



First Lifesaving Biosimilar Drug Coming to U.S. Market *Consumers to See More Choice and Lower Prices*

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Introduction

Following the March 2015 approval by the Food and Drug Administration (FDA) and after nearly a decade of availability in Europe and elsewhere, the nation's first biosimilar drug soon will be available to patients. This will mark the beginning of competition for a class of lifesaving medicines, commonly referred to as *biologic drugs*. This *ConsumerGram* will explore how the introduction of competition for biologic drugs will lead to immense consumer benefits, both in terms of financial benefits and improved medical outcomes for patients. Biologic drug competition will likely lead to an immediate, though modest, reduction in prices – in the range of 15 to 20% -- with increasing price reductions as the market entry, competition and public acceptance intensifies.

What are Biosimilar and Biologic Drugs?

Biosimilars are medically equivalent substitutes for a growing and innovative class of drugs, called *biologics*. Unlike chemical drugs, biologics are large molecule drugs produced in living systems such as plant and animal cells or microorganisms that can be used to make vaccines, proteins, somatic cells and, more generally, medicines. These biologic drugs, while typically very expensive, are often used to treat some of the most serious, life threatening diseases.

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The recent approval by the FDA of the first biosimilar drug, Sandoz's Zarxio, for use in the U.S., will open the market to biosimilar competition. Zarxio is the biosimilar substitute for the biologic originator Neupogen, which is manufactured by Amgen. This biosimilar will be used to treat patients with low white blood cell counts caused by cancer, bone marrow transplants and other medical conditions.

High Cost of R&D and Production Results in Higher Prices

The research and development costs for biologics can run into the billions of dollars, and can take 8 to 10 years to develop.¹ For this reason, biologic originators are provided both patent protection and 12 year market exclusivity in order to recoup these costs, before biosimilar competition is allowed.

In addition, the manufacturing of biological products is more complex and costly than conventional chemical drugs. Unlike formulating, mixing and packaging chemical drugs, biologics are often started from vials, where cells are grown over a period of weeks into larger vats. Essentially harvested from biological sources, like proteins made from living cells, the active ingredient is grown in labs and then extracted for use, including for use in gene therapy. Compared to chemical drugs, the manufacturing process for biologics is very time-consuming and expensive.

Also unlike chemical drugs, where generics are equivalent, producing identical biologics is extremely difficult and may actually be impossible. Biosimilars, by definition, are highly similar to the comparable originator biologic, which means that their makeup may not be identical and may utilize different manufacturing processes. For these reasons, regulatory oversight is extremely important for assuring that biosimilars are, in fact, highly similar to their originator reference product, as well as safe and effective for patients.

¹ Alex Brill, "The Economic Viability of a U.S. Biosimilars Industry," Matrix Global Advisors, February 2015.

Since R&D and production costs are so high, consumer prices are also high. In fact, some biologics cost as much as \$400,000 per year per patient.² While expenditures on pharmaceuticals are increasing faster than other healthcare expenditures, they are increasing much faster for biologics. While the average cost of a biologic in the U.S. is \$45 per day, the cost of chemical drugs average only \$2 per day.³ Some of the difference is the result of lower cost generics. Controlling healthcare costs is a national priority and is the main reason that biosimilar competition is so important.

Biosimilar Competition Will Save Money

The FDA began approving generic (unbranded) chemical prescription drugs around 30 years ago. That led to market entry and price competition, which explains why generic drugs have saved consumers more than \$1 trillion in the last decade, compared to their brand named counterparts.⁴ Effectively, competition from generics has provided more options to doctors and better access to patients – at prices averaging 75% lower than name brand products.⁵ Moreover, generics now comprise almost 80 percent of all prescriptions.

As of 2013, biologic drugs accounted for nearly 30% of total U.S. drug spending, and their growth in expenditures exceeds that of other drug spending.⁶ In the face of this growing demand, the introduction of biosimilars to compete with biologics, like generic drugs, will also produce savings for consumers. However, with the high R&D and manufacturing costs of biosimilars, it is unlikely that the percent reduction from price competition will come close to

² Matthew Herper, "How a \$440,000 Drug is Turning Alexion into Biotech's New Innovation Powerhouse," *Forbes*, Sept. 5, 2012, at <http://www.forbes.com/sites/matthewherper/2012/09/05/how-a-440000-drug-is-turning-alexion-into-biotechs-new-innovation-powerhouse/>; Matthew Herper, "The World's Most Expensive Drugs," *Forbes*, Feb. 22, 2010, at <http://www.forbes.com/2010/02/19/expensive-drugs-cost-business-healthcare-rare-diseases.html>; Erwin A. Blackstone and Joseph P. Fuhr, Jr., "Innovation and Competition: Will Biosimilars Succeed," *Biotechnology Healthcare*, Vol. 9(1), Spring 2012, pp. 24-27 at the National Institute of Health's website at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3351893/>.

³ Steve Pociask, "Lifesaving Drugs at Lower Costs," The American Consumer Institute Center for Citizen Research, 2014, at <http://www.theamericanconsumer.org/wp-content/uploads/2014/07/Biosimilars-ConsumerGram-Final.pdf>.

⁴ "Generic Drug Savings in the U.S.," Fourth Annual Edition, Generic Pharmaceutical Association, 2012, at <http://www.ahipcoverage.com/wp-content/uploads/2012/08/2012-GPHA-IMS-GENERIC-SAVINGS-STUDY.pdf>.

⁵ Steve Pociask, 2014.

