Benefits from Biosimilar Competition
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The U.S. is now developing a process for expedited approval of biosimilars. Biopharmaceuticals are far more complex and costly to develop and produce than chemical drugs. Biosimilars raise greater safety issues because of possible immune responses, are likely to offer smaller percentage price reductions than chemical generics, and probably will obtain smaller market shares. Patents may not be as strong for biopharmaceuticals, which are often made by small firms, suggesting the desirability of greater data exclusively protection. It is better to err on the side of too much protection than too little given the uncertainties involved. This ConsumerGram discusses the tradeoff of encouraging long term innovation versus encouraging competitive alternatives and offers a balanced solution.¹

Biosimilar Drugs as the New Generic

The 1984 Hatch–Waxman Act (H-W) was a compromise between the competing interests of the innovating and imitator companies. Prior to H-W generic drugs had a difficult time gaining approval.² In the 1962 to 1984 period 150 branded drugs lost patent protection, but no generics entered to compete.³ H-W allowed generic development during the period of patent protection without the threat of patent infringement.⁴ More importantly, generic applicants could file an “Abbreviated New

¹ This ConsumerGram is based on the article by Erwin A. Blackstone and Joseph P. Fuhr, Jr., “Biosimilars and Innovation: An Analysis of the Possibility of Increased Competition in Biopharmaceuticals,” Future Medicinal Chemistry, Vol 2, No. 11, 2010, pp.1641-1649. The authors are ACI experts. Dr. Blackstone and Dr. Fuhr are professors of Economics at Temple University and Widener University, respectively.
Drug Application” (ANDA) before the patent expired. Clinical trials were not needed which greatly reduced the time and cost of generic entry.

The current situation facing biopharmaceuticals is strikingly similar to that of chemical drugs before H-W. Since only 2 biopharmaceuticals existed when H-W was passed, it did not address the issue of biopharmaceuticals. However, there are some important differences between biopharmaceuticals and chemical drugs which the FDA must take into account before it allows expedited “generic” entry into the biopharmaceutical market.

The new healthcare law, the Patient Protection and Affordable Care Act (PPACA), has many new provisions beyond health insurance reform, including a provision for a pathway for the approval of biosimilars. Biosimilars are the generic equivalent to branded biopharmaceutical drugs, both of which are produced in living organisms, unlike traditional chemical drugs. However, unlike chemical drugs that can be copied exactly by a generic drug, biosimilars are not identical to brand name biopharmaceuticals – raising debate on whether biosimilars are, in fact, different and thus may not violate the patent rights of branded biopharmaceuticals. While generics can compete with branded chemical drugs once patents have expired or not infringed, until passage of the PPACA there was no pathway for biosimilar entry. Currently, the FDA is developing rules for biosimilar entry.

Biopharmaceuticals are far more complex, costly to produce, and raise far greater safety issues than chemical generics. Currently the FDA is deciding the process to determine what conditions must be met so that an unbranded biopharmaceutical can be considered a biosimilar. Competition can occur between the approved biosimilar and the branded biopharmaceutical, but only after patent and data exclusivity rights no longer apply.\(^5\) In the generic market prices have decreased, in some cases by 80 percent,

\(^5\) Clinical trial data are an important element of the FDA approval process. Making these data available to manufacturers can facilitate the production of biosimilars. Thus, data exclusivity, that is withholding clinical trial data from these potential competitors, can be an important means to prevent the creation of look-alike products that may undermine patent protections.
which has resulted in generics gaining considerable market share. One expects that biosimilar prices will decrease by only 25 percent, but given their higher price of biopharmaceuticals, even such modest savings could be considerable. This has been the experience in the European Union market which has already approved a process for biosimilar competition. A major difference between chemical generics and biosimilars is that the cost of producing biosimilars is much greater than the cost of producing generics. Also, because the biosimilar are not exactly the same, one expects that just like the European Union, the FDA will not allow for automatic substitution, which exists in the generic market. Thus, biosimilars are unlikely to garner a large market share.

**The Key Tradeoff is Data Exclusivity**

One of the major debates concerning the new law was how long should data exclusivity last. The new law sets data exclusivity at 12 years. This means that the biosimilar cannot use the data of the pioneer for 12 years and must conduct its own testing to obtain safety and efficacy evidence. However, there is a tradeoff involved. In order to give biopharmaceutical companies the incentive to invent, they need some patent and data exclusivity protection so that they can recoup the considerable cost of research and development which in biopharmaceuticals is estimated to be around $1.2 billion. Without such protection firms would not bring new drugs to market and new drugs have provided in many cases considerable benefits to society. However, the longer the data exclusivity period is, the longer there is no competition from biosimilars and prices may be higher for a longer time.

So, the government must consider the tradeoff between the benefits of innovation and lower prices in the short run. The government decision comes down to making a type-1 or type-2 error. If the length of protection is too short (type-1 error), the incentive to innovate and spend on R&D will decrease. Some beneficial biopharmaceuticals may not be developed, and patients will not receive the benefits of these new biopharmaceuticals. Conversely, if the length of protection is too long (type-2 error), the price of biopharmaceuticals will be higher for a longer period of time. In the short run consumer welfare will be decreased because of the higher prices.
**Striking a Balance**

Are consumers better off with lower prices and less innovation or higher prices and more innovation? Given the substantial benefits society derives from pharmaceutical innovation, society should favor setting too long a period of protection (type-2 error), rather than too short a period of protection (type-1 error). Thus, because of the importance of new biopharmaceutical drug development, their cost and the likelihood of less secure patents, we concur with erring on the side of too much protection and believe that the government made the right decision in allowing for 12-year data exclusivity. The outcome should encourage longer term innovation that will save lives, over the short term benefits of lower prices. The 12-year period provides a reasonable balance for innovation and competition.