are currently in the very early innings of the emergence of biosimilar therapies.

But it's too early to tell just how big the cost savings will be.

For example, Finland-based pharmaceutical company Orion recently offered its Remsima biosimilar to Norway's drug procurement cooperative at a 69% discount to Remicade, a biologic to treat autoimmune diseases by Merck and Johnson & Johnson. That extreme discount surprised and undercut U.S.-based Hospira, which had offered to sell Norway a competing biosimilar at a 51% discount.

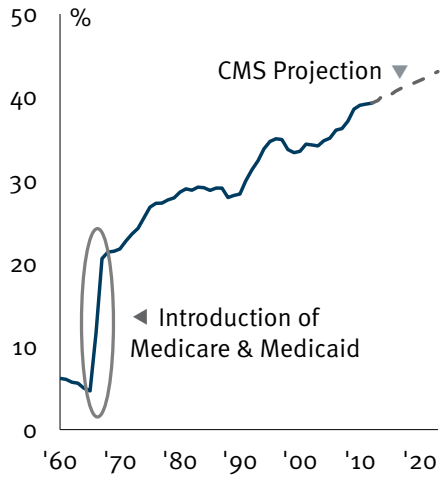
When one considers that health care spending in the U.S. as a percentage of GDP has been rising for years—a trend that should continue (left chart)—while the public sector has been footing an increasing amount of the cost (right chart), the ability to reduce costs through the ongoing development and acceptance of biosimilars is a powerful tool for policymakers.

U.S. Health Expenditures as % of GDP



Source - CMS, BEA, Haver Analytics, RBC Capital Markets

Government as % of Health Spending



Source - CMS, RBC Capital Markets. Note: Medicare, Medicaid, and other government programs (CHIP, Dept. of Defense, Dept. of Veterans' Affairs)

Winners, Losers, and Companies in Between

In our view, we are currently in the very early innings of the emergence of biosimilar therapies.

The first wave of FDA approvals will likely be for drugs that treat inflammatory diseases, such as rheumatoid arthritis, Crohn's disease, colitis, and psoriasis (known as anti-tumor necrosis factor drugs, or anti-TNFs). Our research sources expect these types of drugs to make up 35% of the biologic market this year. Biosimilar treatments for multiple sclerosis and insulin therapies could also achieve approval. Cancer treatments, particularly those that are highly complex and very expensive to produce, will likely be the last group copied into biosimilars.

The biosimilar market is already highly competitive. More than 140 companies of varying sizes and pedigrees around the world are involved in creating copycat treatments.

Some of them are small, privately owned companies that are not publicly listed (a select number of these could come public). Others are listed on exchanges that are not readily accessible to most investors and are rather illiquid. But others are large biotech, pharma, or generic companies with embedded biosimilar units. While not

pure plays, we believe these types of companies offer the best risk-reward as the biosimilar industry takes shape.

Because the industry's competitive dynamics could change considerably over time, we believe it's prudent to focus on the opportunities and risks facing companies during the next few years.

The table below highlights large companies that stand out as potential near-term winners and losers from biosimilar adoption. We focus on *net* benefits because some

Near-term Winners & Losers of Biosimilar Development

Winners		
Novartis	NVS	Switzerland-based Novartis owns Sandoz, one of the world's oldest and largest generic companies. Sandoz is positioning itself to become one of the major biosimilar manufacturers. It received the first U.S. biosimilar approval for its copy of Amgen's Neupogen, and could also be first to market biosimilars for Rituxan, Humira, Enbrel, and Neulasta.
Pfizer	PFE	The acquisition of Hospira, which specializes in acute care and oncology injectables, should position Pfizer as a global leader in biosimilars with a broad portfolio, manufacturing expertise, and reach. Injectables are the primary delivery vehicles of biologic treatments. Hospira has an important partnership with South Korea-based biosimilar company Celltrion, a leader in the industry. Pfizer's core business is less exposed to biosimilar competition than some of its pharma peers.
Actavis	ACT	Actavis possesses an industry-leading generics pipeline. Management continues to shift its portfolio to complex biologic products and has partnered with Amgen on longer-term opportunities in biosimilars.
Boehringer Ingelheim		This private Germany-based pharmaceutical company could be a major player in the biosimilars market.
Neutral		
Amgen	AMGN	Near-term Amgen faces headwinds around biosimilar competition across its Enbrel franchise from 2015–2029. However, long-term opportunities could be significant as it will likely launch a biosimilar of Humira, and its collaborations with Actavis should bear fruit.
Teva	TEVA	The Copaxone franchise is still susceptible to biosimilar pressure despite the company's effort to protect sales through the launch of a 3x/week regimen. However, we have confidence Teva will be a relevant long-term player in biosimilars.
Losers		
AbbVie	ABBV	There is potential for significant erosion of the company's Humira franchise if Sandoz and/or other firms gain approval for competing biosimilars. This is a meaningful earnings risk for a business where about 65% of profits presently come from the drug.
Roche	ROG.VX	Roche has nearly $20B in sales that could be at risk near-term from biosimilar erosion. Still, this company is an established leader in oncology and immuno-oncology because of its Genentech unit. We would expect Roche to be relevant in biosimilars long-term.
Sanofi	SNY	The Lantus franchise is likely to remain at risk with Eli Lilly potentially launching a biosimilar in the 2016–17 time frame. This event will likely keep pressure on an already struggling business.

Source - RBC Dominion Securities, RBC Wealth Management, Corporate filings

companies will be involved in producing biosimilars while at the same time they will face biosimilar competition on their existing drugs.

Additionally, we look at companies for which the biosimilar debate is conflicted—those in between the winners and losers.

Amgen is a good example. On the one hand, the FDA's first approved biosimilar, Zarxio from Novartis' Sandoz unit, was a replica of Amgen's chemotherapy recovery treatment Neupogen. More importantly, Amgen's blockbuster Enbrel franchise seems headed toward a wave of patent expirations from 2015–2029, and could begin to face biosimilar competition soon in Europe and within the next four years in the U.S. On the other hand, Amgen could emerge as a top biosimilar player with a number of products in its development pipeline, including a potential biosimilar offering for AbbVie's blockbuster anti-inflammatory drug Humira.

The next few years should be a promising time for patients who require advanced drug treatments.

We would add that not only will biosimilars compete against the original biologic drug, but also may compete for market share against one or more other biosimilars that target the same biologic.

Conclusion

The proliferation of biosimilars may bring life-saving and life-changing therapies to millions of people who otherwise would not have access to expensive biologic treatments. At the same time, the evolution of biosimilars should create significant revenue opportunities for companies that can successfully develop and market them.

Given the ultra-competitive nature of the biosimilar market and the early stage of development, large pharma and biotech companies with substantial resources and know-how will likely be the near-term winners, in our view.

Additionally, biosimilars should also ease the cost burden facing governments and health care providers, while at the same time push innovation to new heights. But these benefits will not come without drawbacks for companies with biologics nearing patent expiration.

The next few years should be an exciting period for the pharma and biotech industries, as well as a promising time for patients who require advanced drug treatments. The regulatory groundwork has been laid for a truly global biosimilar market to take shape, with expanded U.S. consumption likely to be the major driver.

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