Lifesaving Drugs at Lower Costs

Introduction

The Food and Drug Administration (FDA) began approving generic (unbranded) prescription drugs around 30 years ago, and generic drugs are now saving consumers more than one trillion dollars per decade in healthcare costs over their brand named counterparts. Competition from generics has provided more options to doctors and better access to patients – at prices averaging 75% lower than name brand products.

Like the savings that generic drugs have brought to consumers, there is another opportunity for increasing competition and dramatically reducing pharmaceutical drug costs. This time, it involves a growing, but expensive, innovative class of drugs, called *biologics*, and the potential introduction of their generic-like counterpart, called *biosimilars*. Despite the promise of patient benefits, the FDA has not approved a single biosimilar drug, even though other countries have approved these lifesaving drugs as far back as 2006.

This *ConsumerGram* addresses this issue and calls on the FDA to accelerate its rulemaking so that competitors can enter the market to provide lower cost, lifesaving drugs to American consumers.

Biologics and Biosimilars

Biologics are large molecule drugs produced in living systems such as plant cells or microorganisms. These biologic drugs are often used to treat some of the most serious, life threatening diseases. However, the manufacturing of biological products is more complex and

costly than conventional chemical drugs, and as a result, research and development costs can run into the billions of dollars. This means that patient costs can be extremely expensive.

For example, Soliris, which treats a rare blood disease, is reportedly priced at more than $400,000 per year per patient.[1] Another report cites adalimumab (brand named *Humira*), which treats rheumatoid arthritis or Crohn's disease, costs $50,000 a year; and imiglucerase (brand named *Cerezyme*), which treats Gaucher disease, costs $200,000 a year."[2] Similarly, Elaprase, which is used to treat Hunter's syndrome, may cost $375,000 per year per patient.[3]

Controlling healthcare costs is a national priority. The high cost of pharmaceuticals, especially biologics, has become an important issue in the battle concerning ever increasing healthcare costs. Annual expenditures for healthcare products and services are increasing at a double digit rate, and its prices are increasing considerably faster than overall inflation. Today, the U.S. healthcare accounts for 20% of GDP, of which around half are for pharmaceuticals.

While expenditures on pharmaceuticals are increasing faster than other healthcare expenditures, they are increasing much faster for biologics. The average cost of a biologic in the U.S. is $45 per day compared to only $2 per day for chemical drugs. Because most biologics are under patent protection, they are sold at monopoly prices. However, once patent protection lapses on branded biologic products, biosimilars could be introduced as a substitute product, provided that competitive entry is permitted and regulatory approval is granted. That could lead to lower prices, which would also increase patient access to these lifesaving and quality of life enhancing drugs.

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[1] 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/.

[2] 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] 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.

The European Union, Canada, Australia and a number of Asia counties have already approved the manufacturing and dispensing of biosimilar drugs. Unfortunately, the United States presently has no mechanism in place to allow for biosimilar competition. As such, the benefits of lower prices for consumers cannot occur until the FDA establishes rules for biosimilar entry.

Congress to the FDA: Write Biosimilar Competition Regulations

The new health law, the Patient Protection and Affordable Care Act of 2010, which is subsumed within it the Biological Price Competition and Innovation Act, gave the FDA authority to develop a mechanism for approval of biosimilars somewhat similar to what was done for generics.

In February 2012, the Food and Drug Administration (FDA) announced tentative guidelines for the pathway for biosimilar entry in the United States. The present guidelines take a "totality of the evidence" approach allowing for flexibility in the methodology for determining that a product is a biosimilar to a referenced branded biologic. While the FDA produced another set of guidelines in early 2014, there are still no definitive rules for entry.

Why the Delay?

Unlike chemical drugs which face competition from generic drugs, producing identical biologics is extremely difficult and may actually not be possible. Biosimilars must be bioequivalent or comparable to the original biologic, although their makeup may not be identical and they may utilize different manufacturing processes.

For these reasons, regulatory approval is extremely important for assuring that these substitute drugs are, in fact, similar to branded reference products, effective and safe for patients. While there is need to be cautious, this does not explain the ongoing delay in getting regulations in place to allow competitive entry. The lack of progress by the FDA seems

particularly inexplicable considering that, as previously noted, the European Union, Canada and Australia have regulations in place to allow for biosimilar competition.

There is another reason for delay in establishing market entry guidelines – biologics are very profitable, which provides incentives for some manufactures to impede market entry and delay competition that would otherwise lower prices and profits. For example, one U.S. biologic drug reportedly yields $100 million in profits per month.[4] This means that stalling competition will maintain biologic monopoly pricing far beyond the patent life of name brands. Simply put, until the FDA establishes guidelines for biosimilar entry, the benefits of competition for consumers cannot occur.

