The potential economic impact of Biosimilars in the United States

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The major issue with biosimilars in the United States market is uncertainty. There are more questions than answers but the answers to these questions will have a tremendous impact on how the market for biosimilars will develop not only in the United States but also globally. Currently the United States is developing a pathway for the introduction of biosimilars. The U.S. Food and Drug Administration has the charge of developing this pathway. Among the many issues the FDA faces in determining this pathway are safety, efficacy and even what constitutes a biosimilar. How the FDA establishes the pathway will have a tremendous influence on the competitive impact of biosimilars in the market. Other factors that the FDA must take into account are clinical trials, interchangeability and immunogenicity. Also, affecting the market are data exclusivity, patent protection and insurance reimbursement especially Medicare. Competition from biosimilars in the European Union has decreased price by only around 20 percent which is considerably different from the 80 to 90 percent decrease in price in the chemical generic market. Also, at issue is whether entry will occur through a Biologics License Application (BLA) and not through an abbreviated BLA. The impact of biosimilars on the incentive to innovate and the potential decrease in the development of new life saving biologics will be discussed. We analyze the potential impact of biosimilars taking into account these various issues.

Biography

Joseph P. Fuhr Jr. is a professor of economics at Widener University. He received his Ph.D. in economics from Temple University. Dr. Fuhr is a healthcare economist and has published over 50 academic articles. He has published and presented on biosimilars as well as pharmacoeconomic studies on cost benefit analysis. Dr. Fuhr is a member of the editorial board of Pharmaceutica Analytica Acta.