⁶ Alex Brill, "The Economic Viability of a U.S. Biosimilars Industry," Matrix Global Advisors, February 2015.

matching the experience of the generic drug market. It is estimated that R&D costs for developing a biosimilar are between \$100 and \$200 million, and the cost of building a manufacturing plant is around \$250 million.⁷

How much will biologic competition save for consumers, health plan operators, insurers, businesses and government? There is overwhelming evidence that biosimilar competition will significantly reduce prices for consumers, as well as for the government and the private healthcare sector. While the introduction of Zarxio will represent only the first biosimilar for the U.S. market, the European Union, Canada, Australia and a number of Asian countries have already approved the manufacturing and dispensing of lifesaving biosimilar drugs as far back as 2006. There are currently 3 biosimilar applications before the FDA. Based on the European market's early experience, the savings from competition has been estimated to be 15-20%.⁸ This is a good starting point for what to expect, short term, as the U.S. begins to open up its market to biologic competition. Although the percentage decrease in price is lower for biosimilars than generics, overall savings may be greater since prices are higher. For example, a 20% percent discount on a \$100,000 biologic would save \$20,000 compared to an 80% savings on a \$100 drug which would save \$80.

However, in the years to come, the potential for saving is likely to increase. As more biologic patents expire and more manufacturers enter the market, price competition will be heightened in a number of ways. Initially, as entry occurs, biosimilar competitors will need to establish themselves and gain market share. In order to do this, they could initially lower prices by, say 15 to 20%, in order to differentiate themselves from the established incumbent providers. In addition, this could result in the reference products decreasing their prices, as has already occurred in the EU.

⁷ Erwin A. Blackstone and Joseph P. Fuhr, Jr., "The Future of Competition in the Biologics Market," *Temple Journal of Science, Technology, and Environmental Law*, Summer 2012, pp.1-30.

⁸ Robert Haustein, Christoph de Millas, Ariane Hoer and Bertram Haussler, "Saving Money in the European Healthcare Systems with Biosimilars," *Generics and Biosimilars Initiative Journal*, Vol. 1; 3-4, 2012, pp. 120-6, at <http://gabi-journal.net/saving-money-in-the-european-healthcare-systems-with-biosimilars.html>. Also see Steven Somoens, "Biosimilar Medicines and Cost-Effectiveness," *Clinicoecon Outcomes Research*, No. 3, Feb. 10, 2011, pp. 29-36, at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3169973/>.

Over time, biologics will see additional competition across other products and for the same product. For example, outside of the brand names Neupogen and Zarxio, there are more than a half dozen brands of filgrastim worldwide.⁹ Additional entrants will likely result in greater price reductions in a crowded market.

For this reason, competition may initially decrease prices in the range of 15 to 20%, but as competition becomes more established across brands and more competitors enter the market, there could be additional downward pressure on prices. For example, Steve Miller, chief medical officer at Express Scripts, estimates that some overseas biosimilars are already selling for 30-50% less than the biologic product.¹⁰ This potential savings is consistent with a study by the Congressional Budget Office, which has estimated that biosimilars could, by the fourth year, reduce prices by 40% over originator biologics.¹¹ In Norway, a biosimilar for the reference product Remicade was recently discounted by 72%.¹² In fact, the mere threat of market rivalry can push prices closer toward effective competition, as incumbents hold prices lower to try to impede market entry. This is consistent with the contestable markets theory.¹³

In summary, we expect the percentage savings from biosimilar competition to be significant, but not as intense as the price reductions that occurred with generic drugs, due to the high manufacturing costs of biologic drugs. We expect the initial savings to be in the more modest 15 to 20% range, with the potential of doubling as competition becomes more robust. In dollar terms, the savings may actually be greater because of the higher prices of biologics.

⁹ A list of brand names for filgrastim is available at <http://en.wikipedia.org/wiki/Filgrastim>.

¹⁰ "What's Keeping Less Expensive Biologic Drugs from the U.S. Market?" *PBS Newshour*, April 19, 2014, video at <http://www.pbs.org/newshour/bb/whats-keeping-generic-version-biologic-drugs-u-s-market/>. Also see, "The \$250 Billion Potential of Biosimilars" Industry Update, Express Scripts, April 23, 2013 at [http://lab.express-scripts.com/insights/industry-updates/the-\\$250-billion-potential-of-biosimilars](http://lab.express-scripts.com/insights/industry-updates/the-$250-billion-potential-of-biosimilars).

¹¹ "S. 1695: Biologics Price Competition and Innovation Act of 2007," Congressional Budget Office Cost Estimate, July 25, 2008, at p. 7.

¹² "Orion Pharma Offers an Astonishing 72 Percent Discount on Biosimilar Infliximab in Norway," *First Pharma*, at <http://www.firstwordpharma.com/footer/benefits?tsid=17#axzz3YuNIUndj>.

¹³ For the pioneering work on this, see William J. Baumol, John C. Panzar and Robert D. Willig, *Contestable Markets and the Theory of Industry Structure*, Harcourt Brace Jovanovich, 1982; and William W. Sharkey, *The Theory of Natural Monopoly*, Cambridge University Press, 1982.

Other benefits

The long term potential is for billions of dollars of savings for consumers, as a result of lower prices, which will increase patient access to these lifesaving drugs. That, in turn, will mean better patient outcomes, including fewer hospital readmissions and complications, shorter hospital stays, longer lives, and improved quality of life. All of these patient benefits will lead to increased productivity and lower absenteeism. That will also mean a reallocation of spending that will have stimulative benefits to output and job growth for the economy.

Conclusion

Similar to the savings that generic drugs have brought to consumers, there is another opportunity for increasing competition and dramatically reducing pharmaceutical drug prices. We estimate that the percentage savings will initially be modest, but grow as biologic drug competition is heightened. In the end, there will be more choice and better patient outcomes. This will also mean lower prices and expanded access for patients.