This latest strategy of delay entails developing the biosimilar "drug naming" convention before writing rules for competitive entry. Some manufacturers have argued for the creation of a unique system for International Nonproprietary Names (INNs) that would lead to increased transparency and safety in the U.S. Yet, doctors, pharmacists, and patients have stated that this could create confusion and lead to dangerous medication errors. As three U.S. pharmacy groups stated in a letter to the FDA, "physicians are already pressed for time, and therefore it is imperative that there are no additional and unnecessary obstacles that hinder them from timely decision-making, especially in cases of urgent care."[5]

Similar efforts were rejected by the FDA's European equivalent (the European Medicines Agency) during the biosimilar pathway creation process in the European Union (EU), where the international World Health Organization (WHO) INN system is used, and where the INNs of the original product and the biosimilar version are the same. To date, there have been no significant safety and efficacy issues with biosimilars in Europe. The fact is that European

[4] "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/.
[5] http://www.ncpanet.org/pdf/leg/may12/joint_biosimilar_letter.pdf.

consumers have been benefiting from biosimilar competition since 2006, the same year that the FDA went on record as supporting the WHO INN system.[6]

With this background in mind, the "naming" issue is simply a stall tactic intended to distract the FDA from its lifesaving mission of facilitating the introduction of safe and effective drugs to market. At a minimum, the FDA should put the naming issue on hold, and focus on accelerating its rulemaking for the purpose of encouraging market entry and heightening industry price competition.

Writing biosimilar market entry rules is urgent, because speeding market competition will yield savings both in terms of dollars and lives. In the face of growing demand, biologic drugs are projected to account for up to 75 percent of U.S. pharmaceutical spending by 2020, according to a Senate bipartisan letter.[7] With biologics costing on average 22 times more than traditional drugs, out-of-pocket expenses for patients will rise significantly. The best medical advances in the world are useless if no one can afford to buy them. Therefore, we urge the FDA to reject efforts to introduce a unique INN system, which is currently delaying rulemaking.

If biosimilars rules were in place, what would the benefits be to patients? A look back at the competitive impact from generics provides a useful understanding the potential benefits of spurring market competition.

Drug Competition Works and Benefits Consumers

Thirty years ago, the United States was faced with a similar issue concerning generic chemical drugs. The Hatch-Waxman Act (the Act) was passed with the intention of balancing competition and innovation. The public policy goal was to enhance competition from generics which would lead to lower prices but still provide the branded pharmaceutical companies the

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[6] A copy of the FDA's September 1, 2006 news release supporting the European naming conventions is available at www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm375086.htm.

[7] See http://www.rockefeller.senate.gov/public/index.cfm/files/serve?File_id=be5842b1-e58c-408f-8fc6-09a48fb2ff4d&SK=1E6B4DAA827960DD750BA2319528FFD4.

incentive to innovate. The IMS Institute for Healthcare Informatics has estimated that generic drugs have saved over a trillion dollars in healthcare cost between 2002 and 2011.[8] Generic drugs retail on average at 75% below name brand drugs. The fact is that generic drug competition has worked for the benefit of consumers, and biosimilar competition can work too.

Biosimilar Benefits on Hold

The overwhelming evidence finds that biosimilar competition, if permitted by the FDA, would significantly reduce costs for consumers, as well as for the government and the private healthcare sector. The following highlights a few studies detailing these potential benefits:

- On the low end, savings from biosimilar in Europe has been estimated to be 15-20%.[9] As more biologic patents expire and more manufacturers enter the market, the potential for heightened competition from multiple providers and the resultant savings are likely to grow significantly.
- In fact, some biosimilars are selling for 30-50% less than the biologic product, and, according to Steve Miller, chief medical officer at Express Scripts could save $250 billion over the next ten years from just 11 biosimilar products.[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 brand-name biologics.[11]
- Another report estimated that biosimilar competition could save a quarter of a trillion dollars.[12]

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[8] "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.

[9] 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/.

[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.

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

In summary, the introduction of biosimilar drugs to compete against patent-expired biological name brand drugs would save healthcare costs in the U.S. and improve patient access to lifesaving drugs.

Conclusion

We urge the FDA to remain focused on completing the pathway for biosimilars to bring more affordable treatment options to patients as quickly as possible by encouraging market entry and competition. We also call on the FDA to reject calls to stray from the globally recognized naming system, which is only delaying the focus on writing rules that would permit biosimilar market entry. At a minimum, the FDA should table the naming issue and focus on writing the rules, which would begin the process of getting competitive products into the pipeline for regulatory review.

The FDA needs to move quickly and promulgate rules that will facilitate market entry, heighten industry price competition, save consumers money, and produce better patient outcomes. The benefits of biosimilars provide a clear incentive for FDA action that will serve the public's interest. Consumers deserve better; patients deserve more choice.

[12] Dan Stanton, "Hospira: Biosimilar a Reality in the US with Potential $250bn Healthcare Savings," Biopharma-Reporter.com, January 22, 2014, at http://www.biopharma-reporter.com/Markets-Regulations/Hospira-Biosimilars-a-reality-in-the-US-with-potential-250bn-healthcare-saving.